LICEALL- piperonyl butoxide, pyrethrum extract shampoo Bob Barker Company, Inc.

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.

PURPOSE:

Liquid Lice Treatment for Human Use

USES:

Treats head, pubic (crab) and body lice.

ACTIVE INGREDIENTS:

*Piperonyl Butoxide, Technical …3.0%

Pyrethrum Extract …… 0.3%

* Equivalent to min. 2.4% (butylcarbityl)(6-propylpiperonyl) ether and 0.6% related compounds.

TOTAL INGREDIENTS:

Water, Octylphenoxypoleethanol, Piperonyl Butoxide, Benzyl Alcohol, C13-14 Isoparaffin, Pyrethrum Extract.

KEEP OUT OF THE REACH OF CHILDREN

WARNINGS:

For external use only. Do not use - near eyes $\hat{a} \in \text{``}$ inside nose, mouth or vagina $\hat{a} \in \text{``}$ on lice in eyebrows or eyelashes. See a doctor if lice are present in these areas. Ask a doctor before use if you are $\hat{a} \in \text{``}$ allergic to ragweed. May cause breathing difficulty or an asthmatic attack. When using this product $\hat{a} \in \text{``}$ keep eyes tightly closed and protect eyes with washcloth or towel $\hat{a} \in \text{``}$ if product gets in eyes flush with water right away $\hat{a} \in \text{``}$ scalp itching or redness may occur. Stop use and ask a doctor if $\hat{a} \in \text{``}$ breathing difficulty occurs $\hat{a} \in \text{``}$ eye irritation occurs $\hat{a} \in \text{``}$ skin or scalp irritation continues or infection occurs. Do not freeze. Do not reuse original container.

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.

-SHAKE WELL BEFORE USING-

Treat – apply thoroughly to 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:

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 drycleaned 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. - 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 gray 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 \hat{a} 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 $54\hat{A}^{\circ}$ C $(130\hat{A}^{\circ}$ 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.

PRINCIPAL DISPLAY PANEL: 2 ounce bottle

Liceall

Liquid Lice Treatment for Human Use

KILLS

HEAD LICE (Pediculus Humanus capitis DeG) **BODY LICE** (Pediculus Humanus Humanus L.) **PUBIC (CRAB) LICE** (Phthirus pubis L.)

A NON-FOAMING SHAMPOO

ACTIVE INGREDIENTS:

*Piperonyl Butoxide, Technical 3.0%

Pyrethrum Extract 0.3%

TOTAL INGREDIENTS:

Water, Octylphenoxypolethoxyethanol, Piperonyl Butoxide, Benzyl Alcohol, C13-14 Isoparaffin, Pvrethrum extract.

* Equivalent to min. 2.4% (butylcarbityl)(6-propylpiperonyl) ether and 0.6% related compounds.

KEEP OUT OF THE REACH OF CHILDREN

CAUTION

CONTENTS: 2 fl. oz. (59 ml)

Distributed By: Bob Barker Company, Inc. 134 North Main St., Fuguay-Varina, N.C. 27526



Liquid Lice Treatment for Human Use

HEAD LICE (Pediculus Humanus capitis DeG)
BODY LICE (Pediculus Humanus Humanus L.)
PUBIC (CRAB) LICE (Phthirus pubis L.)

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Tyroditum Extraor		*:		30	**	(80)	# (#)	- 24			*		***	40	٠.	0.070

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Liquid Lice Treatment for Human Use KEEP OUT OF THE REACH OF CHILDREN CAUTION

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 in 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.

Do not freeze. Do not reuse original container.

PEEL BACK HERE AND RESEAL AFTER OPENING

PRINCIPAL DISPLAY PANEL: 1 Gallon Jug

Liceall

Liquid Lice Treatment for Human Use

KILLS

HEAD LICE

(Pediculus Humanus capitis DeG)

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KEEP OUT OF THE REACH OF CHILDREN CAUTION

SEE OTHER PRECAUTIONS ON SIDE PANEL.

CONTENTS: 1 GALLON (3.785 Liters)

DISTRIBUTED BY:

BOB BARKER COMPANY, INC.

134 North Main St.

Fuguay-Varina, N.C. 27526

USES: Treats head, pubic (crab) and body lice.

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- SHAKE WELL BEFORE USING -

Treat - Apply thoroughly to 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 linch wide strand of hair. Place comb as close to scalp as possible and comb with a firm, even motion



HEAD LICE
(Pediculus Humanus capitis DeG)
BODY LICE
(Pediculus Humanus Humanus L.)
PUBIC (CRAB) LICE
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Directions For Use (cont.) away from scalo. • 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.

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LICEALL

piperonyl butoxide, pyrethrum extract shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53247-330
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TOPICAL **Route of Administration**

Active Ingredient/Active Moiety Basis of Strength Ingredient Name Strength PIPERONYL BUTO XIDE (UNII: LWK91TU9AH) (PIPERONYL BUTO XIDE -**PIPERONYL** 3 g in 100 mL UNII:LWK91TU9AH) BUTOXIDE PYRETHRUM EXTRACT (UNII: ZUM06L90GV) (PYRETHRUM EXTRACT -PYRETHRUM 0.3 gUNII:ZUM06L90GV) **EXTRACT** in 100 mL

Inactive Ingredients							
Ingredient Name	Strength						
WATER (UNII: 059QF0KO0R)							
OCTOXYNOL-9 (UNII: 7JPC6 Y25QS)							
BENZYL ALCOHOL (UNII: LKG8494WBH)							
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)							

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:53247-330- 02	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/20/2010	
	NDC:53247-330- 40	3785 mL in 1 JUG; Type 0: Not a Combination Product	04/20/2010	

Marketing Information										
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date							
OTC monograph final	part358G	04/20/2010								

Labeler - Bob Barker Company, Inc. (058525536)

Revised: 9/2019 Bob Barker Company, Inc.