

MAJOR LICE KILLING- piperonyl butoxide, pyrethrum extract shampoo
Major Pharmaceuticals

Major 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.

if you have ever had an allergic reaction to this product or any of its ingredients

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 (1-800-222-1222)

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

**Maximum Strength
Lice Killing
Shampoo**
Lice Treatment
Shampoo & Conditioner

MAJOR[®] NDC 0904-7349-20
Compare to the
active ingredients in RID[®]
Lice Killing Shampoo*

**Maximum Strength
Lice Killing
Shampoo**
Lice Treatment
Shampoo & Conditioner

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

4 FL OZ (118 mL)
Includes One Lice Comb

Hair Length	Recommended Application** for 1 Adult/Child
Short (ear length or shorter)	Day 1: 1 - 2 oz
	Day 7-10: 1 - 2 oz
	Total: 2 - 4 oz
Medium (shoulder length)	Day 1: 2 - 3 oz
	Day 7-10: 2 - 3 oz
	Total: 4 - 6 oz
Long (past shoulder length)	Day 1: 3 - 4 oz
	Day 7-10: 3 - 4 oz
	Total: 6 - 8 oz

*Recommended application dependent upon hair thickness

Important: keep this outer carton for future reference.

Distributed by:
MAJOR[®] PHARMACEUTICALS
Indianapolis, IN 46268
(800) 616-2471
www.majorpharmaceuticals.com

Drug Facts
Active Ingredients **Purposes**
Piperonyl butoxide 4%Lice Treatment
Pyrethrum extract (equivalent to 0.33% pyrethrins)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 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 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 (1-800-222-1222) 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

Drug Facts (continued)

- 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
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- 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 °C to 25 °C (68 °F to 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

*This product is not manufactured or distributed by Bayer HealthCare, owner of the registered trademark RID[®].

LOT NO. EXPIRES

Major
Lice Killing Shampoo
Lice Treatment Shampoo & Conditioner
A Liquid Lice Treatment for Human Use
For the Treatment of Head Lice and Body Lice
Compare to RID Lice Killing Shampoo active ingredients
4 fl oz (118 mL)
Includes One Lice Comb
NDC 0904-7349-20

MAJOR LICE KILLING
piperonyl butoxide, pyrethrum extract shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-7349
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
WATER (UNII: 059QF0KO0R)	
POLYQUATERNIUM-10 (400 CPS AT 2%) (UNII: HB1401PQFS)	
PEG-25 HYDROGENATED CASTOR OIL (UNII: 0ZNO9PJJ9J)	
AMMONIUM LAURETH-2 SULFATE (UNII: 698O4Z48G6)	

Product Characteristics

Color	yellow (Pale yellow to light yellow)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-7349-20	1 in 1 CARTON	11/01/2023	
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	11/01/2023	

Labeler - Major Pharmaceuticals (191427277)**Registrant** - Weeks & Leo Co., Inc. (005290028)

Establishment

Name	Address	ID/FEI	Business Operations
Weeks & Leo Co., Inc.		005290028	manufacture(0904-7349)

Revised: 12/2023

Major Pharmaceuticals