TOPCARE LICE KILLING- piperonyl butoxide, pyrethrum extract shampoo Topco Associates, LLC

Topcare Lice Killing Shampoo

Active Ingredient

Piperonyl butoxide 4%

Pyrethrum extract (equivalent to 0.33% pyrethrins)

Purposes

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. if you have ever had an allergic reaction to this product or any of its ingredients

Ask 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 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 (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

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)

se 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 the head. Longer hair may take $\bf 1$ to $\bf 2$ 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

do not freeze store at controlled room temperature 20°-25°C (68°-77°F) see package insert for additional information

Inactive Ingredients

ammonium laureth sulfate, fragrance, PEG-25 hydrogenated castor oil, polyquaternium-10, purified water, SD-40 alcohol

Questions or comments?

to report serious side effects due to the use of this product call 1-877-974-7167

Additional Information

Hair Length - Recommended Application for 1 Adult/Child

Short (ear length or shorter) Day 1: 1-2 oz; Day 7-10: 1-2oz; Total: 2-4oz

Medium (shoulder length) Day1: 2-3oz; Day 7-10: 2-3oz; Total: 4-6oz

Long (past shoulder length) Day 1: 3-4oz; Day 7-10: 3-4oz; Total: 6-8oz

Important: keep this outer carton for future reference

Package Insert

Consumer Information

LICE KILLING SHAMPOO

For the treatment of Head Lice, Pubic (Crab) Lice and Body Lice

DIRECTIONS

Important: Read warnings before using this product. A second treatment must be done in 7-10 days to kill anu newly hatched lice eggs (nits)

Inspect

examine each household member with a magnifying glass in bright light for lice/eggs (nits)

look for tiny eggs (nits) near scalp, beginning at the back of neck and behind ears examine small sections of hair

eggs (nits) stick to the hair

if either lice or eggs (nits) are found, treat with this product

Treat

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

To Remove Lice and Their Eggs (Nits)

use a special lice/nit or fine-toothed comb (included). Remove any remaining eggs (nits) by hand, using a throwaway glove

hair should remain slightly damp while removing eggs (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 the head. Longer hair may take 1 to 2 hours

lift a 1- to 2-inch wide strand of hair. Place comb firm, even motion away from scalp pin back each strand of hair after combing

clean comb often. Wipe eggs (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/eggs (nits). Repeat combing if necessary check daily for any lice/eggs (nits) that you missed

a second treatment must be done within 7 to 10 days to kill any newly hatched lice/eggs (nits)

if infestation continues, see a doctor for other treatments

1. HEAD LICE

head lice lay small white eggs (nits) on the hair shaft close to the scalp eggs (nits) are most easily found on the back of the neck or behind the ears disinfect hats, hair ribbons, scarves, coats, towels and bed linens by machine washing in hot water [above 54 C (130 F)], then using the hottest dryer setting for at least 20 minutes

items that cannot be washed, dry cleaned or stored may be sprayed with a product designed for this purpose

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

2. PUBIC (CRAB) LICE

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

3. BODY LICE

body lice and their eggs (nits) are generally found in the seams of clothing, particularly in the waistline and armpit areas

body lice feed on skin then return to clothing to lay their eggs (nits)

disinfect clothing by machine washing in hot water [above 54 C (130 F)], then using the hottest dryer setting for at least 20 mintues

do not seal clothing in a plastic bag because eggs (nits) can remain dormant for up to 30 days

Save this insert for future reference

SHAKE WELL BEFORE USING



Topcare

Lice Killing Shampoo

Lice Treament Shampoo & Conditioner

A Liquid Lice Treatment for Human Use

For the Treatment of Head Lice and Body Lice

Compare to RID Lice Killing Shampoo active ingredients

8 fl oz (236 mL)

Includes One Lice Comb

NDC 76162-253-08

TOPCARE LICE KILLING

piperonyl butoxide, pyrethrum extract shampoo

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76162-253
Route of Administration	TOPICAL		

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

Inactive Ingredients		
Ingredient Name	Strength	
ALCOHOL (UNII: 3K9958V90M)		
WATER (UNII: 059QF0KO0R)		
POLYQUATERNIUM-10 (400 CPS AT 2%) (UNII: HB1401PQFS)		
PEG-25 HYDROGENATED CASTOR OIL (UNII: 0ZNO9PJJ9J)		
AMMONIUM LAURETH-2 SULFATE (UNII: 69804Z48G6)		

Product Characteristics		
Color	yellow (Pale yellow to light yellow)	Score
Shape		Size
Flavor		Imprint Code
Contains		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76162-253- 08	1 in 1 CARTON	11/01/2023	
1		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 Drug	M031	11/01/2023	

Labeler - Topco Associates, LLC (006935977)

Registrant - Weeks & Leo Co., Inc. (005290028)

Establishment				
Name	Address	ID/FEI	Business Operations	
Weeks & Leo Co., Inc.		005290028	manufacture(76162-253)	

Revised: 12/2023 Topco Associates, LLC