

**LEADER LICE KILLING- piperonyl butoxide, pyrethrum extract shampoo  
LEADER/ Cardinal Health 110, Inc.**

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**Leader Lice Killing Shampoo**

**Active Ingredient**

Piperonyl butoxide 4%

Pyrethrum extract (equivalent to 0.33% pyrethrins)

**Purposes**

Lice Treatment

**Uses**

treats head, pubic (crab), and body lice

**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 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 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

## Questions or comments?

to report serious side effects due to the use of this product call 1-877-974-7167

## 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

Important: keep this outer carton for future reference

## Package Insert

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

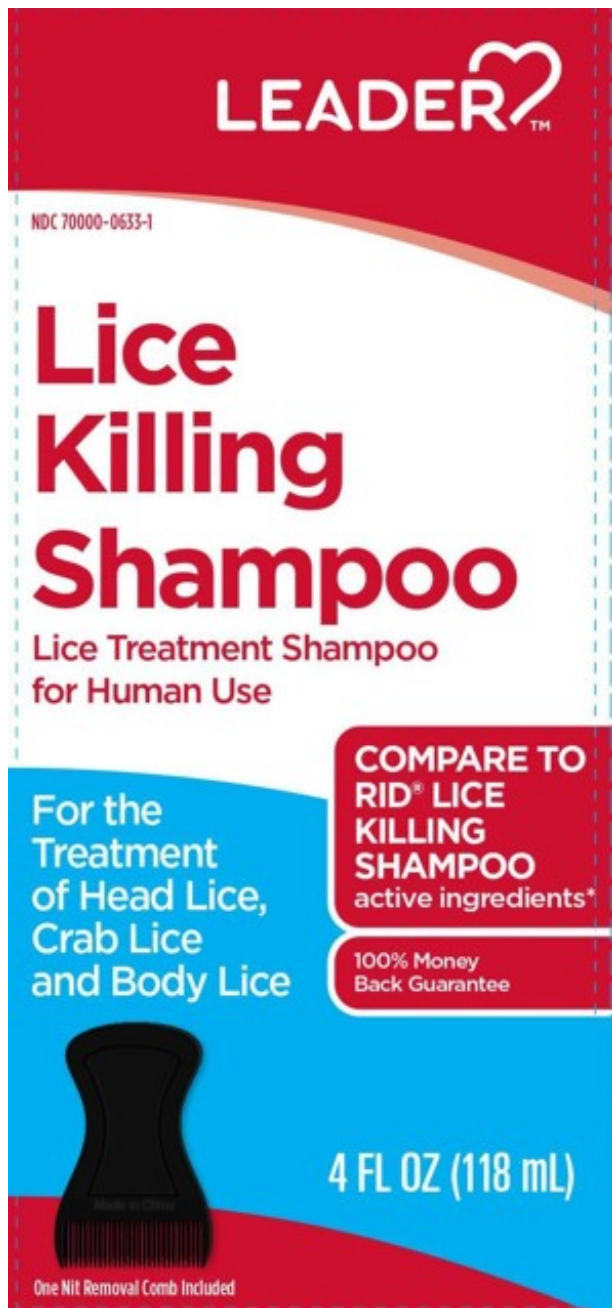
pubic (crab) lice may be contracted by sexual contact  
sexual partners should be treated simultaneously to avoid reinfestation  
lice are very small and look like brown or grey dots on the skin  
pubic (crab) lice usually cause intense itching and lay small white eggs (nits) on the hair shaft generally 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



LEADER

Lice Killing Shampoo

Lice Treatment Shampoo for Human Use

For the Treatment of Head Lice, Crab Lice and Body Lice

Compare to RID Lice Killing Shampoo active ingredients

100% Money Back Guarantee

4 fl oz (118 mL)

One Nit Removal Comb Included

NDC 70000-0633-1

**LEADER LICE KILLING**

piperonyl butoxide, pyrethrum extract shampoo

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0633
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>PYRETHRUM EXTRACT</b> (UNII: ZUM06L90GV) (PYRETHRUM EXTRACT - UNII:ZUM06L90GV)	PYRETHRUM EXTRACT	0.33 g in 100 mL
<b>PIPERONYL BUTOXIDE</b> (UNII: LWK91TU9AH) (PIPERONYL BUTOXIDE - UNII:LWK91TU9AH)	PIPERONYL BUTOXIDE	4 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>POLYQUATERNIUM-10 (400 CPS AT 2%)</b> (UNII: HB1401PQFS)	
<b>PEG-25 HYDROGENATED CASTOR OIL</b> (UNII: 0ZNO9PJJ9J)	
<b>AMMONIUM LAURETH-2 SULFATE</b> (UNII: 69804Z48G6)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0633-1	1 in 1 CARTON	06/21/2023	
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 Drug	M031	06/21/2023	

**Labeler** - LEADER/ Cardinal Health 110, Inc. (063997360)

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

### Establishment

Name	Address	ID/FEI	Business Operations
Weeks & Leo Co., Inc.		005290028	manufacture(70000-0633)

