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, stearalkonium 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

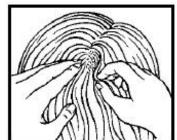
If you suspect head lice - check. Head lice may be hard to locate because they avoid light. Nits are easier to see.



- 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, dryclean 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

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- 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.

Trevose, PA 19053-8433

61-16-360B

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



Safe for use on children over 2 months old







Creme Rinse

Drug Facts

Active ingredient Purpose

each fluit outice) armethrin 280 mg (1%)....Lice treatment

Uses treats head lice

Wamings 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.

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When using this product

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

If pregnant or breast-feed ing, 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
- 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.

- Hirse 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 washoloth or towel.
- leave Nix on the hair for 10 minutes but no longer
- rinse with warm wate



Safe for use on children over 2 months old

COMPLETE Lice Elimination Kit

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 COMPLETE MAXIMUM STRENGTH LICE ELIMINATION

permethrin kit

Product Information

Product Type HUMAN OTC DRUG LABEL Item Code (Source)

NDC:63736-027

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 DEA Schedule

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Permethrin (Permethrin)	Permethrin	560 mg in 59 mL

Inactive Ingredients			
Ingredient Name	Strength		
canada balsam			
cetyl alcohol			
anhydrous citric acid			
FD&C yellow no. 6			
ceteth-10			
propylene glycol			
stearalkonium chloride			
water			
isopropyl alcohol			
methylparaben			
propylparaben			

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

P	ackaging			
#	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	NDA0 19 9 18	06/05/2009	

Part 2 of 2

NIX

tonics, dressings, and other hair grooming aids gel

Product Information

Route of Administration TOPICAL DEA Schedule

Other Ingredients			
Ingredient Kind	Ingredient Name	Quantity	
INGR	water		
INGR	propylene glycol		
INGR	glycerin		
INGR	polyquaternium-10 (1000 MPA.S at 2%)		
INGR	diazolidinyl urea		
INGR	trisodium citrate dihydrate		
INGR	citric acid monohydrate		
INGR	methylparaben		
INGR	propylparaben		
INGR	edetate disodium		

Pa	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		11/15/20 13		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NDA	NDA0 19 9 18	11/15/2013		

Labeler - Insight Pharmaceuticals (176792315)

Revised: 5/2013 Insight Pharmaceuticals