MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
1054	07/17/1998	female	40 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other: scabs on scalp, and longevity

Date of event 09/20/01 **Date of report** 1/6/2003

Describe event or problem

We have not been able to get rid of the problem even with numerous treatments (Rid/Nix) and she continually scratches her head. We also continue to comb through her hair and find several lice. She now has scabs on her scalp, and after 3 months we are very concerned.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

NA

C. Suspect medication(s)

Name: Rid
Nix

Dose, frequency, route use
1 box every 3-4 days

Therapy dates
09/2001 to 12/2001

Diagnosis for use
to repeat every 7 days

Event abated after use stopped or dose reduced
doesn't apply

Lot #
na

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address
The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

phone # (781)449-6487

Health professional
☑ yes ☐ no

Occupation

Also reported to
☐ manufacturer
☐ user facility
☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
1044	02/25/97	female	45 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other:

Date of event 12/25/02 **Date of report** 12/26/2002

Describe event or problem

i have treated my daughter for head lice three times this week alone and i am still seeing live lice! i have used NIX and yes sorry but i used lindane and they are still alive~~~ help~

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix
lindane

Dose, frequency, route use
3 times

Therapy dates
12/23/0 to 12/26/02

Diagnosis for use
head lice

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address
The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

phone # (781)449-6487

Health professional
☑ yes ☐ no

Occupation

Also reported to
☐ manufacturer
☐ user facility
☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
1029	05/30/96	female	45 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event	12/01/02	Date of report	12/8/2002

Describe event or problem

We've treated with tea oil conditioner and then with malathion pesticide, with live adult and nymph lice (as well as nits) surviving all treatments.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: malathion

Dose, frequency, route use	Therapy dates
one dose (each: my child and I both treated, with same non-results)	120102 to 120202

Diagnosis for use

Use on dry hair. Wet scalp thoroughly, working to ends of hair. Leave on 12 hours

Event abated after use stopped or dose reduced

no

Lot #	Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

We are also manually removing nits and lice every other day, working for up to 4 hours at a time. Standard treatment for UK kids is to use plain conditioner or tea tree oil

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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The National Pediculosis Association

P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
1028	02/02/50	female	170 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 11/15/02 **Date of report** 12/4/2002

Describe event or problem

I have tried just about every lice over the counter product & Rx: doctors thought I was nuts, because I still have them, so I went to a psychiatrist & discovered I am not nuts & that resistant lice do exist.

His experience with adolesent teens & resistant lice is that vasoline on the scalp with plastic wrap over it for 3 days seemed to smother the little critters. However any other body hair needed to be shaved. I am trying this.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

I am IgG3 deficient

C. Suspect medication(s)

Name: Kwell

Dose, frequency, route use

?

Therapy dates

10/2002 to 11/2002

Diagnosis for use

lice

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

Rid, Nix, Lindane, Mayonaise, Olive Oil, Green tree oil, Acticin,

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association

P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
1020	07/04/1917	female	113 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other:

Date of event 11/05/1989 **Date of report** 11/17/2002

Describe event or problem

Mother became infested with head lice (along with three others) at her local beauty shop. She did not realize what she had until several months had gone by and she was being driven mad by the crawling, itching and biting. She has tried everything on the market so many times that I guess they're resistant to everything now. How in the name of God can she get rid of these things? I can't see a thing on her hair or scalp, but she insists they're still there. After 13 yars, it's a miracle she hasn't lost her mind. She is not crazy, I assure you. Something is there.. We have used the spray, even called the Terminix man to spray and she's still got her unwelcome guests. What can you suggst? Is there a hospital where a person can go to be de-loused?

Relevant tests/laboratory data

Other relevant history, including preexisting condition

None

C. Suspect medication(s)

Name: Nix

Dose, frequency, route use
as instructed on bottle

Therapy dates
1990 to 2002

Diagnosis for use
I don't understand the question here

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

Rid, same time period
Hair Clean 2000-2001 (?)
R & C between 1990 and 2000

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

Health professional
☑ yes ☐ no

Occupation

Also reported to
☐ manufacturer
☐ user facility
☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
1019	07-23-1996	female	60 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 11-02-2002 **Date of report** 11/17/2002

Describe event or problem

We have treated my daughter for the 6th time. I know she has had this for at least 2 months. We have used RID 1 time and NIX 4 times and after I would treat her I would examine her head when it was still wet after using the comb and I would see live adult lice walking around, I called my doctor and he perscribed some shampoo and used that, and I saw an adult lice that was walking slowly and having a hard time moving. I need to check her again this morning. We did the perscription late last night. I am not sure if that did it.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix
RID and Lindane prescription shampoo

Dose, frequency, route use
RID 1 time NIX 4 times, Lindane 1 time

Therapy dates
11-02-2002 to 11-16-2002

Diagnosis for use
shampoo was used as direction on box, leave on for 10 minutes then rinse. Prescription use

Event abated after use stopped or dose reduced
doesn't apply

Lot #
not known

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
1009	11/09/1990	female	95 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other: vomiting

Date of event 11/02/2002 **Date of report** 11/3/2002

Describe event or problem

Bugs keep coming back. Treated over a week and product says prevents reinfestation for 14 days. It made her sick at her stomach with lots of vomiting.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

none.

C. Suspect medication(s)

Name: Nix
rid bedding spray/ eckard bedding spray

Dose, frequency, route use
Once a day shampooing.
Twice on the first day.

Therapy dates
10/29/2002 to 11/03/2002

Diagnosis for use
Head lice Live and nits. Bugs and nits are both white and brown

Event abated after use stopped or dose reduced
no

Lot # 2e2024

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

Everday that I mentioned. Wed thru today, Sunday.

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

Expiration date

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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phone # (781)449-6487

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P.O. Box 610189, Newton, MA. 02461

Health professional
☑ yes ☐ no

Occupation

Also reported to
☐ manufacturer
☐ user facility
☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
1004	06/21/67	female	135 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☑ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 09/04/02 **Date of report** 10/27/2002

Describe event or problem

R&C product in eye - initial injury resulted in burns and holes in cornea - long term injury includes severe photophobia, eye pain from twinges, stabbing, throbbing and results in headache in behind eye.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

NONE!!!!!!!

C. Suspect medication(s)

Name: R&C .33% pyrethrin, 3% piperonyl butoxide technical

Dose, frequency, route use

5 doasages, 2 doses 7 days apart, June, July and August

Therapy dates

08/05/02 to 10/31/02

Diagnosis for use

Lice infestation

Event abated after use stopped or dose reduced

no

Lot #

C18266

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

Initial injury: diagnosis: sever chemical burn. Prescribed: Voltaren anti-inflammatory drops, Tylenol#3 for pain, eye patch.

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association

P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
999	09/19/98	male	19 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☑ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 10/06/01 **Date of report** 10/18/2002

Describe event or problem

6 mo. old prescribed Kwell Lotion for scabies. Died from Lindane poisening.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

none known

C. Suspect medication(s)

Name: Kwell

Dose, frequency, route use

"bathe the child and give it once a day for three daysö Mother missed one day and

Therapy dates

10/02/01 to 10/05/02

Diagnosis for use

Scabies

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

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Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
997	4-17-51	female	300 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☑ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 6-29-02 **Date of report** 10/14/2002

Describe event or problem

please help I have tried every shampoo on the market plus Ovide and Linadine. I have been to Drs.x3 and my local Health Dept which located eggs. Three times the Dr. said no lice but I do. Daughter has cut my hair short. Husband picked for nits, yet I find I am pulling out half my hair trying to get rid of nits.Please contact me I am desperate.248-588-5512

Relevant tests/laboratory data

Other relevant history, including preexisting condition

hypertension,MS,Depression, Vasculitis,Asthma and Allergy

C. Suspect medication(s)

Name: A-200

Kwell, Ovide, Nix, Pronto, Coconut shampoo, and

Dose, frequency, route use

according to package

Therapy dates

6-29-02 to 10-9-02

Diagnosis for use

head lice

Event abated after use stopped or dose reduced

no

Lot #

n/a

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

all listed above

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association

P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
996	06/07/1992	female	60 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☑ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☑ hospitalization
- ☑ required intervention

other:

Date of event 12/19/99 **Date of report** 10/11/2002

Describe event or problem

My daughter returned to school one day having forgotten everything she had ever learned about Reading and Math. After several doctors visits and letters from her teachers describing her symptoms, (Dizziness, daydreaming, loss of skills, etc) we had her completely evaluated with no definite cause. After reading some info, I realized her problems started after using Lindane on her and 3 foster children on a regular basis. Every 2 weeks when the 3 would arrive back at our house, they were full of lice. Their doctor sent a big bottle of Lindane and I shampooed everyone. We were never warned about possible side effects.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

My daughter was basically healthy until this point. She had a mild lactose intolerance and a sensitivity to chemicals and dyes. The Lindane was given by a doctor, we were never warned about any adverse affects.

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use
1-2 times a month shampooed

Therapy dates
02/1999 to 11/1999

Diagnosis for use
headlice

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products
NONE

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
995	05/11/98	female	42 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 10/10/02 **Date of report** 10/11/2002

Describe event or problem

treated head lice with lindane and the lice did not die

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Kwell

Dose, frequency, route use

1 1/2 oz X 1

Therapy dates

10/10/02 to 10/10/02

Diagnosis for use

head lice

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association

P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
994	10/18/99	female	30 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: shaved head

Date of event 10/10/02 **Date of report** 10/10/2002

Describe event or problem

My 4 children were treated with the product Suleo-M which a Malathion based product. After 1 week the headlice were still prevalent. They were treated again. After a further week the headlice were still prevalent. They were treated again. After a further week the headlice were again present. Yesterday they were treated again and today their hair was shaven off.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: malathion

Dose, frequency, route use
See above

Therapy dates
09/18/02 to 10/10/02

Diagnosis for use
live headlice

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

Over the years 1995 to 2002 various treatments have been used including LYCLEAR, HAIR CONDITIONER, PRIODERM, COMBS

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

Health professional
☑ yes ☐ no

Occupation

Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
992	07/27-95	female	50 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: loss of hair

Date of event 10-2002 **Date of report** 10/9/2002

Describe event or problem

I found headlice on my child treated her with lindane and her hair is now breaking and falling out. Furthermeore even though we have treated properly she is still out of school because she still has nits and every 2 or 3 days we are finding live bugs. It is exspensive and gross. We have treated the whole house including the other 4 of us who live here. I dont know what else to do.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use
1 bottle every 2 weeks until lice are gone

Therapy dates
10/01/02 to 10/10/12

Diagnosis for use
treatent of head lice

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
989	01/14/97	female	55.0 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other: caused lg red blotches and whelps above & behin

Date of event 09/10/02 **Date of report** 10/6/2002

Describe event or problem

Child was treated with OTC pediculicide shampoo/mousse for head lice.Adverse reaction occured during treatment. Product did not get rid of lice or nits

Relevant tests/laboratory data

Other relevant history, including preexisting condition

none

C. Suspect medication(s)

Name: generic lice shampoo
rid mousse

Dose, frequency, route use
used 3-4 oz of product one time repeated in 7 days with mousse

Therapy dates
9-10-02 to 9-17-02

Diagnosis for use
head lice infestation

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products
have used Licefree and Pronto with sucess, also using robicomb presently.

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address
The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

phone # (781)449-6487

Health professional
☑ yes ☐ no

Occupation

Also reported to
☐ manufacturer
☐ user facility
☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
983	09/24/91	female	75 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 9/25/02 **Date of report** 9/25/2002

Describe event or problem

Tried Nix shampoo first. Did not kill lice. Called doctor and was prescribed Lindane and still am finding live lice.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane
nix

Dose, frequency, route use
used nix two times. Second treatment one week later. Used lindane three

Therapy dates
7/14/02 to 9/20/02

Diagnosis for use
Nix not effective at all, doctor prescribed lindane.

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products
none

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
976	02/01/67	female	149 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other: skin rash

Date of event 09/17/02 **Date of report** 9/21/2002

Describe event or problem

I descovered I had lice after noticing it on some children at church. This was 09/14/02. My husband and 2 adult children did not have it. I purchased Nix. I used a clean nit removal comb everyday. On 09/17/02 I found live lice. I phoned my doctor. He prescribed Kwell. I treated everyone in the home vaccummed everything and bagged up all that could not be laundered. The kwell caused a rash on my neck head and chest. I do suffer from Lupus. I have not seen lice on anyone in my family but today I pulled another live critter from my head. I am at my witts end. I have not gone anywhere to avoid infesting others. The two children were severly infested. I have been told they have been treated and are back to school and church. I don't know what else to do. Thank you.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

I have Lupus, raynuads, Minor heart problems, May have had a minor stroke.

C. Suspect medication(s)

Name: Kwell

Dose, frequency, route use
1 time

Therapy dates
09/17/02 to 09/17/02

Diagnosis for use
Lice

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products
Nix 09/14/02 did not work

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address
The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

phone # (781)449-6487

Health professional
☑ yes ☐ no

Occupation

Also reported to
☐ manufacturer
☐ user facility
☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
972	01/20/93	female	80 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 05/02/ **Date of report** 9/16/2002

Describe event or problem

I have been dealing with lice since May 2002-Have used multiple treatments only for them to come back. Some treatments work longer but the still comeback. ihave tried Rid, Nix several times and even Malathion. I am not quite sur what to do anymore

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix
Rid and Malathion

Dose, frequency, route use
unknown

Therapy dates
5/02 to 09/02

Diagnosis for use
head lice

Event abated after use stopped or dose reduced
doesn't apply

Lot #
unknown

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

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P.O. Box 610189, Newton, MA. 02461

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
970	06/24/2000	female	30 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 09/14/2002 **Date of report** 9/14/2002

Describe event or problem

After Two attempts of treating lice infestation with Pediatrician Rx Lindane and Nix (Permethrin) I have pulled out fast moving live lice from the childs hair.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane
Permethrin

Dose, frequency, route use
OTC dosages Lindane x3
Permethrin Nix x1

Therapy dates
9-2-02 to 9-14-02

Diagnosis for use
Lice infestation

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

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P.O. Box 610189, Newton, MA. 02461

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
968	12/23/1976	female	180 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other: difficulty breathing

Date of event 8/8/2002 **Date of report** 9/13/2002

Describe event or problem

each time I have treated my children with ANY prescription or over the counter head lice treatment I have had difficulty breathing for a few days. My 6 yr old son has difficulty breathing from the treatments as well. 8/8/2002 is only the MOST RECENT event

Relevant tests/laboratory data

Other relevant history, including preexisting condition

My 6 yr old son has been diagnosed with asthma.

C. Suspect medication(s)

Name: Ovide
Kwell, Lindane, Nix, Rid, Generic, Permethrin

Dose, frequency, route use
Suggested dose on box and/or prescription. Used twice in a 10 day period, used several

Therapy dates
1996 to 2002

Diagnosis for use
Head Lice

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address
The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

phone # (781)449-6487

Health professional
☑ yes ☐ no

Occupation

Also reported to
☐ manufacturer
☐ user facility
☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
966	06/05/88	female	180 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☑ required intervention

other:

Date of event 7/5/02 **Date of report** 9/9/2002

Describe event or problem

i havehad lice for 5 months i have tried everything

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix rid

Dose, frequency, route use

nix every 2 weeks for 3 weeks and rid was the first dose and it came back in 2

Therapy dates

0000 to 0000

Diagnosis for use

0000

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

0000

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
963	05/20/1993	female	47 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 04/00/ **Date of report** 9/3/2002

Describe event or problem

my child has had this problem for 2 yrs. now. i have tried everything to get rid of this. i am getting no where and it is keeping her out of school.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Kwell

Dose, frequency, route use

she has used nix, and rid

Therapy dates

2000 to 2002

Diagnosis for use

she still has lice

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

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The National Pediculosis Association

P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
950	12/17/1997	female	35 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 08/27/02 **Date of report** 8/28/2002

Describe event or problem

there was really no event - the products just did NOT work - I do not want to use more chemicals on her little head....

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane
Happy Harry's Lice Products

Dose, frequency, route use

I have used the Lindane every 5 days along with combing out her hair every

Therapy dates

8/11/02 to 8/27/02

Diagnosis for use

live bugs and thousands of nits in the scalp and hair

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
949	04/14/94	female	50 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 01/00/ **Date of report** 8/27/2002

Describe event or problem

We have used everything perscribed and unprescribed and nothing has worked. We have doneevrything that the doctors have perscribed. I have five little kids and two teenagers and Ihave tried everything. What can I do. I have even bought new pillows and all.Help me please. By the way we are clean people. Thank you for your time.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

None

C. Suspect medication(s)

Name: Kwell

Nix---Rid---123----Robbie comb, etc.

Dose, frequency, route use

weeky. Dosage unknow.

Therapy dates

08/00 to 08/02

Diagnosis for use

still living (little bastards)

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

Every week.....I have applied it to my kids head several times and I can not get rid of the lice.

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
943	10/09/1942	female	160 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other:

Date of event 10/20/02 **Date of report** 8/22/2002

Describe event or problem

found a lunp and is suspected to cancer, or precancer on breast. Do not know that is sttributed to this. But just to mention.
have used several products such RID, NIX, Lindane lotion, lindane shampoo, acticin, pronto and they all failed.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

none

C. Suspect medication(s)

Name: lindane
mayo. vinegar &mineral oil.

Dose, frequency, route use
multiple times over 4 years.

Therapy dates
1998 to 2002

Diagnosis for use
scabies and lice were dx by doctor and also said had a mite of some kind

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

Expiration date

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

Health professional
☑ yes ☐ no

Occupation

Also reported to
☐ manufacturer
☐ user facility
☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
937	05/01/52	female	125 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: long term affects

Date of event 6/86-7/86 **Date of report** 8/17/2002

Describe event or problem

Three months preganant and given Lindane for scabies. Weight problems,nerve problems,depression, severe stomach problems, hormone problems, incontience both urine and bowel,

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Was 3 months pregnant when used for supposily scabies. Not sure if I really had that.

C. Suspect medication(s)

Name: lindane
sulfa based ointment, sinilar

Dose, frequency, route use

Lindane one time. From neck to soles of feet overnight. Also applied to husband

Therapy dates

6/86 to 7/86

Diagnosis for use

Scabies

Event abated after use stopped or dose reduced

yes

Lot #

Exp. date

Event reappeared after reintroduction

no

NDC # - -

Concomitant medical products

Lindane 5/92 for headlice.

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
936	01/21/87	female	90 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☑ disability
- ☐ life-threatening
- ☑ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: Profound Mental Retardation

Date of event 6/86 **Date of report** 8/17/2002

Describe event or problem

Severe M.R. with mulitple disabilities. Enlarged liver, vison impaired,G.I. tract damage, no speech, motor disability, sensory disability, short in stature, low weight,incontience both urine and bowel, flat back head, excessive hair growth,chewing problems, hormone problems, allergies, Abnormal MRI's, C-T scans and EEG's with abnormal seizure activity

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Damaged in utero, Mother used when she was 3 months preganent

C. Suspect medication(s)

Name: lindane

sulfur based ointment, sinilar

Dose, frequency, route use

Used once

Therapy dates

6/86 to 7/86

Diagnosis for use

Scabies

Event abated after use stopped or dose reduced

yes

Lot #

Exp. date

Event reappeared after reintroduction

no

NDC # - -

Concomitant medical products

Lindane 5/92 for headlice

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association

P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
934	05/31/1961	female	136 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: neurological problems--undiagnosed

Date of event 04/01/02 **Date of report** 8/14/2002

Describe event or problem

Since within a few days of Lindane application I have exhibited neurological problems that continue to worsen.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

none

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use

Applied from neck to feet and left on for 12 hours. One week later was prescribed

Therapy dates

04/01/02 to 04/15/02

Diagnosis for use

Scabies

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association

P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
932	06/29/1971	female	140 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 8/1/2002 **Date of report** 8/13/2002

Describe event or problem

my children ages 16,8,7,12 and 5 contracted head lice. we have recently used both nix and lindane as directed! i have already sprayed my entire house with rid as well as washed all clothing and beddind in the house! we have went through all heads repeately- adleast 7 times piece by piece. right now as i am writing all my children and have our hair saturated in mayonaise as well as our hair rapped in plastic wrap and covered with a shower cap. i am becoming very discouraged and out-raged at the fact that no treatment has been sucessful at this time. we even tried removing all nits and lice with olive oil from the hair. i am now at a loss and am in hopes that you can help my family. we are not dirty people by no means and this lice has become a huge problem. my kids are sitting for hours each day and several times a day for the removal of both nits and lice. they are all

Relevant tests/laboratory data

Other relevant history, including preexisting condition

5 year old is asthmatic and no other conditions known in family

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use

used 2oz per per person.
also used nix

Therapy dates

8/1/2002 to 8/13/2002

Diagnosis for use

head lice-no positive results, still have lice

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

lindane 8/1/02,nix 8/10/02, entire house sprayed with rid 3 times, all clothing and beddind washed. heads saturated in olive oil and now head saturated in mayonaise and wrapped

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association

P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
929	05/06/71	female	188 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☑ required intervention

other:

Date of event 05/02/ **Date of report** 8/11/2002

Describe event or problem

I had an original lice outbreak in May and cleared it up then in end of June and now beginning of August I have lice still. I have used NIX the 1st time and a comb and during the 1st infestation i bought the lice meister comb and since then used it , not every day for the past 3 months but everyday during infestations, and THEY KEEP COMING BACK. I am 31 yrs old . your date of birht was malfunctioning several times

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix

Dose, frequency, route use
1

Therapy dates
05/02 to 05/02

Diagnosis for use
x

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

Health professional
☑ yes ☐ no

Occupation

Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
925	3/9/65	female	120 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: allergic or sensitivity

Date of event 05/08/02 **Date of report** 8/5/2002

Describe event or problem

After applying shampoo to myself and both kids, I developed a headache and almost sick to my stomach. Started within 1/2 hour, and has lasted most of the day. I felt very drowsy too.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

I have no allergies or medical problems.

C. Suspect medication(s)

Name: lindane
1% solution shampoo

Dose, frequency, route use
1% Lindane shampoo used once for 10 or 15 minutes.

Therapy dates
05/08/02 to 05/08/02

Diagnosis for use
Head lice

Event abated after use stopped or dose reduced
yes

Lot #
DIN 00703605

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products
None

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address
The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

phone # (781)449-6487

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
924	4/14/92	female	65 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 3/20/02 | **Date of report** 8/5/2002

Describe event or problem

my children came home with lice after spending a week at 2 full time sitters. (I have no way of knowing if they were infected from school before this week, or at the sitters) When I realized what was happening I treated them with the generic lice treatment from kmart. I combed with the comb provided - but I think it missed some nits -the comb slipped right over them. I did the best I could, then repeated this 10 days later as suggested. I also completely vacuumed, bagged, sprayed, laundered everything they came in contact with.In a month it was obvious it had not worked so I did this all again. Again it did not work, and I tried 2 separate Nix applications/combing -same bad comb - and vacuuming/bagging. Now I am facing continued lice - and don't know what to do. It has been 5 tiring months!

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix
also generic lice medication

Dose, frequency, route use
6 applications

Therapy dates
3/24/02 to 8/5/02

Diagnosis for use
I don't understand

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
922	05/18/94	female	42 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: RASH

Date of event 05/15/02 **Date of report** 8/3/2002

Describe event or problem

MY DAUGHTER HAD HEAD LICE WE WENT AND BOUGHT ALL TYPES OF HEAD LICE PRODUCTS TO GET RID OF IT .. BUT WHEN I FINISH ONE TREATMENT THE NEXT DAY SHE IS SCRATCHING AND I STILL SEE THE EGGS. I TRIED ALMOST EVERY PRODUCT AND CAN'T FIND A CURE .. CAN YOU PLEASE HELP ME AND MY FAMILY .. I CAN'T AFFORD THESE PRODUCTS ANY LONGER

Relevant tests/laboratory data

Other relevant history, including preexisting condition

N/A

C. Suspect medication(s)

Name: Rid

AC200 AND MANY MORE

Dose, frequency, route use

EVERY 7 DAYS FOR 3 MONTHS

Therapy dates

05/15/02 to 08/03/02

Diagnosis for use

STILL COMING BACK. SHE DOESN'T STOP ITCHING

Event abated after use stopped or dose reduced

no

Lot #

N/A

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

0

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association

P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
919	1/21/90	female	85 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 7/26/02 | **Date of report** 7/26/2002

Describe event or problem

Used Equate Lice Killing Shampoo. Found a few live lice after shampooing with product when I did the combing stage of treatment. Child insisted on shower cap due to episode of Arthur seen that day dealing with lice. The next morning child complained of burning sensation to scalp, immediately washed hair with regular shampoo and consulted internet for more info on lice.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Sensitive to nickel, some fragrances, etc., all result in contact dermetitus when contact is made.
Has seasonal allergies. Grass Pollen is only known one due to U of Iowa Ped Study she particiaped in.

C. Suspect medication(s)

Name: generic lice shampoo
Equate (compare to RID)

Dose, frequency, route use
6-8oz once then again 7-10 days later

Therapy dates
7/26/02 to 8/2/02

Diagnosis for use
Actual sighting of lice on head and OTC treatment

Event abated after use stopped or dose reduced
yes

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

Plan on doing manual removal. Allowing child to continue wearing shower cap for psychological comfort.

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
914	10/23/73	male	140 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☑ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: servere breathing problems

Date of event 7/13/2002 **Date of report** 7/21/2002

Describe event or problem

we purchased a nix brand lice treatment with the recommendation of a walmart pharmacist.i was also told to purchase the spray for the furniture and bedding, and i did. The problem is that my husband has severe sarcoidosis which is a lund diease and also attacks all the organs. We didnt think being so upset from the whole instance, we sprayed it, and washed all of our hair in the Nix. That night my husband had a bad breathing spelling and coughing attack and got so sick that he could hardly even sit up. Well I guess we know now and this product will never be used in our household again

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Severe Sarcoidosis with treatment of Methotraxate and 60 mg. of Prednisone a day. Lung involvement and Bone marrow involvement and other organ involvement from the Sarcoidosis.

C. Suspect medication(s)

Name: Nix

na

Dose, frequency, route use

one time

Therapy dates

07-13-2002 to 07-13-2002

Diagnosis for use

child that brought home lice

Event abated after use stopped or dose reduced

doesn't apply

Lot #

na

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

na

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association

P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
910	10/20/94	female	40 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: excessive absence from school

Date of event 09/15/00 **Date of report** 7/18/2002

Describe event or problem

I have been battling pediculosis since September, 2000. It has been a recurring problem that has effected both of my daughters age 6 and 7. I have used every brand lice shampoo, spray, gel, nit remover, etc.; bagged the pillows and toys, washed bedding in hot water and dried at hot temperature, vaccumed carpet and mattresses, etc. I have done everything I could possibly imagine; followed the instructions of the school nurse, teachers, even some of their solutions. I've put mayonaise on my girls' hair, used dog shampoo (which after reviewing this website, I now know is a no-no), had their hair cut and have even dyed their hair. Also, when I spoke to my pediatrician, he prescribed Lindane (which I now also know is a no-no. They have missed so many days of school that I was reported to the School Board Truancy Division. I don't

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name:

Rid, Nix, Pronto, Lindane, and generic brand

Dose, frequency, route use

Follwed the instructions. Have been using on a weekly basis. Used bi-weekly for

Therapy dates

09/15/00 to 07/18/02

Diagnosis for use

Pediculosis

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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phone # (781)449-6487

The National Pediculosis Association

P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
908	1-19-95	female	60 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 7/02 **Date of report** 7/17/2002

Describe event or problem

product (Kwell) appears to kill all live lice on pt, but several days to a week later, crawling lice are present again. Have repeated treatment 3x, after switching to Kwell from OTC treatments. Child has been infested for three months now. I have been checking regularly for nits, but obviously doing something wrong.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Kwell

Dose, frequency, route use
shampoo - every 10 days . repeated 3x.

Therapy dates
6/02 to 7/02

Diagnosis for use
pediculosis capitus

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

Expiration date

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
906	19/20/	male	150 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☑ hospitalization
- ☑ required intervention

other:

Date of event 7/12/2002 **Date of report** 7/16/2002

Describe event or problem

Patient has been on Coumadin for 6 months with a steady INR. He is concommitantly using other drugs, herbal medications, vitamins and supplements before starting on Coumadin. About 10 days prior to admission, the patient doubled up the dose of Chondroitin Sulfate and Glucosamine, and took some Nexium in a prn basis. Following that exposure, patient's INR went up tp 12.9. Following broad search for possible interactions between his big list of other therapy, we concluded that the main culprits are the Glucosamine/Chondroitin Sulfate, which dose had been recently increased. We recommended prompt dicontinuation of such and the INR was down to therapeutic levels in short period of time.
Other than that, we noted a possible interaction between Nexium and Coumadin (Nexium is highly protein bound and

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Patient has a history of Atrial Fibrillation, reason for which he is on Coumadin.

C. Suspect medication(s)

Name: Glucosamine and Chondroitin Sulfate

Dose, frequency, route use: dose was doubled; qd

Therapy dates: 1990 to 7/11/02

Diagnosis for use: osteoarthritis

Event abated after use stopped or dose reduced: yes

Lot #: ?

Exp. date:

Event reappeared after reintroduction: doesn't apply

NDC # - -

Concomitant medical products

Coumadin, 1-2mg PO QD
Nexium, 20mg PO PRN
GARLIC caps, 1cap QD

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address **phone #** (781)449-6487

The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

Health professional ☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
897	12/13/99	female	35 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event	7/10/02	Date of report	7/10/2002

Describe event or problem

No advervse reactions. Products just can't seem to kill and provide resistance to reinfestation

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix
Rdi

Dose, frequency, route use	Therapy dates
used each product, following directions closely. Retreated at recommended interval	6/30/02 to 7/10/02

Diagnosis for use
visible adult lice

Event abated after use stopped or dose reduced
doesn't apply

Lot #	Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

Health professional	Occupation	Also reported to
☑ yes ☐ no		☐ manufacturer ☐ user facility ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
892	08/12/74	female	132 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☑ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: diffiulty breathing; anxiety

Date of event 07/02/02 **Date of report** 7/8/2002

Describe event or problem

I took Lindane shapmoo twice here in korea..please help

Relevant tests/laboratory data

Other relevant history, including preexisting condition

anxiety, shakyness

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use

2wic on for 5 min

Therapy dates

343424 to 45374

Diagnosis for use

fd

Event abated after use stopped or dose reduced

doesn't apply

Lot #

fa

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

fd

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

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The National Pediculosis Association

P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
884	11/16/97	female	32 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 6/17/02 **Date of report** 6/28/2002

Describe event or problem

I had never seen lice, her cousin had them and my daughter had spent all weekend with her. On 6/17/02 We washed her head more as a precaution. Used the comb provided once and since the directions did not say to continue to pick at her hair daily we just checked it by looking each day. She did not show up with actual lice until approx 6/25/02 and her day care found one small just hatched on her head. No nits were discovered. Nix was used on my child on 6/25 after a second pharmacy told me it was the only one that worked. On 6/27 daycare discovered three more lice but no nits??? The product should have killed them. Her cousin who has very long hair used the Nix product right away and continued to have a problem with lice for two weeks straight until her doctor prescribed the malathion. She is still using a lice comb on the childs head. The products do

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name:

Walgreens Brand

Dose, frequency, route use

Used once- covered entire head- shampoo stayed on for 1/2 hour then rinsed

Therapy dates

6/11/02 to 6/11/02

Diagnosis for use

head lice exposure

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

6/17/02 Walgreens brand lice shampoo
6/19/02 used an electronic comb as a precaution, did not find any live lice

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

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Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
881	08/26/91	male	74 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: vitiligo

Date of event 12/00/01 **Date of report** 6/18/2002

Describe event or problem

Probable misdiag of scabies & tx w/ lindane resulting in brown & white blotches over body & face. has since been prescribed products by derm who said the lindane/kwell couldn't do this but until this he had no problems

Relevant tests/laboratory data

Other relevant history, including preexisting condition

previous to the rash he was healthy and never had any problems with his skin whatsoever.

C. Suspect medication(s)

Name: Kwell

Dose, frequency, route use

No directions, thought I was to use until gone

Therapy dates

12/00/01 to 12/04/01

Diagnosis for use

Skin rash

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

Since then he has had hydrocortisone creme. elidel which caused another reaction, sulfidine shampoo

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
880	08/29/47	female	265 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other:

Date of event 20/00/ **Date of report** 6/17/2002

Describe event or problem

Years ago, began w. blisters,itching @night on the wrist & between some fingers. worsened- now up both arms & not just @ night.blister bleed, streaks up arms. worse when hot & sweaty. ointments seem to make it itch more.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

I have allergies & a dermatologist I went to said that I didn't have scabies but atopic dermatitis but I'm not convinced

C. Suspect medication(s)

Name: lindane
cortisone creams

Dose, frequency, route use
don't remember

Therapy dates
2000- to 2002

Diagnosis for use
atopic dermatitis & scabies

Event abated after use stopped or dose reduced
yes

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products
cortisone creams, OTC creams for itch, benadryl

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

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Health professional
☑ yes ☐ no

Occupation

Also reported to
☐ manufacturer
☐ user facility
☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
879	12/05/1955	female	120 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☑ hospitalization
- ☐ required intervention

other:

Date of event 10/19/97 **Date of report** 6/16/2002

Describe event or problem

diagnosed with scabies, prescribed two scabies lotions, developed rash/blisters all over body. Ended up as a dermotology patient for two years as a result of this. Was later told I never had scabies

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Car accident in 1995, hospital for 6 weeks following this, broken pelvis, tibia, femur and fibula. Contracted MRSA as a patient in ICU. Was told I was clear of this before I was treated for scabies.

C. Suspect medication(s)

Name: lindane
LyClear

Dose, frequency, route use
Quellada left over night.LyClear left 24 hours

Therapy dates
09/1997 to 10/1997

Diagnosis for use
Blisters fingers,rash on arm,

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

From October 1997 I was treated with Betnovate and prednasone and various other steroid applications to try bring the reaction under control. I was also given Augmentan

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
- ☐ health professional
- ☐ user facility
- ☐ distributor

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

Expiration date

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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Health professional
☑ yes ☐ no

Occupation

Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
878	1-16-78	female	125 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: flu-like symptoms, salivation

Date of event 6-15-02 | **Date of report** 6/16/2002

Describe event or problem

Used Lindane as prescribed. After one hour of application, I started salivating -- a lot. Then, flu-like symptoms such as dizziness, weakness, and nausea followed.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane shampoo 1%

Dose, frequency, route use
1/3 of bottle

Therapy dates
6-13-02 to 6-15-02

Diagnosis for use
scabies

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

Do not yet know if application was effective.

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

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Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
875	20/00/	male	35 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 06/02/ **Date of report** 6/12/2002

Describe event or problem

Treated 3 kids ages 2,3, and 7 with NIX. Then got prescription pediatrician 5 bottles of OVIDE which didn't work. After ealized that ovide isn't supposed to be used on children under 6 but the doctor prescribed it any way!

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Ovide
NIX shampoo and NIX environment spray

Dose, frequency, route use
several times

Therapy dates
06/06 to 06/02

Diagnosis for use
head lice

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

I am a fanatic about not using pesticides but lost it with this. I sprayed all the mattresses both sides and the entire house.

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

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P.O. Box 610189, Newton, MA. 02461

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
873	05/16/1994	female	50 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other:

Date of event 06/08/2002 **Date of report** 6/11/2002

Describe event or problem

used the rid three times to treat daughter's head lice. None of the medications worked. dr prescribed kwell. after using, huge patches of her hair fell out also looked like something white maybe like dandruff was in the pieces that fell out

Relevant tests/laboratory data

Other relevant history, including preexisting condition

i brushed her about 5 hours later and i think no more hair is falling out. it was enough to be noticable when her hiar dried.

C. Suspect medication(s)

Name: Kwell

Dose, frequency, route use
1 - twice the amount of shampoo a person would use

Therapy dates
06082202 to 06082002

Diagnosis for use
head lice

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

Expiration date

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

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P.O. Box 610189, Newton, MA. 02461

Health professional
☑ yes ☐ no

Occupation

Also reported to
☐ manufacturer
☐ user facility
☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
872	05/06/91	female	75 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 05/20/02 | **Date of report** 6/7/2002

Describe event or problem

Nix ineffective and gave youngest child (7) nausea each treatment.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix

Dose, frequency, route use

Full dose given 3 times within 3 week period

Therapy dates

05/13/02 to /6/03/02

Diagnosis for use

Lice

Event abated after use stopped or dose reduced

yes

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
871	4/3/1999	female	30 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: burn - hair loss

Date of event 6/3/2002 **Date of report** 6/6/2002

Describe event or problem

Treated - her with NIX early May - saw hair loss and failure again treated with NIX 6/3 Burn marks left on her head with possible hair loss - too soon to tell.... I am devistated - plus it did not work!

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Even after the 10 min application I found LIVE Lice.

C. Suspect medication(s)

Name: Nix

Dose, frequency, route use

2 treatment - first one 15 min second only 10 min

Therapy dates

5/10/02 to 6/3/02

Diagnosis for use

lice

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

TODAY 6/6 Olive Oil treatment - trying to drown them i guess - nit picking everyday. Please let me know if you have any info on the red marks or hair loss ??

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address **phone #** (781)449-6487

The National Pediculosis Association

P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
866	4-15-52	male	150 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: skin cancer

Date of event 1/31/01 **Date of report** 6/2/2002

Describe event or problem

misdiagnosed scabies...took lindane and skin cancer had been popping up ever since.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

hiv positive

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use

kept reapplying...no dicertions were given to me

Therapy dates

1/31/01 to 2/3/02

Diagnosis for use

scabies

Event abated after use stopped or dose reduced

doesn't apply

Lot #

05439 169280

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

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Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
865	12-11-72	female	158 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: persistant cough in household occupants after us

Date of event 10/01-1/02 **Date of report** 6/1/2002

Describe event or problem

I was teaching at church on Wed. nights when I noticed lice. My husband and I are the only ones that we observed lice on. I never saw them in my 8 yr old daughters hair. I quit teaching and still continued with the problem for months.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix

Dose, frequency, route use
1/2 conditioner per 2 weeks for 4 mth.(avg)

Therapy dates
10/02 to 1/02

Diagnosis for use
found lice in my hair

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
no

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

phone # (781)449-6487

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
862	10-01-93	female	83 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 52/90/2 **Date of report** 5/31/2002

Describe event or problem

nothing is working

Relevant tests/laboratory data

Other relevant history, including preexisting condition

none

C. Suspect medication(s)

Name:

rid nix lindane

Dose, frequency, route use

once aweek

Therapy dates

5-05 to 5-31

Diagnosis for use

don't understand

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

5-30 lindane, 5-28lindane 5-25 nix 5-23nixs 5-20 rid

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

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Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
861	10/25/94	female	50 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 05/05/02 **Date of report** 5/30/2002

Describe event or problem

I USED RID, NIX, GENERIC, LINDANE, EVERYTHING.NOTHING WORKS. I ORDERED A PRODUCT CALLED NOT NICE TO LICE THAT BASICALLY LOOSENS THE GLUE AND YOU CAN WASH THEM OUT. I AM READY TO TRY ANYTHING. I WORRY ABOUT THE CHEMICALS I AM EXPOSING MY CHILD TO.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Rid
NIX, GENERIC LICE SHAMPOO

Dose, frequency, route use
1X WK X 3 WKS.ENOUGH TO SATURATE HAIR AS

Therapy dates
050502 to 052902

Diagnosis for use
HEAD LICE INFESTATION

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
859	6/16/93	female	105 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 5/01/02 **Date of report** 5/22/2002

Describe event or problem

I HAVE USED ALL OVER THE COUNTER PRODUCTS AND HAVE HAD NO LUCK, I ALSO WENT TO THE DOCTOR AND THEY GAVE HER KWELL SHAMPOO, I HAVE USED THAT AND I AM STILL PULLING OUT KNITS. I NEED TO KNOW WHAT TO DO IT HAS BEEN A MONTH NOW!!!

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Kwell

Dose, frequency, route use
USED ONCE

Therapy dates
5/20/02 to 5/20/02

Diagnosis for use
STILL FINDING EGGS

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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P.O. Box 610189, Newton, MA. 02461

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
857	9-23-98	female	35 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☑ disability
- ☑ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 9/00/01 **Date of report** 5/14/2002

Describe event or problem

I have written to you before, months ago,about my daughter , she developed conjunctivitis and rash, well 9 months later and 10 doctors later she has been put on methotrexate and prednisone

Relevant tests/laboratory data

Other relevant history, including preexisting condition

no prexisting conditions

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use

totalof four times

Therapy dates

9/00/01 to 10/00/01

Diagnosis for use

doctor never saw us he called it in

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

Expiration date

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
855	11/25/1970	female	125 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 07/12/2001 **Date of report** 5/11/2002

Describe event or problem

nothing works doctor said he saw no lice but gave me prescription shamopoo. i used everything else

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use

once in a week

Therapy dates

000000 to 000000

Diagnosis for use

00000

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
849	6-5-63	male	154 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☑ death
- ☑ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☑ hospitalization
- ☐ required intervention

other:

Date of event 7-10-98

Date of report 4/30/2002

Describe event or problem

disability, death

Relevant tests/laboratory data

Other relevant history, including preexisting condition

None

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use

weekly

Therapy dates

11/93 to 11/93

Diagnosis for use

Head Lice

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association

P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
848	5-92	female	685 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☑ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☑ hospitalization
- ☐ required intervention

other:

Date of event 7-98

Date of report 4/27/2002

Describe event or problem

My daughter stsrted to have seisures at home was the first one,then at school

Relevant tests/laboratory data

Other relevant history, including preexisting condition

now she has special edgucation and alot of other problem .

C. Suspect medication(s)

Name: Nix

Dose, frequency, route use

half a bottle

Therapy dates

1998 to 2001

Diagnosis for use

alot of nits and lice in hair

Event abated after use stopped or dose reduced

yes

Lot #

Exp. date

Event reappeared after reintroduction

no

NDC # - -

Concomitant medical products

to many to say

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
841	6-13-68	female	110 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☑ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 4-14-96 **Date of report** 4/5/2002

Describe event or problem

Treated for scabies with lindane. Developed multiple chemical sensitivity almost immediately. Have been disabled with MCS since using lindane.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Had bout with ulcerative colitis from 1986-1989, but had been in remission for 7 years when exposed to Lindane (onset of MCS).

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use

2 applications, 2 days

Therapy dates

4-14-96 to 4-16-96

Diagnosis for use

Scabies.

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
840	19/48/	female	128 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: Dizziness

Date of event 3/12/02 **Date of report** 4/5/2002

Describe event or problem

On 3/12, I suffered mental and visual spinning. I still experience occasional wooziness. Since this happened so close to my taking the lindane, I am suspect that it may be related.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

I suffer from migraines but had no migraine when I suffered the spinning room.

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use

Full body application for 12 hours.

Therapy dates

2/26/02 to 2/28/02

Diagnosis for use

scabies

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

no

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

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P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
838	6/22/71	female	130 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 1/02 | **Date of report** 3/30/2002

Describe event or problem

The pediatrician for my kids insists on me using this product repeatably when me and the nurse have explained they havbe very tiny nits that are hard to remove. it's been 6 months. they tell me to keep using lindane even though am 4 months pregnant .

Relevant tests/laboratory data

Other relevant history, including preexisting condition

kids have asthma. i have diabetes and pregnant. kids range from 14 to 2

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use

once a week

Therapy dates

1/02 to 3/02

Diagnosis for use

headlice

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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The National Pediculosis Association

P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
837	5/95	female	50 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: sores all over head

Date of event 3/15/02 | **Date of report** 3/27/2002

Describe event or problem

I was called from the school that my daughter had lice. I went and bought the Nix brand. When I went to do the 10 day follow up i didn't. The sores on her head were to bad.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix

Dose, frequency, route use
only the one time

Therapy dates
3/13/02 to 3/22/02

Diagnosis for use
lice

Event abated after use stopped or dose reduced
no

Lot #
no

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

Rid 3/26
Mayo 3/26
Tea tree oil 3/27

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
834	12/9/96	female	40 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 3/18/02 **Date of report** 3/18/2002

Describe event or problem

kwell does not work on the ones my daughter has. school principal and nurse could not tell me how the classroom was cleaned of lice

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Kwell

Dose, frequency, route use
shampoo every 5 days

Therapy dates
3/16 to 3/18

Diagnosis for use
headlice

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

olive oil
RID
NIX

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
826	05/10/59	male	235 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other:

Date of event 02/20/02	Date of report 3/5/2002

Describe event or problem

Full body case of sarcoptic mange in human. Lindane treatment failed to control. Lindane has caused shortness of breath, tiredness.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use	Therapy dates
1% lotion.	12/2/01 to 12/9/01

Diagnosis for use

Repeated in February.

Event abated after use stopped or dose reduced

doesn't apply

Lot #	Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

☐ health professional
☐ user facility
☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association

P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

☐ manufacturer
☐ user facility
☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
821	11/28/60	female	115 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: skin reaction

Date of event 2/02 | **Date of report** 3/1/2002

Describe event or problem

Itchy red skin blisters over ear, eye, neck & fingers

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: generic lice shampoo

Dose, frequency, route use

5 treatments in 2 mths

Therapy dates

12/27 to 2/22

Diagnosis for use

Reuse Rid and have dermatologist manage reaction

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association

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Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
820	10/30/91	female	75 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 02/02/ **Date of report** 2/27/2002

Describe event or problem

child has became sick with headachs,stomach achs and not hungry

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Rid max

Dose, frequency, route use

used 3 times

Therapy dates

02/12/02 to 02/22/02

Diagnosis for use

n

Event abated after use stopped or dose reduced

no

Lot #

dk

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

none

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

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Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
815	12/01/45	female	125 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☑ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☑ required intervention

other:

Date of event 02/20/02 | **Date of report** 2/20/2002

Describe event or problem

recurrance of precancerous cells (DCI) in left breast. Rt breast mastectomy 9/01

Relevant tests/laboratory data

Other relevant history, including preexisting condition

update on report of 02/19/02

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use

2-3 times full strengh

Therapy dates

01/98 to 02/98

Diagnosis for use

scabies, misdiagnosis

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

see report of 02/19/02

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association

P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
814	11/17/66	female	150 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☑ required intervention

other:

Date of event 01/20/02 | **Date of report** 2/20/2002

Describe event or problem

Used lindane prescribed on my child and myself and became very ill. Used it for 4 minutes and rinsed it completely and 10 minutes later I felt nauseous, hot flashes and felt faint. Was sick for several days following.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

I have hypoactive thyroid disease. Doctor never mentioned any risks from lindane.

C. Suspect medication(s)

Name: lindane

Mort was in the name 1% generic

Dose, frequency, route use

Used only once

Therapy dates

01/01/02 to 02/20/02

Diagnosis for use

Lice not killed by NIX

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

I also sprayed with NIX spray previous to using the lindane.

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association

P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
812	12/01/45	female	125 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☑ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☑ hospitalization
- ☐ required intervention

other:

Date of event 2/98-2/02

Date of report 2/19/2002

Describe event or problem

Skin lesions, breast cancer, eye problems, joint pain

Relevant tests/laboratory data

Other relevant history, including preexisting condition

allergies: airborn and Latex reactions in respiratory system and in skin. Occasional asthma symptoms.

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use

Shampoo full strength on entire body.

Therapy dates

01/05/98 to 2/02

Diagnosis for use

lice/scabies

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

Numerous antibiotics, Numerous cortisone preparations, diflucan

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

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Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
804	01/04/79	female	110 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☑ disability
- ☐ life-threatening
- ☑ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 01/25/99 **Date of report** 1/26/2002

Describe event or problem

Prescribed elimite cream to apply every night wash off AM.Was in ER 10 days later Pressure headaches in the back of my head disorientation presistent burning tingling stinging feeling in my legs and hands Left side worse Recent diagnosis:cervical cancer

Relevant tests/laboratory data

Other relevant history, including preexisting condition

I never had any major illnesses prior to taking this drug.

C. Suspect medication(s)

Name:

Elimite(permethrin) Topical Cream

Dose, frequency, route use

Several nights For 8-12hr,wash off AM@DR advice

Therapy dates

01/15/99 to 01/25/99

Diagnosis for use

a misdiagnosis of scabies

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

I am currently seeing two neurologist for diagnosed neuropathy

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
800	6-5-96	male	45 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event	Date of report
1-12-02	1/22/2002

Describe event or problem

Used Kwell two times and RID two timesthat caused headaches, dizziness, diahrea, and fatique

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Kwell
RID

Dose, frequency, route use	Therapy dates
RID two times and Kwell (one oz.) two times	1-15-02 to 1-19-02

Diagnosis for use
head lice

Event abated after use stopped or dose reduced
no

Lot #	Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address | **phone #** (781)449-6487

The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

Health professional	Occupation	Also reported to
☑ yes ☐ no		☐ manufacturer ☐ user facility ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
799	5-28-70	female	125 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other:

Date of event 1-12-02	Date of report 1/22/2002

Describe event or problem

Used Kwell two times on my self and a friend, both have headaches, dizziness, diahrea, and fatique

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Kwell

Dose, frequency, route use	Therapy dates
two ounces in two days	1-16-02 to 1-19-02

Diagnosis for use	Event abated after use stopped or dose reduced
head lice	no

Lot #	Exp. date	Event reappeared after reintroduction
		doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address	Operator of device
	☐ health professional ☐ user facility ☐ distributor

	Expiration date
model # _____ catalog # _____ serial # _____ lot # _____ other # _____	If implanted, give date
	If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address	phone # (781)449-6487
The National Pediculosis Association P.O. Box 610189, Newton, MA. 02461	

Health professional	Occupation	Also reported to
☑ yes ☐ no		☐ manufacturer ☐ user facility ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
797	11/22/99	female	31 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other:

Date of event 01/19/2002 **Date of report** 1/19/2002

Describe event or problem

WE can not get rid of the lice, all in household are infected, some of us even have open sores on head, and neckline.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

NA

C. Suspect medication(s)

Name: Rid

Dose, frequency, route use
Shampoo every 10 days, comb out everyday

Therapy dates
10/31 to 01/19

Diagnosis for use
Lice

Event abated after use stopped or dose reduced
no

Lot #
NA

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products
Nix; twice

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address
The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

phone # (781)449-6487

Health professional
☑ yes ☐ no

Occupation

Also reported to
☐ manufacturer
☐ user facility
☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
793	04/09/1978	female	150 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: can't get rid of them

Date of event 01/15/2002 **Date of report** 1/15/2002

Describe event or problem

I've used RID and KWELL shampoos, and cannot GET RID OF THESE THINGS.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Rid

Dose, frequency, route use
Extra Strength, used twice, used 4oz each time

Therapy dates
12/2001 to 1/15/2002

Diagnosis for use
Head lice

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products
Kwell

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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The National Pediculosis Association
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phone # (781)449-6487

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
791	2-2-56	male	290 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☑ death
- ☑ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: prirectal cancer

Date of event 19/92/ **Date of report** 1/14/2002

Describe event or problem

In severce in 1975/76 in that time he was treated for scabies for 8 months. In 1992 he developed cancer on his left buttox because of the extream use of kwell lotion for such a long time might this be the cause for tumer?

Relevant tests/laboratory data

Other relevant history, including preexisting condition

secondary disabilities from cancer.

C. Suspect medication(s)

Name: Kwell

Dose, frequency, route use

every day for 8 months

Therapy dates

11/75 to 6/76

Diagnosis for use

scaibies

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

perianal cancer 1992

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
787	4/8/96	female	39 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 09/01/ **Date of report** 1/10/2002

Describe event or problem

MY DAUGHTER,AGE 5 1/2 YRS, ATTENDS KINDERGARTEN.WE HAVE BEEN SUFFERING THRU REPEATED OUTBREAKS OF HEAD LICE SINCE SEPTEMBER - SHE'LL BE CLEAR THEN IT COMES BACK(2 OTHER CHILDREN IN THE CLASS HAVE ALSO BEEN AFFECTED).I AM VERY DESPARATE.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

MY DAUGHTER & I BOTH HAVE ASTHMA - THE PRODUCTS AGGRAVATE IT.ALSO,I AM PREGNANT & VERY CONCERNED IF THESE PRODUCTS COULD HAVE ADVERSE EFFECT ON MY UNBORN CHILD

C. Suspect medication(s)

Name: Nix
RID/OVIDE

Dose, frequency, route use
EVERY 10 DAYS

Therapy dates
09/01
to
01/02

Diagnosis for use
HEAD LICE

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
786	02/07/96	female	38 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 01/09/02 **Date of report** 1/9/2002

Describe event or problem

My daughter has been sent home 5 times in 8 weeks for lice/nits. We have treated her with over the counter and prescription medication medication. We have followed all of your suggested treatments

Relevant tests/laboratory data

Other relevant history, including preexisting condition

none

C. Suspect medication(s)

Name: Clear
RID, NIX, Quell

Dose, frequency, route use
every 10 days for 2 months

Therapy dates
111001 to 010602

Diagnosis for use
Lice or nits seen by school nurse.

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
785	03/04/52	female	135 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other: nervousness

Date of event	12-01	Date of report	1/7/2002

Describe event or problem

after using lindane, extreme itching and nervousnee.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: --
lindane

Dose, frequency, route use	Therapy dates
1%	to

Diagnosis for use	Event abated after use stopped or dose reduced
head lice	no

Lot #	Exp. date	Event reappeared after reintroduction
		doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

Health professional	Occupation	Also reported to
☑ yes ☐ no		☐ manufacturer ☐ user facility ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
779	1925/09/23	female	120 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 2001/10/15 **Date of report** 12/22/2001

Describe event or problem

My mother, who is 76 years old seem s to get a reoccuring case of head lice, every couple of years. She has no idea how she gets them and this time she does not seem to be able to get rid of them. It has been about 2 1/2 months.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

None of the over the counter medications are working for her at all.

C. Suspect medication(s)

Name: Kwell
Nix

Dose, frequency, route use
used about 15 times in the last 2 1/2 months

Therapy dates
10/15/2001 to 21/12/2001

Diagnosis for use
shower, put on cream rinse, shower off

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address **phone #** (781)449-6487

The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
776	12/29/88	female	48 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☑ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: cancer - medulloblastoma

Date of event 6/13/98 **Date of report** 12/19/2001

Describe event or problem

Diagnosed withtumour. Wondering if could be connection with repeated head lice. Some treated with Kwell - lindane. I would like to know if there has been any coneection made between use of lindane and childhood brain tumours.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

none

C. Suspect medication(s)

Name: Kwell

rid and tea tree oil

Dose, frequency, route use

fairly regularly over about 6 years

Therapy dates

1993 to 1998

Diagnosis for use

recurrent head lice

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

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The National Pediculosis Association

P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
768	01/28/92	female	72 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☑ required intervention

other:

Date of event 11/20/01 **Date of report** 12/12/2001

Describe event or problem

Head lice infestation

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Scabbies Head sores and scabs

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use

10 min rinse apply again in two weeks 1%

Therapy dates

11/22/01 to 12/12/01

Diagnosis for use

Examined found svere head lice infestation

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

Internal antibiotics scabbies cream

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association

P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
761	12-24-90	male	75 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☑ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☑ required intervention
- other:

Date of event 19/93/ | **Date of report** 12/5/2001

Describe event or problem

Used prescribed lindane for scabies treatment. Subsequently experienced seizures w/permanent brain damage, adhd.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

no pre existing medical conditions

C. Suspect medication(s)

Name: Kwell

Dose, frequency, route use

applied and left on overnight

Therapy dates

1993 to 1994

Diagnosis for use

scabies

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association

P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
758	24/02/81	male	147 lbs

B. Adverse event or product problem

Adverse Event

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☑ required intervention

other:

Date of event 07/19/97 **Date of report** 12/3/2001

Describe event or problem

I was 16 at the time. I had been treated twice with lindane for scabies and was itching very badly around my genitals. It got that bad that I applied more of the cream. Four years on I'm still suffering. It's ruining my life. What can I do about it?

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Asthma

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use

I applyed to that area 2-3 times in one week.

Therapy dates

07/1997 to 11/1997

Diagnosis for use

Scabies

Event abated after use stopped or dose reduced

doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

none

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
756	03/31/91	female	93 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 10/01/ **Date of report** 12/1/2001

Describe event or problem

None of the products I have been using for my children seem to be working prescription or not.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix
Lindane1% shampoo

Dose, frequency, route use
Nix-applied liberally all overhead1xevery7-14days

Therapy dates
10/01 to 12/01

Diagnosis for use
Lice

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products
Lindane 1% shampoo 11/17/01

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address
The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

phone # (781)449-6487

Health professional
☑ yes ☐ no

Occupation

Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
753	12/11/93	female	70 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 11/13/01 **Date of report** 11/22/2001

Describe event or problem

Two treatments with lice shampoo, one treatment with lice cream rinse and one treatment with doctor prescribed lindane were all unsuccessful. Even after 18 hours of combing, I was still pulling out live, crawling adults as little as 5 days later.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

none

C. Suspect medication(s)

Name: generic lice shampoo
generic lice cream rinse & lindane

Dose, frequency, route use
2lice shampoo
1 lice cream rinse
1 lindane

Therapy dates
11/13/01 to 11/22/01

Diagnosis for use
none

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products
none

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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phone # (781)449-6487

The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

Health professional
☑ yes ☐ no

Occupation

Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
752	11-23-76	female	300 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 11-19

Date of report 11/20/2001

Describe event or problem

I used the NIX product and my mom used the comb provided and when she got the louse out itself it was still alive. I though that it was to kill lice and their eggs!!!!!

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix

Dose, frequency, route use

used once

Therapy dates

11-19 to 11-20

Diagnosis for use

still got them

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

doesn't apply

NDC # - -

Concomitant medical products

soaked my head in vinegar still did not work!!

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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The National Pediculosis Association

P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
750	06/02/2000	female	30 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: deep cough

Date of event 11-18-2001 **Date of report** 11/19/2001

Describe event or problem

A few hours after treatment, she had very deep cough-from chest-like croup..about 3 weeks ago I had to treat her..and within days I had to take her to the doctor..she had a severe case of croup. I also used spray..all furniture, including her bed

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix

Dose, frequency, route use
used enough to saturate hair...about 1oz

Therapy dates
11-18 to 11-19

Diagnosis for use
Lice

Event abated after use stopped or dose reduced
no

Lot #
0j1708

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

Expiration date

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address
The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

phone # (781)449-6487

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
749	06-27-95	female	42 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 11-16-01 **Date of report** 11/19/2001

Describe event or problem

My daughter reacted with hives, welts, swelling of the wrists, prickly pimples, and intense itching of the affected areas.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix

Dose, frequency, route use
first application and normal dosage

Therapy dates
11-16 to 11-19

Diagnosis for use
single application for head lice and nits

Event abated after use stopped or dose reduced
yes

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products
Used vinegar, mayonnaise, and manual removal

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
745	2-12-95	female	40 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other:

Date of event 11-01 **Date of report** 11/14/2001

Describe event or problem

Live lice were found after treatment. First applied RID then the following day NIX. 2 days later still combing out small imature lice. on 3rd day applied Lice Free. Children complained of stomach ache immediately.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Have had lice within the past 3 months prior

C. Suspect medication(s)

Name: Rid
NIX, lice free

Dose, frequency, route use
followed directions

Therapy dates
11-9-01 to 11-14-01

Diagnosis for use
fou

Event abated after use stopped or dose reduced
yes

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address
The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

phone # (781)449-6487

Health professional
☑ yes ☐ no

Occupation

Also reported to
☐ manufacturer
☐ user facility
☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
744	6/17/52	female	180 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other: Chemical sensitivity worse

Date of event 1/97 **Date of report** 11/11/2001

Describe event or problem

I used Nix and Rid on two occasions. On the second occasion of using Rid I developed a severe rash all over my body including my head. Pharmacist said I was alergic. PLUS, this was NOT killing the lice. Pharmacist said they are resistant.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

Fibromyalgia
Sjogrens

C. Suspect medication(s)

Name: Rid

Dose, frequency, route use	Therapy dates
1	1/97 to 3/97

Diagnosis for use	Event abated after use stopped or dose reduced
lice	no

Lot #	Exp. date	Event reappeared after reintroduction
		yes

NDC # - -

Concomitant medical products

My weight is my business. Not to be reported on the internet. Sorry.

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

Expiration date

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

Health professional	Occupation	Also reported to
☑ yes ☐ no		☐ manufacturer ☐ user facility ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
743	8/20/93	female	62 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: scalp burn

Date of event	11/5/2001	Date of report	11/8/2001

Describe event or problem

My daughter was sent home from school with lice. We treated with RID. It seemed to burn her scalp at the base of her head/neckline.

We also tried Mineral Oil & vinegar.It Failed also.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Rid

mineral oil & vinegar

Dose, frequency, route use	Therapy dates
The whole bottle of RID, used Once.	110/05/200 to 11/09/2001

Diagnosis for use	Event abated after use stopped or dose reduced
Lice	no

Lot #	Exp. date	Event reappeared after reintroduction
		yes

NDC # - -

Concomitant medical products

11/8/2001 Mineral oil/ vinegar equal parts

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

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The National Pediculosis Association

P.O. Box 610189, Newton, MA. 02461

Health professional	Occupation	Also reported to
☑ yes ☐ no		☐ manufacturer ☐ user facility ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
742	10/05/96	female	42 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other: SEVERE IRRITATION TO SCALP & REINFE

Date of event 10/13/01 **Date of report** 11/8/2001

Describe event or problem

FOUND LICE ON 5YR OLD, MD SAID NIX-2 TREATMENT LATER, LINDANE WAS PRESCRIBED. BOUGHT THE LICE MEISTER AND USED THAT TONIGHT. SCHOOL NURSED CHECKED THE KIDS 2X & FOUND NOTHING. 3 WKS LATER & STILL ON MY CHILD'S HEAD, MD SENT SAMPLE TO LAB FINALLY.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

TOO BAD THE MD OFFICE & SCHOOL SYSTEM WEREN'T BETTER EDUCATED ON THIS WEBSITE.

C. Suspect medication(s)

Name: Kwell

NIX

Dose, frequency, route use

30-60ML EVERY 7DAYS IF NEEDED

Therapy dates

10/13/01 to 11/07/01

Diagnosis for use

EVERY 7 DAYS IF NEEDED

Event abated after use stopped or dose reduced

no

Lot #

RX #670585299/N

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

NIX-2X, NOW THE KWELL-THIS IS STILL AN ONGOING CHALLENGE, TONIGHT WE USED THE LICE MEISTER FOR 2HRS STRAIGHT ON BOTH

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____

catalog # _____

serial # _____

lot # _____

other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association

P.O. Box 610189, Newton, MA. 02461

Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
737	6/21/96	female	41 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☑ required intervention

other: it just never ends

Date of event 10/31/2001 **Date of report** 11/1/2001

Describe event or problem

My 5 yr old daughter seems to get head lice all the time without the rest of my household getting this. This seems to occur at least once a month...maybe the over-the-counter and prescribed treatments aren't working on her anymore?

Relevant tests/laboratory data

Other relevant history, including preexisting condition

none

C. Suspect medication(s)

Name: generic lice shampoo and Nix prescribed

Dose, frequency, route use

now i do this at least once a month

Therapy dates

10/31/2002 to 10/31/2001

Diagnosis for use

put in dry hair, let stand ten min. lather,rinse

Event abated after use stopped or dose reduced

yes

Lot #

?

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

same

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

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Health professional

☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
729	8/9/68	female	185 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 4/00-10-01 **Date of report** 10/25/2001

Describe event or problem

I HAVE HAD HEAD LICE FOR ALMOST 2 YEARS I HAVE TRIED EVERYTHING PLEASE HELP ME

Relevant tests/laboratory data

Other relevant history, including preexisting condition

I ALSO HAVE MS

C. Suspect medication(s)

Name: Rid
LINDANE

Dose, frequency, route use
EVERY FEW WEEKS

Therapy dates
4-21
to
5-21

Diagnosis for use
HEAD LICE

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products

LICE ARREST MAYO VASELINE -NIX CUT 10 INCHES OF MY HAIR A PERM DYING MY HAIR COUNTLESS TIMES I AM ON THE VERGE OF USING

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

Expiration date

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

Health professional
☑ yes ☐ no

Occupation

Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
726	4/9/51	male	220 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other:

Date of event 9/10-01 **Date of report** 10/22/2001

Describe event or problem

ACCORDING TO BLOOD TEST MY TESTOSTERONE WENT UP 500 TO 600 POINTS. MY BLOOD TEST SHOWED MY THROID MAY, MAY HAVE BEEN LOWERED.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

HAVE A VERY LOW TESTOSTERONE LEVEL, HIGH LIVER ENZYMES, AND UNKNOWN PITUTARY GLAND OUTPUT.

C. Suspect medication(s)

Name: lindane

Dose, frequency, route use
1%, AND USED TWICE

Therapy dates
9/14/01 to 10/4/01

Diagnosis for use
SCABIES

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

Health professional
☑ yes ☐ no

Occupation

Also reported to
☐ manufacturer
☐ user facility
☐ distributor

If you do NOT want your identity disclosed to the manufacturer, place an ☐

MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
724	04/17/99	male	27 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 10/13/2001 **Date of report** 10/21/2001

Describe event or problem

treated for head lice

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Nix kwell

Dose, frequency, route use

3 times

Therapy dates

10/13/01 to 10/21/01

Diagnosis for use

head lice

Event abated after use stopped or dose reduced

no

Lot #

Exp. date

Event reappeared after reintroduction

yes

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device

- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?

☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

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Health professional

☑ yes ☐ no

Occupation

Also reported to

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- ☐ user facility
- ☐ distributor

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MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
723	9/14/1993	female	100 lbs

B. Adverse event or product problem

Adverse Event & Product Problem

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other: vomiting

Date of event 8/15/2001	Date of report 10/20/2001

Describe event or problem

my daughter was prescribed OVIDE. It had an unbelievably strong odor. I used it on my daughter and she threw up from the fumes of the product. It was a horrible experience for the both of us. I have been fighting the lice problem since July 2001

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Ovide

Dose, frequency, route use	Therapy dates
once	8/15/2001 to 8/15/2001

Diagnosis for use	Event abated after use stopped or dose reduced
LICE	yes

Lot #	Exp. date	Event reappeared after reintroduction
		no

NDC # - -

Concomitant medical products

Have used NIX over and over again but still have lice and nits.

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address	Operator of device
	☐ health professional ☐ user facility ☐ distributor

	Expiration date
model # _____ catalog # _____ serial # _____ lot # _____ other # _____	If implanted, give date
	If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address	phone # (781)449-6487
The National Pediculosis Association P.O. Box 610189, Newton, MA. 02461	

Health professional	Occupation	Also reported to
☑ yes ☐ no		☐ manufacturer ☐ user facility ☐ distributor

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MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
722	11/3/94	female	45 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 10/17/01 **Date of report** 10/17/2001

Describe event or problem

this has been going on since aug.tried 4 different shampoos,then rx shampoo from dr.nothing ridding the permanently.

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: malathion

Dose, frequency, route use
1.5ml

Therapy dates
8/8/01 to 10/17/01

Diagnosis for use
headlice reoccurring

Event abated after use stopped or dose reduced
no

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products
used pronto,nix,rid then rx aug - oct.every 10 days

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
- ☐ health professional
- ☐ user facility
- ☐ distributor

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

Expiration date

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address

phone # (781)449-6487

The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

Health professional
☑ yes ☐ no

Occupation

Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

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MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
716	06-13-94	female	74 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☐ hospitalization ☐ required intervention
other:

Date of event 10-01-01 **Date of report** 10/15/2001

Describe event or problem

Daughters have been treated with Lindane 3% and over the counter medications twice. Still finding live lice

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: Kwell

Dose, frequency, route use
3%

Therapy dates
10-01-01 to 10-10-01

Diagnosis for use
Head Lice

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
yes

NDC # - -

Concomitant medical products
Nix Creme

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
☐ health professional
☐ user facility
☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

Concomitant medical products

E. Reporter

Name and address
The National Pediculosis Association
P.O. Box 610189, Newton, MA. 02461

phone # (781)449-6487

Health professional
☑ yes ☐ no

Occupation

Also reported to
☐ manufacturer
☐ user facility
☐ distributor

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MedWatch

Triage Unit Sequence #

A. Patient Information

Patient Identifier	Date of birth	Sex	Weight
712	2-11-91	female	80 lbs

B. Adverse event or product problem

Product Problem

Outcomes attributed to adverse event

- ☐ death
- ☐ disability
- ☐ life-threatening
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ required intervention

other:

Date of event 10/12/01 **Date of report** 10/12/2001

Describe event or problem

head lice appeared in july of 2001 we used lindane 4 times and now we are using the olive oil treatment, hair washing daily

Relevant tests/laboratory data

Other relevant history, including preexisting condition

C. Suspect medication(s)

Name: lindane
olive oil, nix

Dose, frequency, route use
10 days

Therapy dates
7/15/01 to 9/30/01

Diagnosis for use
?

Event abated after use stopped or dose reduced
doesn't apply

Lot #

Exp. date

Event reappeared after reintroduction
doesn't apply

NDC # - -

Concomitant medical products

D. Suspect medical device

Brand name

Type of device

Manufacturer name and address

Operator of device
- ☐ health professional
- ☐ user facility
- ☐ distributor

Expiration date

model # _____
catalog # _____
serial # _____
lot # _____
other # _____

If implanted, give date

If explanted, give date

Device available for evaluation?
☐ yes ☐ no ☐ returned to manufacturer __/__/____

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Name and address
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phone # (781)449-6487

Health professional
☑ yes ☐ no

Occupation

Also reported to
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- ☐ user facility
- ☐ distributor

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