

TOPCARE LICE KILLING- piperonyl butoxide, pyrethrum extract shampoo

Topco Associates LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Topco Associates LLC. Lice Killing Shampoo Drug Facts

Active ingredients

Piperonyl butoxide 4%

Pyrethrum extract (equivalent to 0.33% pyrethrins)

Purpose

Lice treatment

Uses

treats head, pubic (crab), and body lice

Warnings

For external use only

Do not use

- near eyes
- inside nose, mouth, or vagina
- on lice in eyebrows or eyelashes. See a doctor if lice are present in these areas.

Ask a doctor before use if you are

- allergic to ragweed. May cause breathing difficulty or an asthmatic attack.

When using this product

- keep eyes tightly closed and protect eyes with a washcloth or towel
- if product gets into eyes, flush with water right away
- 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

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

- **Important: Read warnings before use**

Adults and children 2 years and over:

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 this product

Treat

- shake well before using
- apply thoroughly to **DRY HAIR** or other affected area. For head lice, first apply behind ears and
to back of neck.
- allow product to remain for 10 minutes, but no longer
- use warm water to form a lather, shampoo, then thoroughly rinse
- for head lice, towel dry hair and comb out tangles

Remove lice and their eggs (nits)

- use a fine-tooth or special lice/nit comb. Remove any remaining nits by hand (using a throw-away glove).
- hair should remain slightly damp while removing nits
- if hair dries during combing, dampen slightly with water
- for head lice, part hair into sections. Do one section at a time starting on top of head. Longer hair may take 1 to 2 hours.
- lift a 1- to 2-inch wide strand of hair. Place comb as close to scalp as possible and comb with a firm, even motion away from scalp.
- pin back each strand of hair after combing
- clean comb often. Wipe nits away with tissue and discard in a plastic bag. Seal bag and discard to prevent lice from coming back.
- after combing, thoroughly recheck for lice/nits. Repeat combing if necessary.
- check daily for any lice/nits that you missed
- a second treatment must be done in 7 to 10 days to kill any newly hatched lice
- if infestation continues, see a doctor for other treatments

Children under 2 years: ask a doctor

Other information

- store at 20-25°C (68-77°F)
- avoid excessive heat
- keep carton for important product information
- see Consumer Information Insert for additional information

Inactive ingredients

benzyl alcohol, C13-C14 isoparaffin, fragrance, polyoxyethylene (1,1,3,3-tetramethyl butyl) phenyl ether, purified water, xanthan gum

Questions or comments?

1-888-423-0139

Consumer Information

Steps to Success with 1-2-3 Lice Control System

Complete lice control for your family and home.

Step 1: Treat

Lice Killing Shampoo

See Usage Guidelines to estimate how much product you will need.

NOTE:

- Shake well before using.
- Use towels to protect child's eyes from treatment and prevent clothes from getting wet.
- Apply Lice Killing Shampoo thoroughly to **DRY HAIR** or other affected area.
- Wetting the hair dilutes the treatment making it less effective.
- Also, lice can hold their breath when immersed in water making it difficult for the active ingredient to penetrate the lice.



- For head lice, thoroughly massage shampoo into scalp, behind the ears and to the back of the neck. Lice can crawl up and down the shaft of the hair very quickly so it is important to apply the treatment from the roots to the ends of the hair.



- Allow product to remain on the hair (or other affected area) for 10 minutes, but no longer.



- Add warm water and massage to form a lather.
- Rinse thoroughly.



- For head lice, towel dry hair and comb out tangles.
- Proceed to Step 2.
- **A second treatment must be done in 7 to 10 days to kill any newly-hatched lice.**

| Usage Guidelines | Hair Length | Short (ear length or shorter) | | Medium (shoulder length) | | Long (past shoulder length) | |
|------------------|--------------------------------------|----------------------------------|--------------------|-----------------------------|--------------------|--------------------------------|--------------------|
| | Approximate Amount for 1 Adult/Child | First Application: | 1 oz - 2 oz | First Application: | 2 oz - 3 oz | First Application: | 3 oz - 4 oz |
| | | Second Application: | 1 oz - 2 oz | Second Application: | 2 oz - 3 oz | Second Application: | 3 oz - 4 oz |
| | | Total: | 2 oz - 4 oz | Total: | 4 oz - 6 oz | Total: | 6 oz - 8 oz |

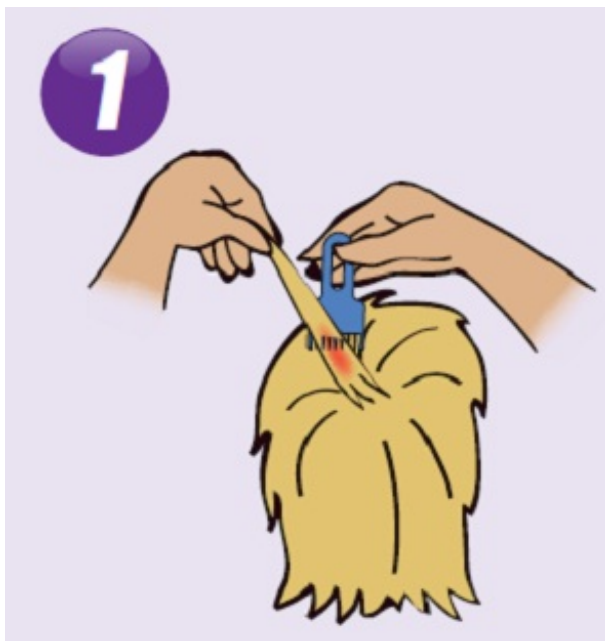
Step 2: Remove

Lice/Nit Comb

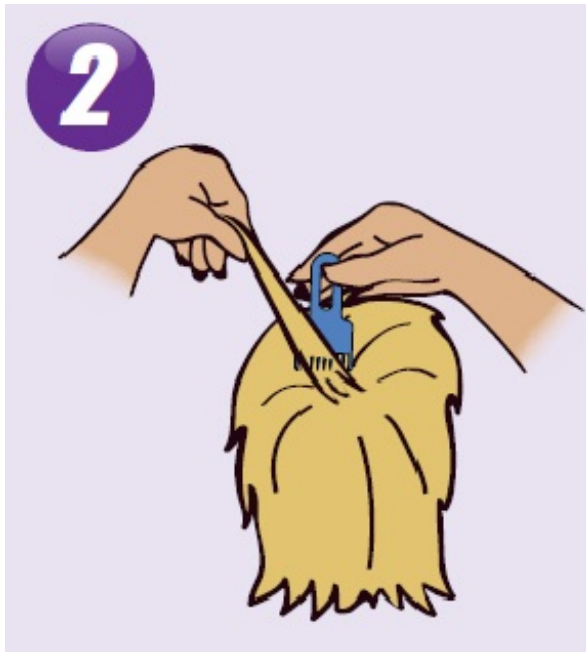
Combing must be done **AFTER** use of Lice Killing Shampoo (Step 1). Combing out eggs & nits* is an **essential step** to complete lice control.

NOTE:

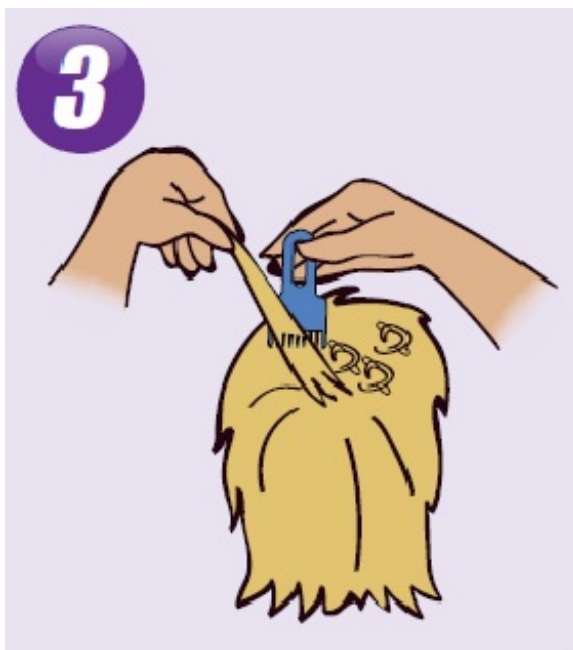
- A fine-toothed comb or the special lice/nit removing comb (included) must be used to remove lice, eggs, and nits from hair.
- Before starting have on hand
 - extra towels
 - bobby pins or hair clips
 - facial tissues or paper towels
 - regular comb for parting and detangling hair
 - detangler/conditioner to make combing easier
- Find a distraction for your child (e.g. books, TV, game).



- Apply detangler/conditioner and comb out damp hair with a regular wide-tooth comb to take out snarls and tangles.
- Hold the Lice/Nit comb with the teeth facing you.



- Working one section at a time, lift a 1- to 2- inch wide strand of hair.
- Place comb as close to the scalp as possible and comb with a firm, even motion away from scalp, from the roots to the end of the hair (newly-laid eggs are found near the roots of the hair so it is important to get the teeth very close to the scalp). Make sure the teeth are deeply embedded into the strands as you comb through.
- Always comb away from the head.
- Wipe eggs and nits from the teeth of the comb with a tissue or paper towel.



- Pin back the 1- to 2-inch wide strand you just finished combing with a bobby pin or hair clip.
- Lift up another 1- to 2-inch wide strand and repeat the combing procedure.
- When one section has been combed and pinned, repeat the process for another

section of hair. Continue to comb hair 1- to 2-inches at a time until entire head has been combed and pinned.



- Keep the hair damp during combing and re-apply detangler/conditioner as needed.
- After you have combed and pinned the entire head, remove all bobby pins or hair clips and rinse hair thoroughly with warm water. If desired, you may also wash with regular shampoo.
- Discard all the used tissues or paper towels into a bag, seal and dispose to prevent lice from coming back.

* Nits are empty eggshells left behind when lice hatch from eggs.

Step 3: Control

Home Lice, Bedbug & Dust Mite Spray

- Use Home Lice, Bedbug & Dust Mite Spray to kill lice and their eggs on mattresses, furniture, car interiors and other non-washable items. A regular disinfectant spray will not kill lice and their eggs.
- After spraying the infested area, vacuum rugs and carpets. Dispose of the vacuum cleaner bags after use.
- Wash all clothes, towels, washable hats, scarves, coats and bed linens in hot water. Dry in high heat for at least 20 minutes.
- Dry clean non-washables.
- Personal combs and brushes may be disinfected by soaking in hot water [above 54°C (130°F)] for at least 10 minutes.
- Place stuffed toys in plastic bags and seal them for 4 weeks.

Checklist

- Home and auto upholstery
- Bike/sport helmets

- Mattresses, pillows, pillowcases
- Coats, scarves, earmuffs, gloves
- Bed linen
- Play mats
- Towels
- Clothing
- Stuffed animals, toys
- Barrettes/hair ornaments
- Headphones
- Hair rollers
- Hats
- Combs and brushes
- Headbands
- Baseball caps

Daily Checking

TO PREVENT REINFESTATION:

- Carefully inspect infested family member **daily** for at least 2 weeks. If you see eggs or nits, repeat Step 2.
- Check other family members for Head Lice. If anyone in the family is infested, follow Step 1 and Step 2. Repeat Step 3 with any articles or items with which they have come into contact.

Second Application

Repeat the same procedures within 7-10 days for

Step 1: Treat and Step 2: Remove

There may be some eggs that were not combed out after the first treatment. These eggs will hatch and need to be killed with the second treatment.

DID YOU KNOW?

Head Lice

- Lay small white eggs (nits) on hair shaft close to scalp.
- Nits are most easily found on back of neck or behind ears.
- Disinfect hats, hair ribbons, scarves, coats, towels, and bed linens by machine washing in hot water [above 54°C (130°F)], then using hottest dryer cycle for at least 20 minutes.
- Items that cannot be washed (bedspreads, blankets, pillows, stuffed toys, etc.) should be dry-cleaned or sealed in a plastic bag for 4 weeks, then removed outdoors and shaken out very hard before using again.
- Items that cannot be washed, dry-cleaned, or stored may be sprayed with a product designed for this purpose, such as a Home Lice, Bedbug & Dust Mite Spray.
- Soak all combs and brushes in hot water [above 54°C (130°F)] for at least 10 minutes.
- Vacuum all carpets, mattresses, upholstered furniture, and car seats that may have been used by affected people.

Pubic (Crab) Lice

- May be transmitted by sexual contact. Sexual partners should be treated simultaneously to avoid reinfestation.
- Lice are very small and look like brown or grey dots on skin.
- Usually cause intense itching and lay small white eggs (nits) on the hair shaft generally close to the skin surface.
- May be present on the short hairs of groin, thighs, trunk, and underarms, and occasionally on the beard and mustache.
- Disinfect underwear by machine washing in hot water [above 54°C (130°F)], then using hottest dryer cycle for at least 20 minutes.

Body Lice

- Body Lice and their eggs (nits) are generally found in the seams of clothing particularly in waistline and armpit area.
- Body Lice feed on skin then return to clothing to lay their eggs.
- Disinfect clothing by machine washing in hot water [above 54°C (130°F)], then using hottest dryer cycle for at least 20 minutes.
- Do not seal clothing in a plastic bag because nits can remain dormant for up to 30 days.

Distributed By

Perrigo ®

Allegan, MI 49010

: 8660000J5

Lice Killing Shampoo

Drug Facts

Active ingredients

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Purpose

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Ask a doctor before use if you are allergic to ragweed. May cause breathing difficulty or an asthmatic attack.

When using this product

- keep eyes tightly closed and protect eyes with a washcloth or towel
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- 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

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

- **Important: Read warnings before use**

Adults and children 2 years and over:

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
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- shake well before using
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Children under 2 years: ask a doctor

Other information

- store at 20-25°C (68-77°F). Avoid excessive heat.

Inactive ingredients benzyl alcohol, C13-C14 isoparaffin, fragrance, polyoxyethylene (1,1,3,3-tetramethyl butyl) phenyl ether, purified water, xanthan gum

Questions?

800-719-9260

Principal Display Panel

TopCare health™

COMPARE TO RID® LICE KILLING SHAMPOO ACTIVE INGREDIENTS

MAXIMUM STRENGTH

Lice Killing Shampoo

Lice Treatment

Works Fast to Kill Lice & Their Eggs

For Treatment of Head, Crab & Body Lice

8 FL OZ (236 mL)

2 NIT REMOVAL COMBS INCLUDED



TOPCARE LICE KILLING

piperonyl butoxide, pyrethrum extract shampoo

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:36800-866

| | |
|-------------------------|---------|
| Route of Administration | TOPICAL |
|-------------------------|---------|

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------|------------------|
| PIPERONYL BUTOXIDE (UNII: LWK91TU9AH) (PIPERONYL BUTOXIDE - UNII:LWK91TU9AH) | PIPERONYL BUTOXIDE | 4 g in 100 mL |
| PYRETHRUM EXTRACT (UNII: ZUM06L90GV) (PYRETHRUM EXTRACT - UNII:ZUM06L90GV) | PYRETHRUM EXTRACT | 0.33 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| BENZYL ALCOHOL (UNII: LKG8494WBH) | |
| C13-14 ISOPARAFFIN (UNII: E4F12ROE70) | |
| WATER (UNII: 059QF0KO0R) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |

Product Characteristics

| | | | |
|-----------------|--|---------------------|--|
| Color | YELLOW (cloudy to transparent, cream to straw) | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:36800-866-16 | 1 in 1 CARTON | 09/05/2007 | 07/08/2011 |
| 1 | | 59 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 2 | NDC:36800-866-34 | 1 in 1 CARTON | 09/10/2012 | |
| 2 | | 236 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 |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part358G | 09/05/2007 | |

Labeler - Topco Associates LLC (006935977)