

NIX- permethrin shampoo
Insight Pharmaceuticals

Nix® Lice Killing Creme Rinse

Drug Facts

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

Use

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 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.

Directions

Inspect

- all household members should be checked by another person for lice and/or nits (eggs)
- use a magnifying glass in bright light to help you see the lice and nits (eggs)
- use a tool, such as a comb or two unsharpened pencils to lift and part the hair
- look for tiny nits near the scalp, beginning at the back of the neck and behind the ears
- small sections of hair (1-2 inches wide) should be examined at a time

- unlike dandruff, nits stick to the hair. Dandruff should move when lightly touched.
- if either lice or nits (eggs) 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

balsam canada, cetyl alcohol, citric acid, FD&C yellow no. 6, fragrance, hydrolyzed animal protein, hydroxyethylcellulose, polyoxyethylene 10 cetyl ether, propylene glycol, stearylalkonium chloride, water, isopropyl alcohol 5.6 g (20%), methylparaben 56 mg (0.2%), and propylparaben 22 mg (0.08%)

Questions or comments?

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

For a description of all of our products visit us at **www.nixlice.com**

PRINCIPAL DISPLAY PANEL - 2 FL OZ Bottle Carton

The #1 Choice of Pharmacists

Nix®

Permethrin

LICE TREATMENT

**Complete Lice
Treatment System**

**Single Application Kills Lice & Their Eggs
And Prevents Reinfestation For 14 days**

This package contains
all of the following:

- **Nix Creme Rinse
(Permethrin)**
- **Metal Lice Comb with
Detangling Feature**
- **Disposable Application
Gloves**
- **Hair Salon Cape**
- **5' × 5' Drop Cloth**

**Contains Everything
Needed For An
Application**

NET WT 2 FL OZ (59 ml)



NIX® Creme Rinse

INDICATIONS

NIX® Creme Rinse is indicated for the treatment of infestation with head lice and their nits (eggs). This unique creme rinse leaves the hair manageable and easy to comb.

WHAT ARE HEAD LICE?

Head lice are small insects that live and feed on the human scalp causing itching and irritation. They range in colour from beige to black. Lice lay eggs, called nits, on the hair shaft close to the scalp. The nits are tiny, oval shaped and shiny, and range in colour from creamy white to brown. Nits normally hatch in 7 to 10 days. The adult lice cannot survive away from the head for much more than 24 hours.

HOW DOES A LICE INFESTATION SPREAD?

Head lice spread easily, primarily by close head-to-head contact with persons who have lice and occasionally by sharing personal articles such as clothing, hats, combs, hair accessories, towels and bed linen.

WHAT TO DO IF YOU OR A MEMBER OF YOUR FAMILY HAS HEAD LICE

Head lice affect millions of people each year, especially school-aged children. They **do not** transmit or cause disease and are **not** a sign of poor personal hygiene. A head lice infestation can be effectively

treated with a topical pediculicide and ovicide treatment (a treatment effective at destroying lice and their eggs) such as NIX Creme Rinse.

DIRECTIONS FOR USE OF NIX® CREME RINSE

1. Wash the hair with **conditioner-free shampoo**. Do not use a conditioner. Rinse with water and towel dry thoroughly.
2. Shake NIX bottle well. Apply a sufficient amount of NIX (1/2 to 1 bottle) to thoroughly saturate the hair and scalp, especially behind the ears and at the base of the neck.
3. Leave NIX on the hair for **10 minutes**.
4. Rinse NIX off hair with water.
5. Towel dry hair.
6. Comb hair with regular comb to remove tangles.
7. Remove nits: Part hair into sections; starting as close to the scalp as possible, remove the nits using the nit removal comb provided. Be sure to comb to the end of the hair shaft. The nit comb should be disinfected by soaking in hot water after each use. Inspect full head of hair thoroughly for any stray nits. The nit removal procedure should be repeated daily for the 7 days following treatment.

A single application is usually sufficient to eliminate a head lice infestation. The active ingredient in NIX persists on the hair for 10 days, even after subsequent washing with a conditioner-free shampoo. If you see live lice or nits after the first application, the residual effect should kill these. If you still see live lice or nits on the 7th day (or after) following the first application, NIX Creme Rinse should be applied a second time, as described above.

HOW TO HELP PREVENT REINFESTATION

Cleaning of personal articles is also an important part of head lice management and may help prevent reinfestation. Personal belongings including recently worn clothing, towels and bed linens should be machine washed in hot water and dried using the hot cycle of the dryer for at least 20 minutes. Personal articles of clothing or bedding that cannot be washed may be dry cleaned or sealed in a plastic bag for a period of two weeks. Combs and brushes should be disinfected by soaking in hot water (above 130°F/54°C) for 5 to 10 minutes.

Children should be advised not to use any borrowed combs or brushes, nor wear anyone else's clothes, especially hats.

Inspect all family members from time to time for any new lice infestation. If a new infestation is found treat with NIX Creme Rinse.

PRECAUTIONS

General: Head lice infestation is often accompanied by itching, redness, and swelling. Treatment with NIX may temporarily worsen these conditions. Do not use if allergic to any of its ingredients, synthetic pyrethroids or pyrethrin, or chrysanthemums. Discontinue use if reaction occurs.

Eye Irritation: NIX is not irritating to eyes; however, if it should get into them, rinse eyes immediately with water.

In Case of Swallowing: Consult your doctor or Poison Control Centre immediately.

Use in Pregnant or Nursing Women: There are no adequate or well-controlled studies in pregnant or nursing women. Consult a doctor before using this drug.

Use in Children: NIX is safe and effective in children two months of age and older. Safety and effectiveness in children less than two months of age have not been established. Consult your doctor.

Keep out of reach of children. To prevent accidental ingestion by children, the remaining contents of NIX should be discarded after use.

ADVERSE REACTIONS

In clinical studies, occasional itching has been known to occur. This is usually a consequence of head lice infestation itself, but may be temporarily worsened following treatment with NIX. Other reactions which are less frequent include: stinging/burning, tingling, numbness or discomfort, redness, and swelling or rash of the scalp. All these reactions are mild and temporary.

MEDICINAL INGREDIENT

Permethrin is the active ingredient in NIX Creme Rinse; it is present at a concentration of 1%.

NON-MEDICINAL INGREDIENTS (ALPHABETICALLY)

In addition, NIX Creme Rinse also contains the following non-active components: balsam Canada, cetyl alcohol, citric acid, FD&C Yellow No. 6, fragrance, hydrolyzed animal protein, hydroxyethylcellulose, isopropyl alcohol, parabens, polyoxyethylene cetyl ether, propylene glycol, stearalkonium chloride and water.

Comments or Questions ? 1-888-542-3546 or visit us at www.insightpharma.com

Distributed by: INSIGHT Pharmaceuticals Corp.

Langhorne, PA 19049-1749

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NIX			
permethrin shampoo			
Product Information			
Product Type	HUMAN OTC DRUG	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
Cetyl alcohol (UNII: 936JST6JCN)			
citric acid monohydrate (UNII: 2968PHW8QP)			
FD&C yellow no. 6 (UNII: H77VEI93A8)			
propylene glycol (UNII: 6DC9Q167V3)			
stearalkonium 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:63736-024-03	1 in 1 CARTON		
1		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	

Labeler - Insight Pharmaceuticals (176792315)

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