

**NIX COMPLETE MAXIMUM STRENGTH LICE ELIMINATION- permethrin**  
**Insight Pharmaceuticals LLC**

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**Nix<sup>®</sup> Complete Maximum Strength Lice Elimination 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<sup>®</sup> 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<sup>®</sup>. Rinse with water.
- towel dry hair so it is damp but not wet
- shake the bottle of Nix<sup>®</sup> well
- completely saturate the hair and scalp with Nix<sup>®</sup>. Begin to apply Nix<sup>®</sup> behind the ears and at the back of the neck.
- keep Nix<sup>®</sup> out of the eyes. Protect the eyes with a washcloth or towel.
- leave Nix<sup>®</sup> 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](http://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.

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EPA EST. NO. 91705-NJ-001

**Dist. by** INSIGHT Pharmaceuticals Corp.

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**PRINCIPAL DISPLAY PANEL**

**Nix<sup>®</sup> Complete Lice Treatment Kit**  
Permethrin Creme Rinse (1%)

Creme Rinse 2 Bottles 2 fl oz (59 mL) EACH,  
Combing Gel 2 fl oz (59 mL), Lice Comb, Lice Control Spray 5 fl oz (147.86 mL)  
**nixlice.com**





# NIX COMPLETE MAXIMUM STRENGTH LICE ELIMINATION permethrin kit

Product Information			
Product Type	HUMAN OTC DRUG	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; Type 0: Not a Combination Product	11/15/2013	

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

# 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	1 g in 100 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)	
STEARALKONIUM CHLORIDE (UNII: 0OUO26BB88)	
WATER (UNII: 059QF0K00R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)	

## 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		59 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

## 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 COMBING

inert gel

#### Product Information

Route of Administration TOPICAL

#### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
POLYQUATERNIUM-10 (125 MPA.S AT 2%) (UNII: L45WU8S981)	
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		59 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

#### 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)