

HERKLIN LICE TREATMENT- piperonyl butoxide, pyrethrum
Estrella Brands, 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 Kit

Drug Facts

Active ingredients

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.

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

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, 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)

- 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

- do not freeze
- store at controlled room temperature. 20 °C to 25 °C (68 °F to 77 °F)
- Questions or comments call (XXX) XXX-XXXX
- see package insert for additional information

Inactive ingredients

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

HERKLIN Lice Treatment Kit (72902-003-08)

STOP LICE FROM SPREADING • Controla la propagación de piojos

DON'T share combs, brushes, hats, etc. No compartas peines, cepillos o sombreros.

CHECK hair periodically to detect lice early. REVISÉ el cabello periódicamente para detectar los piojos oportunamente.

WASH ALL clothes, sheets and bedlinens recently used in hot water. LÁVATE TODA la ropa, las sábanas y las fundas de cama que hayan sido usadas recientemente, en agua caliente.

LICE KILLING SHAMPOO

Drug Facts
Active Ingredient Piperonyl butoxide 4%..... LICE TREATMENT
Purpose Treats head lice, pubic (crab) lice, and body lice.
Warnings For external use only. Do not use near eyes, inside nose, mouth, or vagina. See a doctor if lice are present in these areas. Ask a doctor before use if you are allergic to pyrethrin. May cause breathing difficulty or an asthmatic attack.
When using this product Use warm water to form a lather and shampoo. Rinse thoroughly. Do not use on wet hair. Do not use on children under 2 years of age. See a doctor for other treatments.
Directions Read warnings before use. Adults and children 7 years and over: Apply to dry hair. Massage into hair. Rinse thoroughly. Do not use on wet hair. Do not use on children under 2 years of age. See a doctor for other treatments.
Other information See package insert for additional information.
MADE IN USA
 Distributed by: Estrella Brands
 Manhattan Beach, CA 90266
 Estrella-Brands.com
 RMSTRONG®
 LOT NO. _____
 EXPIRES _____

HERKLIN®

LICE TREATMENT & PREVENTION KIT

With Natural Head Lice Repellent to help prevent lice reinfestation after shampoo treatment
 Con repelente de piojos natural para ayudar a prevenir la reinfestación de piojos después del tratamiento con shampoo

PLUS NATURAL HEAD LICE REPELLENT TO PREVENT REINFESTATION

HERKLIN®

LICE TREATMENT & PREVENTION KIT

Kills Lice & Eliminates Nits*

Mata los piojos y elimina las liendres*

ONLY 3 STEPS / SOLO 3 PASOS:

- 1 ELIMINATE / Eliminar
- 2 REMOVE / Retirar
- 3 CONTROL / Controlar

Effective & safe for ages 2+
 Eficaz y seguro para mayores de 2 años

LICE COMB INCLUDED
 INCLUYE PEINE LIENDRERA

*Proper use of nit comb removes and kills nits.
 *El uso adecuado del peine liendrera elimina y mata las liendres.

24/7 SUPPORT

Ayuda las 24 horas

BILINGUAL HOW-TO VIDEOS:
 Videos bilingües de instrucciones:

YouTube

Visit **HERKLIN USA** on YouTube for step-by-step videos.
 Visita nuestro canal de YouTube para ver las instrucciones paso a paso.

NEED HELP? / NECESITAS AYUDA?
 Call (844) HERKLIN (437-3546)

(24/7) SUPPORT

FOLLOW US / SIGUENOS EN:
 Facebook, YouTube, Instagram
 /HerkinUSA

HerkinUSA.com



HERKLIN Lice Treatment Shampoo 8oz/236ml (72902-000-08)

Drug Facts (continued)

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. ● 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

MADE IN U.S.A. HER6002A0317

MAXIMUM STRENGTH

38 YEARS
AÑOS

HERKLIN®

LICE TREATMENT

Piperonyl butoxide 4%
 Pyrethrum extract (0.33% pyrethrins)

Kills Lice & Eliminates Nits*

Mata los piojos y elimina las liendres*

Effective & safe for ages 2+
 Eficaz y seguro para mayores de 2 años

8 fl oz (236 ml)

*Proper use of nit comb removes and kills nits.
 *El uso adecuado del peine liendrera elimina y mata las liendres.

Important: keep outer carton for complete information.

Drug Facts
Active ingredients
 Piperonyl butoxide 4%..... LICE TREATMENT
 Pyrethrum extract (equivalent to 0.33% pyrethrins)..... LICE TREATMENT
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. 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. 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, 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.

DO NOT PRINT!
 space reserved for LOT & EXP

HERKLIN LICE TREATMENT

piperonyl butoxide, pyrethrum kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72902-003
---------------------	----------------	---------------------------	---------------

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72902-003-08	1 in 1 KIT	04/01/2019	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	236 mL

Part 1 of 1

HERKLIN LICE TREATMENT

piperonyl butoxide, pyrethrum shampoo

Product Information

Item Code (Source)	NDC:72902-000
---------------------------	---------------

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PIPERONYL BUTOXIDE (UNII: LWK91TU9AH) (PIPERONYL BUTOXIDE - UNII:LWK91TU9AH)	PIPERONYL BUTOXIDE	40 mg in 1 mL
PYRETHRUM EXTRACT (UNII: ZUM06L90GV) (PYRETHRUM EXTRACT - UNII:ZUM06L90GV)	PYRETHRUM EXTRACT	3.3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PEG-25 HYDROGENATED CASTOR OIL (UNII: 0ZNO9PJJ9J)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72902-000-08	1 in 1 CARTON		

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 final	part358G	04/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358G	04/01/2019	

Labeler - Estrella Brands, LLC (116929354)

Revised: 2/2019

Estrella Brands, LLC