

HERKLIN LICE TREATMENT- piperonyl butoxide, pyrethrum extract shampoo
Marcas USA 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.

Herklin Lice Treatment

Drug Facts

Active Ingredients

Piperonyl butoxide 4%.....Lice Treatment

Pyrethrum extract (equivalent to 0.33 % pyrethrins.....Lice Treatment

☐ Inactive Ingredients

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

Purpose

Treatment head, pubic (crab), and body lice

☐ Uses

☐☐ *Uses* treats head lice, pubic (crab) lice, 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 us 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 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.

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, begin 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)

- 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.
- 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 °C to 25 ° C (68 °F to 77 °F)
- Questions or comments call (844) 437-5546
- see package insert for additional information

Consumer Information

Kills Lice & Eliminates Nits in 3 simple steps

STEP 1: APPLY • APLIQUE

Apply shampoo **on dry hair** for 10 minutes.



STEP 2: REMOVE • RETIRE

Remove lice and nits with comb provided.



STEP 3: REPEAT • REPITA

Repeat treatment 1 week later.



Detailed Instructions Inside

BILINGUAL HOW-TO VIDEOS

Visit HERKLINE USA on YouTube for step-by-step videos.



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Made in U.S.A

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Principal Display Panel - 236 mL Bottle Carton

MAXIMUM STRENGTH

• PROUDLY SERVING FAMILIES FOR •

38

YEARS

HERKLIN®

LICE TREATMENT

Piperonyl butoxide 4%

Pyrethrum extract (0.33% pyrethrins)

Kills Lice &

Eliminates Nits*

Effective & safe for ages 2+

NEED HELP? •

Toll

Free

(844) HERKLIN

(437-5546)

INCLUDES:

Shampoo, Lice
& Nit Comb

LICE COMB INCLUDED

2 fl oz (59 mL)

☐*Proper use of nit comb removes nits



HERKLIN LICE TREATMENT			
piperonyl butoxide, pyrethrum extract shampoo			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75940-192
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
PEG-25 HYDROGENATED CASTOR OIL (UNII: 0ZNO9PJJ9J)	
POLYQUATERNIUM-10 (125 MPA.S AT 2%) (UNII: L45WU8S981)	
ALCOHOL (UNII: 3K9958V90M)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75940-192-09	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/16/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358G	07/16/2018	

Labeler - MarcasUSA LLC (016139820)**Registrant** - MarcasUSA LLC (016139820)**Establishment**

Name	Address	ID/FEI	Business Operations
Weeks & Leo Co.Inc		005290028	manufacture(75940-192)

Revised: 7/2018

MarcasUSA LLC