

## **WALGREENS LICE KILLING- piperonyl butoxide, pyrethrum extract shampoo**

### **Walgreens CO**

*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.*

-----

### **Lice Killing Shampoo Drug Facts**

#### **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

### **Package Insert**

**Principal Display Panel**



## Walgreens LICE KILLING SHAMPOO

### LICE TREATMENT SHAMPOO FOR HUMAN USE

Maximum Strength  
Compare to RID® LICE KILLING SHAMPOO  
2 fl oz (59ml)

## WALGREENS LICE KILLING

piperonyl butoxide, pyrethrum extract shampoo

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-1253
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
-----------------	-------------------	----------

<b>PIPERONYL BUTOXIDE</b> (UNII: LWK91TU9AH) (PIPERONYL BUTOXIDE - UNII:LWK91TU9AH)		PIPERONYL BUTOXIDE	4 g in 100 mL	
<b>PYRETHRUM EXTRACT</b> (UNII: ZUM06L90GV) (PYRETHRUM EXTRACT - UNII:ZUM06L90GV)		PYRETHRUM EXTRACT	0.33 g in 100 mL	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
WATER (UNII: 059QF0KO0R)				
ALCOHOL (UNII: 3K9958V90M)				
POLYQUATERNIUM-10 (400 MPA.S AT 2 %) (UNII: HB1401PQFS)				
PEG-25 HYDROGENATED CASTOR OIL (UNII: 0ZNO9PJJ9J)				
AMMONIUM LAURETH-2 SULFATE (UNII: 698O4Z48G6)				
<b>Product Characteristics</b>				
Color	yellow (cloudy to transparent, cream to straw)	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-1253-02	1 in 1 CARTON	02/21/2019	
1		59 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0363-1253-08	1 in 1 CARTON	02/25/2019	
2		237 mL in 1 BOTTLE; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final		part358G	02/21/2019	

**Labeler** - Walgreens CO (008965063)

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

## Establishment

Name	Address	ID/FEI	Business Operations
Weeks & Leo Co., Inc.		005290028	manufacture(0363-1253)