# HERKLIN LICE TREATMENT- piperonyl butoxide, pyrethrum extract MARCASUSA 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 & Prevention Kit

#### **Active ingredient**

Piperonyl butoxide 4%

Pyrethrum extract (equivalent to 0.33% pyrethrins)

#### Uses

treats head, pubic (crab), and body lice

#### Purpose

Lice treatment

#### 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 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)
- 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

### **Consumer Information - Package Insert**

English Insert



#### Maximum Strength Lice Killing Shampoo **Kills Lice &** Eliminates Nits\*

Piperonyl butoxide 4% Pyrethrum extract (0,33% pyrethrins)

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.



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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



\*Proper use of nit comb removes nits.

#### Spanish insert



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

CONTACT AN EXPERT

24 HOUR HOTLINE

THE (844) HERKLIN (437-5546)

HERKUN 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

#### 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.

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#### 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





\*El uso adecuado del peine liendrera elimina las liendres,

### RECOMMENDED APPLICATION

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

58-253-5-0

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- · 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 driver cycle for at least 20 minutes

#### Body lice

- · body lice and their eggs (nits) are generally found in the seams of clothing particularly in waisfline and ampit area · body lice feed on skin then return to dothing to lay their
- eggs · disinfect dothing by machine washing in hot water (above 54 °C (130 °F)), then using hottest dryer cycle for at least
- 20 minutes do not seal dothing in a plastic bag because nits can remain dormant for up to 30 days

#### CANTIDAD RECOMENDADA

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

Aplicación recomendada dependiendo del grosor del pelo

#### ¿SABÍA QUE?

#### Piojos de la cabeza

- ponen pequeños huevos blancos illendres) en el cabello cerca del cuero. cabe udo
- · las liendres se encuentran habitualmente en la parte posterior del cuello o detrás de las oreias
- desinfecte sombreros, cintas para el cabello, bufandas, abrigos, toallas y ropa de carria 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
- · Jos artículos que no se pueden Javar (colchas, mantas, almohadas, pejuches, etc.) se deben jimpiar en seco o sejar en una bolsa de plástico durante 4 semanas, y luego sacar al aire libre y sacudir bier 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 sumería todos los peines y cepillos en aqua caliente (a más de 54 °C)
- (130 °F)) al menos 10 minutos
- · aspire lodas las allombras, colchones, muebles tapizados y asientos de automóvil que hayan sido usados por personas alectadas

#### Piojos púbicos (ladillas)

 pueden ser transmittidos por contacto sexual. Las pareias sexuales. deben ser tratadas simultáneamente para evitar infestaciones

· las piojas son muy pequeños y perecen puntos memores o grises en la piel

- · habitualmente causan un picor intenso y ponen pequeños huevos blancos (liendres) en la parte del vello cercana a la superficie de la piel -
- pueden encontrarse en el vello corto de la ingle, los musios, el
- tronco y las axilas, y ocasionalmente en la barba y el bigote desirriecte la ropa interior lavándola a máquina con agua caliente (a. más de 54 °C (130 °F), y usando el ciclo de secado más callente alments 20 minutos

#### Piojos del cuerpo

- · los pipios del cuerpo y sus huevos (liendres) se suelen encontrar en las costuras de la ropa, particularmente en las zonas de la cintura. y las axias
- los piolos del cuerpo se alimentan de la piel y luego vuelven a la ropa para poner sus huevos
- · desirriecte la ropa lavándola a máquina con agua caliente (a más de 54 °C (130 °F), y usando el cido 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 dias

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#### **Principal Display Panel**

### Herklin

#### LICE TREATMENT 7 PREVENTION KIT

With Natural Head Lice Repellent to help prevent Lice reinfestation after shamporr treatment

con repelente de piojos natural para ayudar prevenir la reinfestacion de piojos despues del tratmiento con shampoo

### Plus NATURAL HEAD LICE REPLEELLENT TO PREVENT REINFESTATION

Kills Lice & Eliminates Nits\*

Mata Los piojos y elimina las liendres

ONLY 3 STEPS/ SOLO 3 PASOS

1 Eliminate 2 Remove 3 Control

Effective & Safe for ages 2+

### **CAUTION: KEEP OUT OF REACH OF CHILDREN**

Instrucciones en español incluidas

SHAMPOO 8 FL OZ

Natural lice repellent spray

**1 NIT REMOVAL COMB** 



### HERKLIN LICE TREATMENT

piperonyl butoxide, pyrethrum extract kit

Product Infor	mation							
Product T ype	HUMAN (	DTC DRUG	DRUG Item Code (Source)		Ν	NDC:75940-182		
Packaging								
# Item Code		Package Description		Marketing S	Start Date	te Marketing End Date		te
1 NDC:75940-182	-08 I IN I CARION	I; Type 0: Not a Combina	tion Product	0 1/0 3/20 14				
Quantity of Pa	rts							
Part #	Package Qu	antity		Total Product Quantity				
Part 1 0 BOTTLE			118 mL					
Part 1 of 1								
LICE KILL	ING							
piperonyl butoxi	de, pyrethrum ex	tract shampoo						
		-						
<b>Product Infor</b>	mation							
Route of Admini	stration	TOPICAL						
Active Ingred	ient/Active Moi	•						
		gredient Name			Basis of S		Strength	1
PIPERONYL BUT UNII:LWK91TU9AI		1TU9AH) (PIPERONYL E	SUTOXIDE -		PIPERONYL BUTO XIDE		40 mg in 1 m	nL
<b>PYRETHRUM EXT</b> UNII:ZUM06L90G		6L90GV) (PYRETHRUM	EXTRACT -		PYRETHRUN EXTRACT	М	3.3 mg in 1 mL	
UNII.ZUM06L90G	v)				EATRACT		III I IIIL	
Inactive Ingre	dients							
		Ingredient Na	me				Strength	
POLYQUATERNI	UM-10 (400 MPA.S	AT 2%) (UNII: HB1401P	QFS)					
AMMO NIUM LAU	RETH-2 SULFATE	(UNII: 698O4Z48G6)						
ALCOHOL (UNII:								
WATER (UNII: 059								
PEG-25 HYDROG	ENATED CASTOR	<b>OIL</b> (UNII: 0ZNO9PJJ9J)	)					
Product Chara	acteristics							
Color		ansparent, cream to strav	v)		Score			
Shape					Size			
Flavor					Imprin	nt Code		
Contains								

Packaging						
# Item Code	Package Description		Marketing Start Date	Marketing End Date		
1	237 mL	in 1 BOTTLE; Type 0: Not a Combination Product				
Marketing Information						
Marketing Ca	tegory	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph	final	part358G	02/01/2014			
OTC monograph	final	part358 G	0 2/0 1/20 14			
OTC monograph	final	part358G	02/01/2014			
OTC monograph Marketing			02/01/2014			
	Info		02/01/2014 Marketing Start Date	Marketing End Date		

## Labeler - MARCASUSA LLC (016139820)

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

### Establishment

Name	Address	ID/FEI	Business Operations
Weeks & Leo Co., Inc.		005290028	manufacture(75940-182)

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MARCASUSA LLC