

NIX COMPLETE MAXIMUM STRENGTH LICE ELIMINATION- permethrin
Insight Pharmaceuticals

Nix® Complete Maximum Strength Lice Elimination Kit

Creme Rinse

Drug Facts

Active ingredient (in each fluid ounce)

Permethrin 280 mg (1%)

Purpose

Lice treatment

Uses

treats head lice

Warnings

For external use only

Do not use

- on children under 2 months of age
- near the eyes
- inside the nose, ear, mouth, or vagina
- on lice in eyebrows or eyelashes.
See your doctor.

Ask a doctor before use if you are

- allergic to ragweed. May cause breathing difficulty or an asthmatic episode.

When using this product

- keep eyes tightly closed and protect eyes with a washcloth or towel
- if product gets into the eyes, immediately flush with large amounts of water
- scalp itching or redness may occur

Stop use and ask a doctor if

- breathing difficulty occurs
- eye irritation occurs
- skin or scalp irritation continues or infection occurs

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Important: Read warnings before use:

■ **Adults and children 2 months old and older**

Inspect

- check each household member with a magnifying glass in bright light for lice/nits (eggs)
- look for tiny nits near scalp, beginning at back of neck and behind ears
- examine small sections of hair at a time
- unlike dandruff which moves when touched, nits stick to the hair
- if either lice or nits are found, treat with Nix Creme Rinse

Treat

- wash hair with a shampoo without conditioner. Do not use a shampoo that contains a conditioner or a conditioner alone since this may decrease the activity of Nix. Rinse with water.
- towel dry hair so it is damp but not wet
- shake the bottle of Nix well
- completely saturate the hair and scalp with Nix. Begin to apply Nix behind the ears and at the back of the neck.
- keep Nix out of the eyes. Protect the eyes with a washcloth or towel.
- leave Nix on the hair for 10 minutes, but no longer
- rinse with warm water
- towel dry hair and comb out tangles
- if live lice are seen seven days or more after the first treatment, a second treatment should be given

Remove Lice/Nits

- remove nits by combing the hair with the special small tooth comb provided. Remaining nits may be removed by hand (using a throw-away glove), or cutting the nits out.
- use the nit comb provided and make sure the hair remains slightly damp while removing nits
- if the hair dries during combing, dampen it slightly with water
- part the hair into 4 sections. Work on one section at a time. Longer hair may take more time (1-2 hours).
- start at the top of the head on the section you have picked
- with one hand, lift a 1-2 inch wide strand of hair. Get the teeth of the comb as close to the scalp as possible and comb with a firm, even motion away from the scalp to the end of the hair.
- use clips to pin back each strand of hair after you have combed out the nits
- clean the comb completely as you go. Wipe the nits from the comb with a tissue and throw away the tissue in a sealed plastic bag to prevent the lice from coming back.
- after combing, recheck the entire head for nits and repeat combing if necessary
- check the affected head daily to remove any nits that you might have missed

Other information

- read all the directions in the Consumer Information Insert and warnings before use. Keep the carton. It contains important information.
- store at 20° to 25°C (68° to 77°F)

Inactive ingredients

canada balsam, cetyl alcohol, citric acid anhydrous, FD&C yellow no. 6, fragrance, hydrolyzed animal protein, hydroxyethyl cellulose, polyoxyethylene 10 cetyl ether, propylene glycol, stearylalkonium chloride, water, isopropyl alcohol, methylparaben, propylparaben

Combing Gel

For external use only. Avoid contact with the eyes.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away

Directions

- Use after shampooing with lice killing Nix creme rinse. When you finish combing, rinse hair thoroughly with warm water. **Nix Combing Gel does not kill lice and nits.** Read all the directions in the Consumer Information Insert before use.

Ingredients

purified water, propylene glycol, glycerin, polyquaternium-10, diazolidinylurea, hydroxyethyl cellulose, sodium citrate dihydrate, citric acid, methylparaben, propylparaben, disodium EDTA

Distributed by Insight Pharmaceuticals Corp. 900 Northbrook Drive, Suite 200 Trevose, PA 19053-8433

Nix®

PERMETHRIN

Lice Treatment Creme Rinse

THE FACTS OF LICE

Please read all information before using Nix® Creme Rinse.

If you or a member of your household has head lice, don't panic. Keep calm.

Anyone can get head lice - **it has nothing to do with cleanliness or poor hygiene.** Head lice are treatable and very rarely cause serious health problems.

What are head lice?

- head lice are small insects that live and feed on the human scalp
- they may get as big as sesame seeds and are brown
- lice do not fly or jump from one person to another. They can only crawl.

What are nits?

- nits are lice eggs laid on the hair near the scalp. One louse may lay over 100 nits.
- nits are oval shaped, tiny and greyish-white
- they are attached to hair with a waterproof glue-like substance that cannot be washed out or blown away

Because nits (eggs) hatch in about one week, all nits must be removed to stop lice.

How do head lice spread?

- head lice spread easily from close head-to-head or hand-to-head contact with persons who have lice
- they may also spread by sharing hats, helmets, scarves, headphones, brushes, combs, bedding and clothing

How do you know if you have lice?

- itching is the most common symptom
- scratching behind the ears or the back of the neck is a sign that you should check for head lice
- scabs or blood spots may be seen

How do you prevent the spread of lice?

- do not share or borrow personal items like combs, brushes, or headbands

- do not share or borrow hats, sweaters, coats, scarves, helmets, headphones, pillows or stuffed animals
- store hats in coat sleeves and hang coats separately, so that they do not touch other people's hats and coats
- wash under fingernails when you first see lice or nits (eggs)
- check your child's head daily when you hear of a lice outbreak in day care or school

How to use NIX[®] Creme Rinse?

Inspect

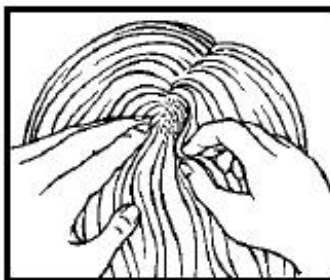
If you suspect head lice - check. Head lice may be hard to locate because they avoid light. Nits are easier to see.



- check each household member with a magnifying glass in bright light for lice/nits (eggs)
- look for tiny nits near scalp, beginning at back of neck and behind ears
- examine small sections of hair at a time
- unlike dandruff which moves when touched, nits stick to the hair
- if either lice or nits are found, treat with Nix Creme Rinse

Treat

- wash hair with a shampoo without conditioner. Do not use a shampoo that contains a conditioner or a conditioner alone since this may decrease the activity of Nix[®]. Rinse with water.
- towel dry hair so it is damp but not wet
- shake the bottle of Nix[®] well



- completely saturate the hair and scalp with Nix[®]. Begin to apply Nix[®] behind the ears and at the back of the neck.
- keep Nix[®] out of the eyes. Protect the eyes with a washcloth or towel.
- leave Nix[®] on the hair for 10 minutes, but no longer
- rinse with warm water
- towel dry hair and comb out

tangles

- if live lice are seen seven days or more after the first treatment, a second treatment should be given



Remove Lice/Nits

Treatment kills lice but does not remove the nits.

- remove nits by combing the hair with the premium comb provided. Remaining nits may be removed by hand (using a throw-away glove), or cutting the nits out.
- use the nit comb provided and make sure the hair remains slightly damp while removing nits
- if the hair dries during combing, dampen it slightly with water
- part the hair into 4 sections. Work on one section at a time. Longer hair may take more time (1-2 hours).
- start at the top of the head on the section you have picked
- with one hand, lift a 1-2 inch wide strand of hair. Get the teeth of the comb as close to the scalp as possible and comb with a firm, even motion away from the scalp to the end of the hair.
- use clips to pin back each strand of hair after you have combed out the nits
- clean the comb completely as you go. Wipe the nits from the comb with a tissue and throw away the tissue in a sealed plastic bag to prevent the lice from coming back.
- after combing, recheck the entire head for nits and repeat combing if necessary
- check the affected head daily to remove any nits that you might have missed



Clean home and personal items

After using Nix® Creme Rinse, it is very important to clean personal items and your home to prevent the spread of lice. Nits may live away from the human head for about 7-12 days. Lice may live away from the human head for about 1 day.

- all personal head gear (hats, hair ribbons, etc.), scarves, coats, towels and bed linens should be washed in hot water (above 130°F), then dried in the dryer using the hottest cycle for at least 20 minutes
- personal combs, including nit combs, and brushes should be soaked in hot water (above 130°F) for at least 10 minutes
- personal articles such as clothing, bedspreads, blankets, pillows or

stuffed animals that cannot be washed should be dry-cleaned or sealed tightly in a plastic bag for a period of at least 4 weeks. Items should be taken out of the plastic bag outdoors and shaken out very hard before using again.

- for anything you cannot wash, dry-clean or store in a plastic bag, use a lice control spray.
- vacuum everywhere. Vacuum all carpets, mattresses, upholstered furniture and car seats that may have been used by infested household members.



Warnings

For external use only

Do not use

- on children under 2 months of age
- near the eyes
- inside the nose, ear, mouth, or vagina
- on lice in eyebrows or eyelashes. See your doctor.

Ask a doctor before use if you are

- allergic to ragweed. May cause breathing difficulty or an asthmatic episode.

When using this product

- keep eyes tightly closed and protect eyes with a washcloth or towel
- if product gets into the eyes, immediately flush with large amounts of water
- scalp itching or redness may occur

Stop use and see a doctor if

- breathing difficulty occurs
- eye irritation occurs
- skin or scalp irritation continues or infection occurs

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Questions or comments?

call **1-888-LICE LINE (1-888-542-3546)**,
Monday to Friday, 9 AM - 5 PM EST

www.nixlice.com

Distributed by:

INSIGHT Pharmaceuticals, LLC.

Trevoze, PA 19053-8433

61-16-360B

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PRINCIPAL DISPLAY PANEL - Kit Carton

Nix®

PERMETHRIN

Have questions?

Call our expert hotline

888.542.3546

PEDIATRICIAN RECOMMENDED

#1

TREATMENT

Safe for use on children over 2 months old

COMPLETE Maximum Strength

Lice Elimination Kit

BONUS!

LICE CONTROL

SPRAY INCLUDED

Includes

Exclusive Lice

Removal &

Hair Detangler

Comb

Creme Rinse 2 Bottles 2 fl oz (59 mL) EACH,

Combing Gel 2 fl oz (59 mL), Lice Comb

nixlice.com

Nix

PERMETHRIN

Have questions?
Call our expert hotline
888.542.3546



Safe for use on children over 2 months old

COMPLETE Maximum Strength Lice Elimination Kit

BONUS!
LICE CONTROL
SPRAY INCLUDED



Includes
Exclusive Lice
Removal &
Hair Detangler
Comb

nixlice.com

Instrucciones En Español/Includes
Creme Rinse 2 Bottles 2 fl oz (59 mL) EACH,
Combing Gel 2 fl oz (59 mL), Lice Comb

Creme Rinse

Drug Facts

Active ingredient Purpose
(in each fluid ounce)
Permethrin 280 mg (1%)...Lice treatment

Uses treats head lice

Warnings

For external use only

Do not use

- on children under 2 months of age
 - near the eyes
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Stop use and ask a doctor if

- breathing difficulty occurs
- eye irritation occurs
- skin or scalp irritation continues or infection occurs

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Important: Read warnings before use:

- Adults and children 2 months old and older inspect
 - check each household member with a magnifying glass in bright light for lice/nits (eggs)
 - look for tiny nits near scalp, beginning at back of neck and behind ears
 - examine small sections of hair at a time
 - unlike dandruff which moves when touched, nits stick to the hair
 - if either lice or nits are found, treat with Nix Creme Rinse
- Treat**
- wash hair with a shampoo without conditioner. Do not use a shampoo that contains a conditioner or a conditioner alone since this may decrease the activity of Nix. Rinse with water.
 - towel dry hair so it is damp but not wet
 - shake the bottle of Nix well
 - completely saturate the hair and scalp with Nix. Begin to apply Nix behind the ears and at the back of the neck.
 - keep Nix out of the eyes. Protect the eyes with a washcloth or towel.
 - leave Nix on the hair for 10 minutes, but no longer
 - rinse with warm water

Nix

PERMETHRIN



Safe for use on children over 2 months old

COMPLETE Lice Elimination Kit

Nix

Have questions?
Call our expert hotline
888.542.3546



Creme Rinse (continued)

- towel dry hair and comb out tangles
- if live lice are seen seven days or more after the first treatment, a second treatment should be given Remove Lice/Nits
- remove nits by combing the hair with the special small tooth comb provided.

NIX

PERMETHRIN



Safe for use on children over 2 months old

COMPLETE Maximum Strength Lice Elimination Kit

BONUS!
LICE CONTROL
SPRAY INCLUDED



Includes
Exclusive Lice
Removal &
Hair Detangler
Comb

nixlice.com

Crème Rinse 2 Bottles 2 fl oz (59 mL) EACH,
Combing Gel 2 fl oz (59 mL), Lice Comb

Instrucciones En Español / Includes

- Remaining nits may be removed by hand (using a throw-away glove), or cutting the nits out.
- use the nit comb provided and make sure the hair remains slightly damp while removing nits
- if the hair dries during combing, dampen it slightly with water
- part the hair into 4 sections. Work on one section at a time. Longer hair may take more time (1-2 hours).
- start at the top of the head on the section you have picked
- with one hand, lift a 1-2 inch wide strand of hair. Get the teeth of the comb as close to the scalp as possible and comb with a firm, even motion away from the scalp to the end of the hair.
- use clips to pin back each strand of hair after you have combed out the nits
- clean the comb completely as you go. Wipe the nits from the comb with a tissue and throw away the tissue in a sealed plastic bag to prevent the lice from coming back.
- after combing, recheck the entire head for nits and repeat combing if necessary
- check the affected head daily to remove any nits that you might have missed

Other information

- read all the directions in the Consumer Information Insert and warnings before use. Keep the carton. It contains important information.
- store at 20° to 25°C (68° to 77°F)

Inactive Ingredients

canada balsam, cetyl alcohol, citric acid anhydrous, FD & C yellow no. 6, fragrance, hydrolyzed animal protein, hydroxyethyl cellulose, polyoxyethylene 10 cetyl ether, propylene glycol, stearyltrimonium chloride, water, isopropyl alcohol, methylparaben, propylparaben

Combing Gel

For external use only. Avoid contact with the eyes. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away

Directions

- Use after shampooing with lice killing Nix creme rinse. When you finish combing, rinse hair thoroughly with warm water. Nix Combing Gel does not kill lice and nits. Read all the directions in the Consumer Information Insert before use.



Expiration Date
Lot #

NO VARNISH AREA

Combing Gel (continued)

Ingredients purified water, propylene glycol, glycerin, polyquaternium-10, diazolidinylurea, hydroxyethyl cellulose, sodium citrate dihydrate, citric acid, methylparaben, propylparaben, disodium EDTA

Distributed by Insight Pharmaceuticals Corp.
900 Northbrook Drive, Suite 200
Trevose, PA 19053-8433 40-16-360E

NIX COMPLETE MAXIMUM STRENGTH LICE ELIMINATION

permethrin kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63736-027
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63736-027-06	1 in 1 CARTON		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	2 BOTTLE	118 mL
Part 2	1 BOTTLE	59 mL

Part 1 of 2

NIX

permethrin shampoo

Product Information

Item Code (Source)	NDC:63736-024
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Permethrin (UNII: 509F88P9SZ) (Permethrin - UNII:509F88P9SZ)	Permethrin	560 mg in 59 mL

Inactive Ingredients

Ingredient Name	Strength
canada balsam (UNII: K304VI98I3)	
cetyl alcohol (UNII: 936JST6JCN)	
anhydrous citric acid (UNII: XF417D3PSL)	
FD&C yellow no. 6 (UNII: H77VEI93A8)	
ceteth-10 (UNII: LF9X1PN3XJ)	
propylene glycol (UNII: 6DC9Q167V3)	
stearylalkonium chloride (UNII: 0OUO26BB88)	
water (UNII: 059QF0K00R)	
isopropyl alcohol (UNII: ND2M416302)	
methylparaben (UNII: A2I8C7HI9T)	
propylparaben (UNII: Z8IX2SC1OH)	

Product Characteristics

Color	ORANGE (Light Orange)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63736-024-02	59 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019918	06/05/2009	

Part 2 of 2

NIX

tonics, dressings, and other hair grooming aids gel

Product Information

Route of Administration	TOPICAL
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	water (UNII: 059QF0KO0R)	
INGR	propylene glycol (UNII: 6DC9Q167V3)	
INGR	glycerin (UNII: PDC6A3C0OX)	
INGR	polyquaternium-10 (1000 MPAS at 2%) (UNII: GMR4PEN8PK)	
INGR	diazolidinyl urea (UNII: H5RIZ3MPW4)	
INGR	trisodium citrate dihydrate (UNII: B22547B95K)	
INGR	citric acid monohydrate (UNII: 2968PHW8QP)	
INGR	methylparaben (UNII: A2I8C7HI9T)	
INGR	propylparaben (UNII: Z8IX2SC1OH)	
INGR	edetate disodium (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		59 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		11/15/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019918	11/15/2013	

Labeler - Insight Pharmaceuticals (176792315)

Revised: 5/2013

Insight Pharmaceuticals