

DISCOUNT LICE TREATMENT- piperonyl butoxide, pyrethrum extract

Discount drug mart

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.

Discount Drug Mart complete lice treatment

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

Principal Display Panel

discount Drug mart

Complete lice treatment Kit

1 treat shampo

2 remove spray

3 control aerosol

Lice Killing Shampoo

Drug Facts (continued)

- hair should remain slightly damp while massaging into
- if hair dries during shampoo, shampoo again 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.
- if 1 to 1 1/2 inch wide strands of hair, place comb as close to scalp as possible and comb with a firm, even motion away from scalp.
- run each section of hair after combing
- clean comb often. Wipe dry away with tissue and discard in a plastic bag. Do not bag and discard to prevent lice from crawling back.
- after combing, thoroughly wash hair. Repeat combing if necessary.
- check only for any lice 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: see a doctor

Other information

- do not heat
- store at controlled room temperature, 20° to 25° C (68° F to 77° F)
- see package insert for additional information

Inactive ingredients
 mentholum bromatum, fragrance, PEG-20 hydrogenated castor oil, polybutene-10, polyethylene glycol-15

Lice, Bedbug & Mite Spray

Exposure to temperatures above 130° F may cause burning.

WARNINGS FOR USE
 Do not use if you are pregnant or trying to become pregnant with this product in a major treatment area with lice.

State Wet Before Using Not For Use on Humans

Use Restrictions when used indoors: Do not use on children or pets to control lice and mites. Do not use on dogs, cats, birds, or other animals. Do not use on humans. Do not use on clothing or bedding. Do not use on furniture. Do not use on walls, ceilings, or floors. Do not use on pets, birds, or other animals. Do not use on children or pets. Do not use on humans. Do not use on clothing or bedding. Do not use on furniture. Do not use on walls, ceilings, or floors.

Lice, Bedbug & Mite Spray

Storage and Disposal
 Do not store in areas where children or pets may be exposed. Do not store in areas where children or pets may be exposed. Do not store in areas where children or pets may be exposed. Do not store in areas where children or pets may be exposed.

Important Note: Do not use if you are pregnant or trying to become pregnant with this product in a major treatment area with lice.

COMPLETE LICE TREATMENT KIT

COMPLETE LICE TREATMENT KIT

STEP 1 TREAT

SHAMPOO

MAXIMUM STRENGTH Lice Killing Shampoo & Conditioning in One

- Works Fast to Kill Lice & Eggs

STEP 2 REMOVE

SPRAY WITH COMB

Egg & Nit Combining Spray

- Makes Combining Easier
- Helps Remove Lice Eggs

STEP 3 CONTROL

AEROSOL

Kills Lice & Their Eggs on Car Interiors, Furniture, Mattresses & Other Non-washable Items

CAUTION: KEEP OUT OF REACH OF CHILDREN

See back & inner panels for First Aid and additional Precautionary Statements

4 fl oz (118 mL) Shampoo
 2 fl oz (59 mL) Combining Spray
 Net Wt. 5 oz (142 g) Lice, Bedbug & Mite Spray

Lice Killing Shampoo

Drug Facts

Active Ingredients

Ingredient	Purpose
Piperonyl Butoxide 4%	• Lice Treatment
Pyrethrum extract (equivalent to 0.33% pyrethrins)	• Lice Treatment

Use: see back, inside comb, and body lice

Warnings: For external use only

Do not use:

- on eyes
- inside nose, mouth, or vagina
- on face in children or on face, hair, or body in infants
- on face in infants or on face, hair, or body in children
- if you are pregnant or trying to become pregnant

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
- avoid getting it on face, hair, or body
- avoid breathing it in
- if you breathe it in, stop using and get medical help
- if you have trouble breathing, stop using and get medical help

Precautionary Statements:

- avoid contact with eyes, nose, mouth, or vagina
- avoid contact with face, hair, or body in children
- avoid contact with face, hair, or body in infants
- avoid contact with face, hair, or body in children
- avoid contact with face, hair, or body in children
- avoid contact with face, hair, or body in children

DISCOUNT LICE TREATMENT

piperonyl butoxide, pyrethrum extract kit

Product Information	
Product Type	HUMAN OTC DRUG
Item Code (Source)	NDC:53943-255

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53943-255-01	1 in 1 CARTON; Type 0: Not a Combination Product	01/03/2014	

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	118 mL

Part 1 of 1

LICE KILLING

piperonyl butoxide, pyrethrum extract shampoo

Product Information	
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
POLYQUATERNIUM-10 (400 MPAS AT 2%) (UNII: HB1401PQFS)	
AMMONIUM LAURETH-2 SULFATE (UNII: 698O4Z48G6)	
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		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 final	part358G	02/01/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358	10/28/2010	

Labeler - Discount drug mart (047741335)**Registrant** - Weeks & Leo Co., Inc. (005290028)**Establishment**

Name	Address	ID/FEI	Business Operations
Weeks & Leo Co., Inc.		005290028	manufacture(53943-255)

