

**QUALITY CHOICE LICE TREATMENT- piperonyl butoxide, pyrethrum extract**  
**Chain Drug Marketing Association**

*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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**Quality Choice 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)
- 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**

Quality Choice

The all in one lice solution for your family

Compare to the Active Ingredients in RID® Shampoo†

with maximum strength Shampoo

1 treat shampoo

2 remove comb/gel

3 control spray

Instrucciones en español incluidas

**Lice Killing Shampoo**

**Drug Facts (continued)**

- hair should remain slightly damp while removing nits
- If hair dries during combing, dampen lightly 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 2 inches wide strand of hair, place comb as close to scalp as possible and comb with it from even motion away from scalp.
- go back each strand of hair after combing
- Clean comb often. Wipe it away with tissue and discard in a plastic bag. Soak bag and discard to prevent lice from coming back.
- after combing, thoroughly checks for lice/nits. Repeat combing if necessary.
- check only 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** see a doctor

**Other information**

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

**Inactive ingredients**  
 piperonyl butoxide, pyrethrum, PPD-15 hydroquinone calcium, 4-hydroxybenzoic acid, purified water, SLS-40 alcohol

**Lice, Bedbug & Mite Spray**

**Warnings**

- Immediately call a Poison Control Center or doctor
- Do not inhale vomiting or fumes that do so by a Poison Control Center or doctor • Do not give any liquid to the person • Do not give anything by mouth to an unconscious person

**For eyes**

- If hair eyes open and rinse slowly and gently with water for 15-20 minutes • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye • Call a Poison Control Center or doctor for further treatment advice

**For skin**

- Move person to fresh air • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible • Call a Poison Control Center or doctor for further treatment advice

**For skin or clothing**

- Rinse off contaminated clothing • Rinse skin immediately with plenty of water for 15-20 minutes • Call a Poison Control Center or doctor for further treatment advice

How the product container or label with you when calling a Poison Control Center or doctor, or going for treatment.

**NOTE TO PHYSICIAN:** Contains petroleum distillate - vomiting may cause aspiration pneumonia.

**DIRECTIONS FOR USE**  
 It is a violation of federal law to use this product in a manner inconsistent with its labeling.

**SHAKE WELL BEFORE USING**  
 Remove protective cap. Hold container upright with nozzle away from you. Depress trigger and spray from a distance of 8 to 10 inches.

**To Kill Lice and Louse Eggs:** Spray in an inconspicuous area to test for possible staining or discoloration. Repeat again after drying and then proceed to spray entire area to be treated. Hold container upright with nozzle away from you. Depress valve and spray from a distance of 8 to 10 inches. Spray each square foot for three seconds. Spray to the point of dampness, but not wet-off. Allow all exposed surfaces to dry thoroughly before use.

**Spray only those parts of bedding, including mattresses and furniture that cannot be either laundered or dry cleaned. Do not use on sheets or pillowcases.**

**Bedbugs:** Spray mattresses, particularly around tufts and seams. Take beds apart and spray into all crevices, treat boxsprings, moldings and floors. If lice infestations should occur on humans, use a product labeled for use on humans. Spray to the point of dampness, but not wet-off. After mattress is dry cover with mattress cover and sheet. Do not use mattress without cover. Repeat infestation occurs, but not more than once every two weeks.

**Exposed Stages of Grain Mites:** Spray into cracks and crevices or other areas where these insects tend to congregate. Spray 30 seconds for each 100 square feet of surface. Keep area closed for 45 minutes for 1 hour after treatment. Spray to the point of dampness, but not wet-off. Repeat infestation occurs, but not more than once every two weeks. Repeat stored food products in the home should be disposed of.

**Lice, Bedbug & Mite Spray**

**STORAGE AND DISPOSAL**

**KEEP OUT OF REACH OF CHILDREN.**

**Do not contaminate water.** Food or feed by storage or disposal. **Pesticide Storage:** Store in a cool, dry area away from inaccessible to children and pets and away from heat, sparks and open flame. Do not transport or store below 32° F. Do not freeze. **Pesticide Disposal and Container Handling:** Do Not Puncture or Recycle! Recycle! container, do not reuse or refill this container. If empty: Place in trash or after for recycling if available. **If partly filled,** call your local solid waste agency for disposal instructions.

**Never consume all kinds of eat, storage or handling of this material not in strict accordance with directions given hereon.**

EPA Reg. # 10000-04-0000 EPA Est. # 4430-01-10000

**Lice & Egg Combing Gel**

**Use**  
 Use on one after lice killing shampoo

**Warnings**  
 For external use only. Keep out of the reach of children. If product gets into the eyes, immediately flush with water.

**Directions**  
 1. Apply liberally to wet hair.  
 2. Massage thoroughly until hair is evenly coated.  
 3. Use the special comb provided to remove nits/eggs.  
 4. Repeat or use comb periodically by days.  
 5. Re-check for nits/eggs before rinsing out.  
 6. Use as often as desired.

**Other information To Prevent Reinfestation**

- All personal headgear (scarves, cloths and bed linens) should be disinfected by machine washing in hot water and drying using hottest drying cycle for at least 20 minutes.
- Personal articles of clothing or bedding that have been exposed to lice and cannot be washed may be dry-cleaned or sealed in a plastic bag for a period of 2 weeks.
- Combs and brushes may be disinfected by soaking in hot water (rather than 120° F) for 5-10 minutes.
- Thorough vacuuming of rooms inhabited by infected persons is recommended.
- Inanimate objects such as mattresses and carpets should be treated with bedding spray to remove the lice infestation process.

**Ingredients:** Water, (Acetic Acid, Potassium Hydroxide, Polyethylene Glycol, Polychloro 20, Polychloro 20, Hydroxyethylcellulose, Disodium Citrate, Methylparaben, Ethylparaben, Fragrance)

This product is not manufactured by Bayer HealthCare, distributor for Bayer HealthCare.

**Important:** Keep this container carbon for future reference.

Batch Code: Exp Date:

**QUALITY CHOICE**

# COMPLETE LICE TREATMENT KIT

The All In One Lice Solution For Your Family

Compare to the active ingredients in RID® SHAMPOO

With Maximum Strength Shampoo

# COMPLETE LICE TREATMENT KIT

The All In One Lice Solution For Your Family

**Step 1: TREAT** SHAMPOO  
 Kills Head Lice, Body Lice & Pubic (Crab) Lice

**Step 2: REMOVE** COMB  
 Special Nit Removal Comb • Gentle to Hair

**Step 3: CONTROL** GEL & SPRAY  
 Gel: Natural Combing Easier • Natural Residue Lice Eggs  
 Spray: With Lice And Bedbugs For Use on Bedding, Etc. NOT FOR USE ON HUMANS OR ANIMALS

Made in the U.S.A.

**Instrucciones en español incluidas**

KEEP OUT OF REACH OF CHILDREN  
**CAUTION:**  
 See Side Panel for Additional Precautionary Statements

**Lice Killing Shampoo**

**Drug Facts**

**Active ingredients**  
 Piperonyl butoxide, Pyrethrum extract (equivalent to 0.33% pyrethrin I), Purified water, SLS-40 alcohol

**Purpose**  
 Lice treatment

**Use:** scalp, head, pubic (crab), and body lice

**Warnings**  
 For external use only

**Do not use**

- near eyes
- inside nose, mouth, or vagina
- on face in eyebrows or eyelashes. See a doctor if lice are present in those areas.

**Use as directed before use or you are**

- allergic to pyrethrin. May cause breathing difficulty or an asthma attack.

**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 • 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
- **children 2 years and over:**
  - check each household member with a magnifying glass in bright light for lice/nits/eggs
  - look for nits near scalp, beginning at back of head and behind ears
  - examine small sections of hair at a time
  - unless bandoff which moves when touched, nits stick to the hair
  - if other lice or nits are found, treat with this product

**Treat**

- wash thoroughly to dry hair or other affected areas. 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 lathered shampoo, then thoroughly rinse
- for head lice, wash dry hair and comb out tangles
- **Remove lice and their eggs (nits)**
  - use a fine-tooth or special lice comb. Remove any remaining nits by hand using a fine-toothed comb.

# QUALITY CHOICE LICE TREATMENT

piperonyl butoxide, pyrethrum extract kit

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-525

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-525-01	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 MPA.S AT 2%) (UNII: HB1401PQFS)				
AMMONIUM LAURETH-2 SULFATE (UNII: 698O4Z48G6)				
ALCOHOL (UNII: 3K9958V90M)				
WATER (UNII: 059QF0K00R)				
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** - Chain Drug Marketing Association (011920774)

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

### Establishment

Name	Address	ID/FEI	Business Operations
Weeks & Leo Co., Inc.		005290028	manufacture(63868-525)

