

**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.*

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**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 (72902-001-02)**

**Drug Facts (continued)**

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**RMSTRONG®** **MADE IN U.S.A.**  
 Distributed by: Estrella Brands 58-253-02v3.0  
 Manhattan Beach, CA 90266 • Estrella-Brands.com HER1003A0518

**Drug Facts (continued)**

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**Kills Lice & Eliminates Nits\* in 3 Simple Steps**  
 Mata los piojos y elimina las liendres en 3 sencillos pasos

**STEP 1: APPLY • APLIQUE**

Apply shampoo *on dry hair* for 10 minutes. Aplique el shampoo *sobre el cabello seco* por 10 minutos.

**STEP 2: REMOVE • RETIRE**

Remove lice and nits with comb provided. Retire los piojos y liendres con el peine incluido.

**STEP 3: REPEAT • REPITA**

Repeat treatment 1 week later. Repita el tratamiento en una semana.

Detailed Instructions Inside  
 Instrucciones detalladas en el interior

**BILINGUAL HOW-TO VIDEOS:**  
 Videos bilingües de instrucciones:



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



**MAXIMUM STRENGTH**

**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

NEED HELP? • ¿NECESITAS AYUDA?  
 Toll Free (844) HERKLIN (437-5546)

INCLUDES: Shampoo, Lice & Nit Comb

INCLUYE: Shampoo y peine para piojos y liendres

**LICE COMB INCLUDED**  
 Incluye peine liendreras

2 fl oz (59 mL)

\*Proper use of nit comb removes nits.  
 \*El uso adecuado del peine liendreras elimina las liendres.

**Drug Facts**

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 Piperonyl butoxide 4% . . . . . Lice treatment  
 Pyrethrum extract (equivalent to 0.33% pyrethrins) . . . . . Lice treatment

**Uses** treats head, pubic (crab), and body lice

**Warnings**  
 For external use only

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**Stop use and ask a doctor if**

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**Directions**

- **Important:** Read warnings before use
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  - check each household member with a magnifying glass in bright light for lice/nits (eggs)

**Drug Facts (continued)**

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58-253-02v1.0 HER1003A0518

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 Mata piojos y elimina las liendres

Effective and safe for the whole family  
 Eficaz y seguro para toda la familia

2 fl oz (59 mL)

**Important:** keep outer carton for complete information.

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**DO NOT PRINT!**  
 space reserved for LOT & EXP

# HERKLIN LICE TREATMENT

piperonyl butoxide, pyrethrum kit

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72902-001
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## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72902-001-02	1 in 1 KIT	04/01/2019	

## Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	59 mL

## Part 1 of 1

# HERKLIN LICE TREATMENT

piperonyl butoxide, pyrethrum shampoo

## Product Information

<b>Item Code (Source)</b>	NDC:72902-000
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<b>Route of Administration</b>	TOPICAL
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## Active Ingredient/Active Moiety

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

## Inactive Ingredients

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

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72902-000-02	1 in 1 CARTON		
1		59 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	

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**Labeler** - Estrella Brands, LLC (116929354)

Revised: 2/2019

Estrella Brands, LLC