

NIX COMPLETE LICE TREATMENT- permethrin
Insight Pharmaceuticals LLC

Nix Complete Lice Treatment Kit

[1 Eliminate] 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

- 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/or nits (eggs)
- use a tool, such as a comb or two unsharpened pencils to lift and part the hair
- look for tiny nits near scalp, beginning at back of neck and behind 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 (or 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, methylparaben, propylparaben

Questions?

1-888-542-3546

[2 Remove] Combing Gel & Comb

Product Facts

Uses

To detangle and comb the hair

Warnings

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 (1-800-222-1222) right away.

Directions

- use after shampooing with lice killing creme rinse
- towel dry hair
- apply combining gel until all the hair and scalp is thoroughly wet with product
- make sure product covers the area behind the ears and at the nape of the neck where there are more likely to be nits
- part hair into sections and clip back
- use the enclosed special-toothed comb to comb out dead lice and nits
- comb out one section at a time
- it is extremely important to comb out dead lice and nits
- if hair begins to dry, reapply additional product
- when you finish combing, rinse hair thoroughly with warm water.

Other Information

- Nix Combing Gel does not kill lice and nits
- Pesticide free
- Keep carton for full information and warnings. Read all warnings and directions before use.
- Visit our website at nixlice.com

Ingredients

water, propylene glycol, glycerin, polyquaternium-10, diazolidinyl urea, hydroxyethylcellulose, sodium citrate dihydrate, citric acid, methylparaben, propylparaben, disodium EDTA

[3 Control] Nix ® Lice Control Spray

Active ingredient:

PERMETHRIN 0.25%

(CAS # 52645-53-1)

Other ingredients:

99.75%

100.00%

NOT FOR USE ON HUMANS. READ ENTIRE LABEL BEFORE EACH USE. SHAKE BOTTLE WELL BEFORE USING.**Precautionary Statements****ENVIRONMENTAL HAZARDS**

This product is extremely toxic to fish and aquatic organisms. To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters.

Directions For Use

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

For Use in Non-food Areas of Homes**Indoor Application**

Surface Spraying: **To kill lice and louse eggs**, spray in an inconspicuous area to test for possible staining or discoloration. Inspect again after drying, then proceed to spray entire area to be treated. Spray from a distance of 8 to 10 inches. Treat only those garments and parts of bedding, including mattresses and furniture, that cannot be either laundered or dry cleaned. Allow all treated articles to dry thoroughly before use.

To control bedbugs: Spray mattresses lightly, particularly around tufts and seams. Take beds apart and spray in all joints. Allow all sprayed articles to dry thoroughly before use.

- Do not use in food/feed areas of food/feed handling establishments, restaurants or other areas where food/feed is commercially prepared or processed. Do not use in serving areas while food is exposed or facility is in operation. Serving areas are areas where prepared foods are served such as dining rooms, but excluding areas where foods may be prepared or held.
- In the home, cover all food handling surfaces, cover or remove all food and cooking utensils or wash thoroughly after treatment.
- Application is prohibited directly into sewers or drains, or into any area like a gutter where drainage to sewers, storm drains, water bodies, or aquatic habitat can occur. Do not allow the product to enter any drain during or after application.

Storage and Disposal

Do not contaminate water, food or feed by storing or disposal.

Pesticide Storage and Spill Procedures: Keep from freezing. Store upright at room temperature. Avoid exposure to extreme temperatures. In case of spill or leakage, soak up with an absorbent material such as sand, sawdust, earth, fuller's earth, etc. Dispose of with chemical waste.

Pesticide Disposal: If partly filled – Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain. **Container Disposal:** If empty – Nonrefillable container.

Do not reuse or refill this container. Place in trash or offer for recycling if available.

EPA REG. NO. 64321-1-75406

EPA EST. NO. 91705-NJ-001

PRINCIPAL DISPLAY PANEL

Part 2	1 BOTTLE	59 mL
Part 3	1 BOTTLE	147 mL

Part 1 of 3

NIX CREME

permethrin rinse

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PERMETHRIN (UNII: 509F88P9SZ) (PERMETHRIN - UNII:509F88P9SZ)	PERMETHRIN	280 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
CANADA BALSAM (UNII: K304VI98B)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
CETETH-10 (UNII: LF9X1PN3XJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARALKONIUM CHLORIDE (UNII: 0OUO26BB88)	
WATER (UNII: 059QF0K00R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	

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		2 in 1 CARTON		
1		59 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

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

Part 2 of 3

NIX COMBING

inert gel

Product Information

Route of Administration TOPICAL

Inactive Ingredients

Ingredient Name	Strength
POLYQUATERNIUM-10 (125 MPA.S AT 2%) (UNII: L45WU8S981)	
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
1		59 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		11/15/2013	

Part 3 of 3

NIX LICE CONTROL

permethrin spray

Product Information

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PERMETHRIN (UNII: 509F88P9SZ) (PERMETHRIN - UNII:509F88P9SZ)	PERMETHRIN	25 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	75 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
1		147.86 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		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 LLC (055665422)