

TOPCARE COMPLETE LICE TREATMENT KIT- piperonyl butoxide, pyrethrum extract

Topco Associates, LLC

Topcare Lice Treatment 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)

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

Additional Information

Hair Length - Recommended Application for 1 Adult/Child

Short (ear length or shorter) Day 1: 1-2 oz; Day 7-10: 1-2oz; Total : 2-4oz

Medium (shoulder length) Day1: 2-3oz; Day 7-10: 2-3oz; Total: 4-6oz

Long (past shoulder length) Day 1: 3-4oz; Day 7-10: 3-4oz; Total: 6-8oz

Largo del cabello - Cantidad recomendada para 1 adulto/niño

Corto (hasta la oreja o más corto) Dia 1: 1-2oz; Dia7-10: 1-2oz; Total: 2-4oz

Medio (hasta el hombro) Dia1: 2-3oz; Dia 7-10: 2-3oz; Total: 4-6oz

Largo (más abajo del hombro) Dia 1: 3-4oz; Dia 7-10: 3-4oz; Total: 6-8oz

Important: keep this outer carton for future reference

Package Insert

3-STEP PROCESS FOR LICE TREATMENT

See center for complete product information.

Step 1 • Treat

Apply Lice Killing Shampoo

Age	Sex	Product	Directions	Notes
Infant	Male/Female	1oz • 1oz	1oz • 1oz	1oz • 1oz
Child 1-12	Male/Female	1oz • 1oz	1oz • 1oz	1oz • 1oz
Adult	Male/Female	1oz • 1oz	1oz • 1oz	1oz • 1oz

NOTE: Wash hair with shampoo before application. Apply shampoo to scalp and hair. Rub into hair and scalp. Rinse thoroughly with water. Repeat application in 7-10 days. For best results, use a comb to remove lice and eggs after shampooing.

Step 2 • Remove

Comb out lice and eggs with fine-tooth comb and Lice & Egg Combing Spray

This product should be used AFTER Lice Killing Shampoo (Step 1). Combing is an important step to remove eggs. Use a fine-tooth comb to remove lice and eggs. Apply combing spray to hair after combing.

Step 3 • Control

Treat the home with Home Lice, Bedbug & Dust Mite Spray

Use Home Lice, Bedbug & Dust Mite Spray to treat the home. Follow directions on the label. Spray in bedrooms, bathrooms, and other areas where lice may be found.

Did You Know?

Lice are common in homes with children. They can cause itching and discomfort. Home Lice, Bedbug & Dust Mite Spray can help eliminate lice from your home. Use it regularly to keep your home free of lice.

PROCESO DE 3 PASOS PARA EL TRATAMIENTO CONTRA PJOJOS

Consulte el envase para obtener información completa de los productos.

Fase 1 • Tratar

Aplicar el champú matamoscas

Unidad	Gramos	Oz	Libras
1 gramo	1 gramo	0.035 oz	0.008 lbs
1 onza	28.35 g	1 onza	0.125 lbs
1 libra	453.59 g	16 onzas	1 libra

Wash hair with shampoo before application. Apply shampoo to scalp and hair. Rub into hair and scalp. Rinse thoroughly with water. Repeat application in 7-10 days. For best results, use a comb to remove lice and eggs after shampooing.

Fase 2 • Remover

Retirar piojos y huevos con un peine para piojos o otro peine de dientes finos y aerosol para retirar piojos y huevos

This product should be used AFTER Lice Killing Shampoo (Step 1). Combing is an important step to remove eggs. Use a fine-tooth comb to remove lice and eggs. Apply combing spray to hair after combing.

Fase 3 • Control

Tratar su hogar con el spray contra piojos, chinches y ácaros para el hogar

Use Home Lice, Bedbug & Dust Mite Spray to treat the home. Follow directions on the label. Spray in bedrooms, bathrooms, and other areas where lice may be found.

¿Sabe Usted?

Lice are common in homes with children. They can cause itching and discomfort. Home Lice, Bedbug & Dust Mite Spray can help eliminate lice from your home. Use it regularly to keep your home free of lice.

Consumer Information 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

SHAKE WELL BEFORE USING

CHAMPÚ PARA MATAR PIOJOS

Para el tratamiento de piojos de cabeza, piojos púbicos (ladillas) y piojos del cuerpo

Para uso externo solamente.

No lo use

cerca de los ojos

dentro de la nariz, boca o vagina

para piojos en las cejas o pestañas. Consulte a un doctor si hay piojos en estas áreas.

Pregúntele a un doctor antes de usarlo si

es alérgico a la ambrosía. Puede provocar dificultades para respirar o un ataque asmático.

Cuando use este producto

mantenga los ojos bien cerrados y protéjalos con una toallita o toalla

si el producto entra en los ojos, enjuáguese inmediatamente con agua

puede experimentar picazón o enrojecimiento del cuero cabelludo.

Deje de usarlo y consulte a un doctor si

tiene dificultad para respirar

presenta irritación de los ojos

prevalece la irritación de la piel o el cuero cabelludo o se presenta una infección.

Si está embarazada o lactando, antes de usarlo pregunte a un profesional médico.

Manténgalo fuera del alcance de los niños. Si e traga, obtenga ayuda médica o póngase en contacto de inmediato con el Centro de Control de Envenenamientos

INSTRUCCIONES

IMPORTANTE: LEA LAS ADVERTENCIAS ANTES DE USAR ESTE PRODUCTO. UN SEGUNDO TRATAMIENTO DEBE SER REALIZADO ENTRE 7 Y 10 DIAS PARA ELIMINAR LA REPRODUCCIÓN DE NUEVOS PIOJOS Y HUEVECILLOS (LIENDRES).

Inspeccione

Examine a cada uno de los integrantes de la familia bajo luz brillante con una lupa en busca de piojos o huevecillos (liendres)

usque los huevecillos (liendres) en el cabello, comenzando en la parte posterior del cuello y detrás de las orejas

examine áreas pequeñas del cabello

a diferencia de la caspa, la cual se mueve al tocarla, los huevecillos (liendres) permanecen adheridos al cabello

si encuentra piojos o huevecillos (liendres) trate las áreas afectadas con este producto.

Tratamiento

aplique sobre todo el cabello seco u otras áreas afectadas. Para liendres de cabeza primero aplique detrás de las orejas y en la parte posterior del cuello

deje el producto durante 10 minutos, pero no se exceda del tiempo sugerido

use agua tibia para formar espuma, lave con champú y luego enjuague muy bien

para liendres de cabeza, seque el cabello con una toalla y desenrede con un peine.

Para eliminar los piojos y sus huevecillos (liendres)

use un peine de dientes finos o un peine especial para piojos y liendres. Remueva todos las huevecillos (liendres) restantes a ano usando guantes desechables

el pelo debe permanecer húmedo mientras se remueven los huevecillos (liendres)

si el pelo se seca mientras es peinado, humidézcalo con agua

para liendres de cabeza, divida el pelo en secciones. Revise una sección a la vez comenzando por la parte de arriba de la cabeza. Si tiene pelo largo le puede tomar de 1 o 2 horas

levante mechones de una pulgada de ancho. Ponga el peine lo más cerca posible del cuero cabelludo y peine con movimientos parejos y firmes

sujete cada mechón de pelo después de peinar limpie el peine con frecuencia. Limpie los huevecillos (liendres) con un papel toalla y tirlvelas en una bolsa plástica. Cierre la bolsa y

tírela para prevenir que los piojos vuelvan a aparecer

después de peinar, vuelva a revisar para ver si encuentra piojos o huevecillos (liendres). Si fuera necesario repita el procedimiento

revise a diario para ver si aparece algún piojo o huevecillo (liendres)

se debe efectuar un segundo tratamiento a los 7 a 10 días para matar los huevecillos nuevos (liendres)

si la plaga continua se debe consultar con el doctor para hacer otros tratamiento.

Otra Información

no lo congele

protéjalo del calor excesivo

vea la información adicional en el anexo del paquete

Ingredientes Inactivos ,lauril sulfato de amonio, lauril sulfato de amonio, fragancia, PEG-25 aceite de ricino hidrogenado, policuaternio-10, alcohol desnaturalizado SD 40-B, agua

1. PIOJOS DE LA CABEZA

Los piojos de cabeza ponen huevos blancos (liendres) en los hebra del cabello cerca del cuero cabelludo. Las liendres son fáciles de encontrar en la parte posterior del cuello o detrás de las orejas.

Desinfecte los sombreros, cintas para el cabello, bufandas, abrigos, toallas y sábanas lavándolos en lavadora con agua caliente [a una temperatura de más de 54 C (130 F)], y luego séquelos en la secadora a la temperatura más alta durante un mínimo de 20 minutos.

Los artículos que no pueden ser lavados (cubrecamas, frizas, almohadas, juguetes de peluche, etc.) deben ser limpiados en seco o deben ser sellados en bolsas plásticas por 4 semanas, después sacados a la intemperie y sacudidos enérgicamente antes de ser usados otra vez.

artículos que no pueden ser lavados, limpiados en seco o guardados deben ser rociados con productos designados para este fin.

Sumerja todos los peines y cepillos en agua caliente, [por más de 54 C (130 F)] por lo menos por 10 minutos.

Limpie las alfombras, colchones, muebles tapizados y asientos del carro que pueden haber sido usados por personas infectadas.

2. PIOJOS PÚBLICOS (LADILLAS)

Los piojos púbicos (ladillas) pueden adquirirse por contacto sexual.

Compañeros sexuales deben ser tratados simultáneamente para evitar contagios.

Los piojos son muy pequeños y parecen puntos cafés o grises sobre la piel.

Piojos púbicos producen picazón muy intensa y ponen huevos muy pequeños (liendres) en los mechones de pelo cerca de la superficie de la piel.

Los piojos púbicos pueden encontrarse en los pelos cortos de las ingles, muslos, tórax y axilas, y ocasionalmente pueden encontrarse en la barba, párpados y bigote.

Desinfecte la ropa interior lavándola en lavadora con agua caliente [a una temperatura de más de 54 C (130 F)], y secándola luego en la secadora a la temperatura más alta durante un mínimo de 20 minutos.

3. PIOJOS DE CUERPO

Los piojos de cuerpo (y sus liendres) son generalmente encontrados en los dobladillos de la ropa, particularmente en el elástico de la cintura o en la zona de la axila.

Las liendres del cuerpo se alimentan de la piel y luego retornan a la ropa para depositar sus huevos (liendres).

Desinfecte la ropa lavándola en la lavadora en agua caliente [a una temperatura de más de 54 C (130 F)], y luego use el ciclo más caliente de la secadora por más caliente de la secadora por más de 20 minutos.

No selle la ropa dentro de una bolsa de plástico debido a que los huevecillos (liendres) pueden permanecer en estado inactivo durante un período de hasta 30 días.

Guarde las instrucciones para futuras referencias.

AGÍTESE MUY BIEN ANTES DE USAR

Principal Display Panel

TopCare

Maximum Strength

Complete Lice Treatment Kit

Compare to RID® Lice Killing Shampoo Active Ingredients

Eliminates Lice from Your Home & Family

Shampoo 4 fl oz (118 mL)

Lice Spray Net Wt. 5 oz (142 g)

Combing Spray 2 fl oz (59 mL)

1 Metal Lice Comb

CAUTION: KEEP OUT OF REACH OF CHILDREN

See back and side panels for additional information

Product Information

Item Code (Source) NDC:76162-253

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
ALCOHOL (UNII: 3K9958V90M)	
WATER (UNII: 059QF0KO0R)	
AMMONIUM LAURETH-2 SULFATE (UNII: 69804Z48G6)	
POLYQUATERNIUM-10 (400 MP.A.S AT 2%) (UNII: HB1401PQFS)	
PEG-25 HYDROGENATED CASTOR OIL (UNII: 0ZNO9PJ9J)	

Product Characteristics

Color	yellow	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76162-253-04	118 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	12/09/2020	

Part 2 of 2

COMBING SPRAY

other preparations (i.e., those preparations that do not fit another category) not applicable

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	TRIDECETH-12 (UNII: YFY3KG5Y7O)	
INGR	PANTHENOL (UNII: WW9CM0067Z)	
INGR	CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)	
INGR	GLYCERIN (UNII: PDC6A3C00X)	
INGR	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
INGR	METHYLCHLOROISOTHIAZOLINONE/METHYLISOTHIAZOLINONE MIXTURE (UNII: 15O9QS218W)	
INGR	WATER (UNII: 059QF0KO0R)	
INGR	POLYSORBATE 20 (UNII: 7T1F30V5YH)	
INGR	AMODIMETHICONE (800 CST) (UNII: 363Z2T48P7)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		10/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M031	10/01/2023	

Labeler - Topco Associates, LLC (006935977)

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

Establishment

Name	Address	ID/FEI	Business Operations
WEEKS & LEO COMPANY, INC.		005290028	manufacture(76162-255)

Revised: 12/2024

Topco Associates, LLC