

**TOPCARE LICE KILLING CREME RINSE- permethrin lotion**  
**Topco Associates LLC**

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**Topco Associates LLC. Lice Killing Creme Rinse Drug Facts**

**Active ingredient (in each fluid ounce)**

Permethrin 280 mg (1%)

**Purpose**

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. (1-800-222-1222)

## **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 the 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 the creme rinse. Rinse with water.
- towel dry hair so it is damp but not wet
- shake the bottle well
- completely saturate the hair and scalp with the creme rinse. Begin to apply the creme rinse behind the ears and at the back of the neck.
- keep the creme rinse out of the eyes. Protect the eyes with a washcloth or towel.
- leave the creme rinse 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 and warnings in the Consumer Information Insert before use. Keep the carton. It contains important information.
- store at 20 to 25°C (68 to 77°F)

### **Inactive ingredients**

abies balsamea (balsam canada) extract, anhydrous citric acid, butylparaben, ceteth-10, cetyl alcohol, ethylparaben, FD&C yellow no. 6, fragrance, hydrolyzed animal protein, hydroxyethyl cellulose, isopropyl alcohol, methylparaben, phenoxyethanol, propylene glycol, propylparaben, purified water, stearalkonium chloride

### **Questions or comments?**

**1-888-423-0139**

### **Consumer Information**

#### **Permethrin Lotion, 1%**

#### **Lice Treatment Creme Rinse**

#### **THE FACTS OF LICE**

*Please read all information before using Lice Treatment 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 the creme rinse

### I. Inspect

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



- 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 the creme rinse



### II. 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 the creme rinse. Rinse with water.
- towel dry hair so it is damp but not wet
- shake the bottle well
- completely saturate the hair and scalp with the creme rinse. Begin to apply the creme rinse behind the ears and at the back of the neck.
- keep the creme rinse out of the eyes. Protect the eyes with a washcloth or towel.
- leave the creme rinse 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



### **III. Remove Lice/Nits**

***Treatment kills lice but does not remove the 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



#### **IV. Clean home and personal items**

*After using the 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, spray with 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. (1-800-222-1222)

**Questions or comments? 1-800-719-9260**

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**Package/Label Principal Display Panel**

FAMILY PACK

COMPARE TO NIX® CREME RINSE

ACTIVE INGREDIENT

Lice Killing Creme Rinse

PERMETHRIN LOTION1% - LICE TREATMENT

WITH A SINGLE APPLICATION:

Kills Lice & Their Eggs

Prevents Reinfestation for 14 Days

SAFE:

Approved for use on Children Over 2 Months of Age

INCLUDES:

2 BOTTLES CREME RINSE – 2 FL OZ (59 mL) EACH

NDC 36800-629-26

**TopCare**  
health™

**FAMILY PACK**

COMPARE TO  
NIX® CREME RINSE  
ACTIVE INGREDIENT\*

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WITH A SINGLE APPLICATION:

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Instrucciones En Español Incluidas



**INCLUDES:**  
2 BOTTLES CREME RINSE • 2 FL OZ (59 mL) EACH  
2 NIT REMOVAL COMBS

**Drug Facts**

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

**Use** treats head lice

**Warnings**

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**Directions**

**Inspect**

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Certified Sourcing  
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SFI-01052



Approved for Use on Children Over 2 Months of Age

**SAFE!**

PERMETHRIN LOTION 1% • LICE TREATMENT

# Lice Killing Creme Rinse

TopCare<sup>®</sup> health™

### Drug Facts (continued)

- 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 the creme rinse
- Treat**
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  - towel dry hair so it is damp but not wet
  - shake the bottle well
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  - leave the creme rinse on the hair for 10 minutes, but no longer
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- store at 20 to 25°C (68 to 77°F)

**Inactive ingredients** abies balsamea (balsam canada) extract, anhydrous citric acid, butylparaben, ceteth-10, cetyl alcohol, ethylparaben, FD&C yellow no. 6, fragrance, hydrolyzed animal protein, hydroxyethyl cellulose, isopropyl alcohol, methylparaben, phenoxyethanol, propylene glycol, propylparaben, purified water, stearylalkonium chloride

**Questions or comments?** 1-888-423-0139

\*This product is not manufactured or distributed by  
INSIGHT Pharmaceuticals Corp., distributor of Nix® Creme Rinse.

TopCare<sup>®</sup> health™

COMPARE TO  
NIX<sup>®</sup> CREME RINSE  
ACTIVE INGREDIENT\*

# Lice Killing Creme Rinse

PERMETHRIN LOTION 1% • LICE TREATMENT

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ELK GROVE VILLAGE, IL 60007  
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QUESTIONS? 1-888-423-0139  
topcare@topco.com  
www.topcarebrand.com



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This TopCare<sup>®</sup> product is laboratory  
tested to guarantee its highest quality.  
Your total satisfaction is guaranteed.



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## TOPCARE LICE KILLING CREME RINSE

permethrin lotion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-629
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
PERMETHRIN (UNII: 509F88P9SZ) (PERMETHRIN - UNII:509F88P9SZ)	PERMETHRIN	1 mg in 100 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
BALSAM FIR LEAFY TWIG (UNII: H1TFV1454Z)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
BUTYLPARABEN (UNII: 3QPII3FV8)	
CETETH-10 (UNII: LF9X1PN3XJ)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ETHYLPARABEN (UNII: 14255EXE39)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
STEARALKONIUM CHLORIDE (UNII: 0OUO26BB88)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-629-26	2 in 1 CARTON	01/31/2020	
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
ANDA	ANDA076090	01/31/2020	

**Labeler** - Topco Associates LLC (006935977)