

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

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

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: DAY 7-10: TOTAL:	1 – 2 oz 1 – 2 oz 2 – 4 oz
MEDIUM (shoulder length)	DAY 1: DAY 7-10: TOTAL:	2 – 3 oz 2 – 3 oz 4 – 6 oz
LONG (past shoulder length)	DAY 1: DAY 7-10: TOTAL:	3 – 4 oz 3 – 4 oz 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

Public (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

NOTE TO OUR CUSTOMERS:

When viewing proof with Acrobat, always activate "Overprint Preview" Preferences / General / Page Display / Use Overprint Preview / Always

Job: 149278
Ticket Number:354001
File Name: 149278f
Inks: Black
Proof Date: 8/1/2017

HERKLIN[®]

LICE TREATMENT

Piperonyl butóxido 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
HER7091A0317

*El uso adecuado del peine liendreras elimina las liendres.

CANTIDAD RECOMENDADA

Largo del cabello	Cantidad recomendada ^a 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

^aAplicación 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, alfileres, 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, almohadadas, 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

NOTE TO OUR CUSTOMERS:

When viewing proof with Acrobat, always activate "Overprint Preview" Preferences / General / Page Display / Use Overprint Preview / Always

Job: 149278

Ticket Number:354001

File Name: 149278b

Inks: Black

Proof Date: 8/1/2017

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: DAY 7-10: TOTAL:	1 – 2 oz 1 – 2 oz 2 – 4 oz
MEDIUM (shoulder length)	DAY 1: DAY 7-10: TOTAL:	2 – 3 oz 2 – 3 oz 4 – 6 oz
LONG (past shoulder length)	DAY 1: DAY 7-10: TOTAL:	3 – 4 oz 3 – 4 oz 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

Public (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

NOTE TO OUR CUSTOMERS:

When viewing proof with Acrobat, always activate "Overprint Preview" Preferences / General / Page Display / Use Overprint Preview / Always

Job: 149278
Ticket Number: 354001
File Name: 149278f
Inks: Black
Proof Date: 8/1/2017

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
HER7091A0317

*El uso adecuado del peine liendreras elimina las liendres.

CANTIDAD RECOMENDADA

Largo del cabello	Cantidad recomendada ^a 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

^aAplicación 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, almohadadas, 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

NOTE TO OUR CUSTOMERS:

When viewing proof with Acrobat, always activate "Overprint Preview" Preferences / General / Page Display / Use Overprint Preview / Always

Job: 149278
Ticket Number:354001
File Name: 149278b
Inks: Black
Proof Date: 8/1/2017

Principal Display Panel



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: 698O4Z48G6)	
ALCOHOL (UNII: 3K9958V90M)	
WATER (UNII: 059QF0KO0R)	
PEG-25 HYDROGENATED CASTOR OIL (UNII: 0ZNO9PJ9J)	

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 Drug	M031	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)