

**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 (72902-002-08) | HERKLIN Lice Treatment Shampoo  
8oz/236ml (72902-000-08)**



**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 pelo 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 7-10 days later.**  
 Repita el tratamiento 7-10 días después.

**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 HERKLIN USA en YouTube para videos paso a paso.



**Kills Lice & Eliminates Nits\***  
*Mata los piojos y elimina las liendres\**  
 Effective & safe for ages 2+  
*Eficaz y segura para mayores de 2 años*



**NEED HELP? • ¿NECESITA 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 liendres* 8 fl oz (236 mL)  
 \*Proper use of nit comb removes nits.  
 \*El uso adecuado del peine liendres elimina las liendres.

**STOP LICE FROM SPREADING**  
*Controla la propagación de piojos*

-  **DON'T share combs, brushes or hats.**  
 NO comparta peines, cepillos o sombreros.
-  **CHECK hair periodically to detect lice early.**  
 REVISE el cabello periódicamente para detectar los piojos temprano.
-  **WASH ALL clothes, sheets and towels recently used, in hot water.**  
 LAVAR TODA la ropa, las sábanas y las toallas usadas recientemente, en agua caliente.

**Drug Facts**

**Active ingredients** Piperonyl butoxide 4% . . . . . Lice treatment  
**Purposes** Pyrethrum extract (equivalent to 0.33% pyrethrins) . . . . . 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)

**Drug Facts (continued)**

- 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

**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

**MADE IN U.S.A.**  
**Distributed by: Estrella Brands**  
 Manhattan Beach, CA 90266  
 Estrella-Brands.com

 58-253-08V3.0  
 HER1002A0317

LOT NO.

EXPIRES

**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



Distributed by: Estrella Brands  
Manhattan Beach CA, 90266 • Estrella-Brands.com

MADE IN U.S.A.

HER6002A0317



\*Proper use of nit comb removes and kills nits.  
\*El uso adecuado de la peine liendreras elimina y mata las liendres.

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

**Drug Facts**

**Active ingredients**  
Piperonyl butoxide 4%..... Lice treatment  
Pyrethrum extract..... Lice treatment

(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 ● 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.

DO NOT PRINT!  
space reserved  
for LOT & EXP

Distributed by MarcasUSA, LLC  
El Segundo CA, 90245 • HerklinUSA.com

**HERKLIN LICE TREATMENT**

piperonyl butoxide, pyrethrum kit

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72902-002
---------------------	----------------	---------------------------	---------------

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72902-002-08	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: 059QF0KO0R)	

### 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)