

LICE KILLING- piperonyl butoxide, pyrethrum extract shampoo Weeks & Leo Co., 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.

Herklin Lice Killing shampoo

Active ingredient

Piperonyl butoxide 4%

Pyrethrum extract (equivalent to 0.33% pyrethrins)

Uses

treats head, pubic (crab), and body lice

Purpose

Lice treatment

Warnings

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 into 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 the 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°-25°C (68°-77°F)
- to report serious side effects due to the use of this product call 515-276-1586
- see package insert for additional information

Inactive ingredients

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

Package Insert

HERKLIN[®] LICE TREATMENT

Piperonyl butoxide 4%
Pyrethrum extract (0.33% pyrethrins)

Maximum Strength Lice Killing Shampoo

**Kills Lice &
Eliminates Nits***

HERKLIN offers a comprehensive and effective treatment to eliminate lice and nits. Follow steps accordingly in order to eliminate the root cause. Applying treatment only takes 3 simple steps.

DOSAGE AND USAGE

The entire family should be checked. Apply treatment to those members who show signs of live lice.



STEP 1: APPLY

With dry hair, apply sufficient shampoo amount to moisten all of the hair, massage then **leave for 10 minutes**, then rinse with water.



STEP 2: REMOVE

Remove lice and nits while hair is wet, using the included comb.



STEP 3: REPEAT

Repeat treatment 7-10 days later.



To treat body and pubic lice (crabs), apply in the same way in the affected areas.

EXPERT SUPPORT



HOW-TO VIDEOS

*Proper use of nit comb removes nits.



CONTACT AN EXPERT

TOLL FREE (844) HERKLIN (437-5546)
24 HOUR HOTLINE

58-253v5.0
HER7001A0317

RECOMMENDED APPLICATION

Hair Length	Recommended Application [†] for 1 Adult/Child	
SHORT (ear length or shorter)	DAY 1:	1 – 2 oz
	DAY 7-10:	1 – 2 oz
	TOTAL:	2 – 4 oz
MEDIUM (shoulder length)	DAY 1:	2 – 3 oz
	DAY 7-10:	2 – 3 oz
	TOTAL:	4 – 6 oz
LONG (past shoulder length)	DAY 1:	3 – 4 oz
	DAY 7-10:	3 – 4 oz
	TOTAL:	6 – 8 oz

[†]Recommended application dependent upon hair thickness

DID YOU KNOW?

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 dry-cleaned 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 grey 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

- 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 °C (130 °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

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HERKLIN[®]

LICE TREATMENT

Piperonyl butoxide 4%
Pyrethrum extract (0.33% pyrethrins)

HERKLIN ofrece un tratamiento integral y efectivo para erradicar los piojos y las liendres. Debe seguirlo al pie de la letra para eliminar de raíz el padecimiento. La aplicación es muy sencilla, con sólo 3 pasos.

Shampoo contra los piojos (máxima potencia)
**Mata los Piojos y
Elimina las Liendres***

DOSIS Y MODO DE EMPLEO

Se deberá revisar a toda la familia y aplicar el tratamiento solamente a quienes se les detecten piojos vivos.



PASO 1: APLIQUE

Con el cabello seco, aplique suficiente cantidad asegurándose de humedecer con el shampoo todo el cabello, dar un masaje y dejar actuar durante 10 minutos, posteriormente enjuagar con abundante agua.



PASO 2: RETIRE

Retire los piojos y liendres mientras el cabello está húmedo, usando el peine incluido.



PASO 3: REPITA

Repita el tratamiento 7-10 días después.



Para tratar los piojos del cuerpo y del pubis (ladillas), aplicar de la misma manera en las áreas afectadas.

APOYO DE EXPERTOS



VIDEOS DE
INSTRUCCIONES



CONTACTAR A UN EXPERTO

TOLL FREE: (844) HERKLIN (437-5546)
LÍNEA DIRECTA DE 24 HORAS

58-253v5.0
HER7001A0317

*El uso adecuado del peine liendreras elimina las liendres.

CANTIDAD RECOMENDADA

Largo del cabello	Cantidad recomendada ¹ para 1 adulto/niño	
CORTO (hasta la oreja o más corto)	DÍA 1:	1 - 2 oz
	DÍA 7-10:	1 - 2 oz
	TOTAL:	2 - 4 oz
MEDIO (hasta el hombro)	DÍA 1:	2 - 3 oz
	DÍA 7-10:	2 - 3 oz
	TOTAL:	4 - 6 oz
LARGO (más abajo del hombro)	DÍA 1:	3 - 4 oz
	DÍA 7-10:	3 - 4 oz
	TOTAL:	6 - 8 oz

¹Aplicación recomendada dependiendo del grosor del pelo

¿SABÍA QUE?

Piojos de la cabeza

- ponen pequeños huevos blancos (liendres) en el cabello cerca del cuero cabelludo
- las liendres se encuentran habitualmente en la parte posterior del cuello o detrás de las orejas
- desinfecte sombreros, cintas para el cabello, bufandas, abrigos, toallas y ropa de cama lavándolos a máquina con agua caliente (a más de 54 °C (130 °F)), y usando el ciclo de secado más caliente al menos 20 minutos
- los artículos que no se pueden lavar (colchones, mantas, almohadas, peluches, etc.) se deben limpiar en seco o sellar en una bolsa de plástico durante 4 semanas, y luego sacar al aire libre y sacudir bien antes de volver a usar
- los artículos que no se pueden lavar; limpiar en seco o almacenar, se pueden rociar con productos diseñados para este propósito
- sumerja todos los peines y cepillos en agua caliente (a más de 54 °C (130 °F)) al menos 10 minutos
- aspire todas las alfombras, colchones, muebles tapizados y asientos de automóvil que hayan sido usados por personas afectadas

Piojos públicos (ladillas)

- pueden ser transmitidos por contacto sexual. Las parejas sexuales deben ser tratadas simultáneamente para evitar infestaciones

- los piojos son muy pequeños y parecen puntos marrones o grises en la piel
- habitualmente causan un picor intenso y ponen pequeños huevos blancos (liendres) en la parte del vello cercano a la superficie de la piel
- pueden encontrarse en el vello corto de la ingle, los muslos, el tronco y las axilas, y ocasionalmente en la barba y el bigote
- desinfecte la ropa interior lavándola a máquina con agua caliente (a más de 54 °C (130 °F)), y usando el ciclo de secado más caliente al menos 20 minutos

Piojos del cuerpo


- los piojos del cuerpo y sus huevos (liendres) se suelen encontrar en las costuras de la ropa, particularmente en las zonas de la cintura y las axilas
- los piojos del cuerpo se alimentan de la piel y luego vuelven a la ropa para poner sus huevos
- desinfecte la ropa lavándola a máquina con agua caliente (a más de 54 °C (130 °F)), y usando el ciclo de secado más caliente al menos 20 minutos
- no selle la ropa en una bolsa de plástico porque las liendres pueden permanecer latentes hasta 30 días

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Approved By:					Date	

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LICE KILLING SHAMPOO

For the treatment of Head Lice, Pubic (Crab) Lice and Body Lice

DIRECTIONS

Important: Read warnings before using this product. A second treatment must be done in 7-10 days to kill any newly hatched lice eggs (nits)

Inspect

examine each household member with a magnifying glass in bright light for lice/eggs (nits)

look for tiny eggs (nits) near scalp, beginning at the back of neck and behind ears

examine small sections of hair

eggs (nits) stick to the hair

if either lice or eggs (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

To Remove Lice and Their Eggs (Nits)

use a special lice/nit or fine-toothed comb (included). Remove any remaining eggs (nits) by hand, using a throwaway glove

hair should remain slightly damp while removing eggs (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 the head. Longer hair may take 1 to 2 hours

lift a 1- to 2-inch wide strand of hair. Place comb firm, even motion away from scalp pin back each strand of hair after combing

clean comb often. Wipe eggs (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/eggs (nits). Repeat combing if necessary

check daily for any lice/eggs (nits) that you missed

a second treatment must be done within 7 to 10 days to kill any newly hatched lice/eggs (nits)

if infestation continues, see a doctor for other treatments

1. HEAD LICE

head lice lay small white eggs (nits) on the hair shaft close to the scalp

eggs (nits) are most easily found on the back of the neck or behind the ears

disinfect hats, hair ribbons, scarves, coats, towels and bed linens by machine washing in hot water [above 54 C (130 F)], then using the hottest dryer setting for at least 20 minutes

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

2. PUBIC (CRAB) LICE

pubic (crab) lice may be contracted by sexual contact

sexual partners should be treated simultaneously to avoid reinfestation

lice are very small and look like brown or grey dots on the skin

pubic (crab) lice usually cause intense itching and lay small white eggs (nits) on the hair shaft generally close to the skin surface

pubic (crab) lice may be present on the short hairs of the groin, thighs, trunk, and

underarms, -and occasionally on the beard, eyelids, and mustache
disinfect underwear by machine washing in hot water [above 54 C (130 F)], then using
the hottest dryer setting for at least 20 minutes

3. BODY LICE

body lice and their eggs (nits) are generally found in the seams of clothing, particularly in
the waistline and armpit areas

body lice feed on skin then return to clothing to lay their eggs (nits)

disinfect clothing by machine washing in hot water [above 54 C (130 F)], then using the
hottest dryer setting for at least 20 minutes

do not seal clothing in a plastic bag because eggs (nits) can remain dormant for up to
30 days

Save this insert for future reference

LICE KILLING

piperonyl butoxide, pyrethrum extract shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11383-310
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
POLYQUATERNIUM-10 (400 MPA.S AT 2%) (UNII: HB1401PQFS)	
AMMONIUM LAURETH-2 SULFATE (UNII: 69804Z48G6)	
ALCOHOL (UNII: 3K9958V90M)	
WATER (UNII: 059QF0KO0R)	
PEG-25 HYDROGENATED CASTOR OIL (UNII: 0ZNO9PJJ9J)	

Product Characteristics

Color	yellow (Cloudy to transparent , cream to straw)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11383-310-02	1 in 1 CARTON	05/17/2021	
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	05/17/2021	

Labeler - Weeks & Leo Co., Inc. (005290028)

Registrant - Weeks & Leo Co., Inc. (005290028)

Establishment

Name	Address	ID/FEI	Business Operations
Weeks & Leo Co., Inc.		005290028	manufacture(11383-310)

Revised: 6/2021

Weeks & Leo Co., Inc.