

LICE TREATMENT - permethrin lotion
Rebel Distributors Corp

Permethrin Lotion 1%

ACTIVE INGREDIENT

Active ingredient (in each fluid ounce)

Permethrin 280 mg (1%)

PURPOSE

Lice treatment

USE

Treats head lice

WARNINGS

For external use only

DO NOT USE

on children under 2 months of age

- near the eyes
- inside the nose, ear, mouth, or vagina
- on lice in eyebrows or eyelashes. See your doctor.

ASK A DOCTOR BEFORE USE IF YOU ARE

- allergic to ragweed. May cause breathing difficulty or an asthmatic episode.

WHEN USING THIS PRODUCT

- keep eyes tightly closed and protect eyes with a washcloth or towel
- if product gets into the eyes, immediately flush with large amounts of water
- scalp itching or redness may occur

STOP USE AND SEE A DOCTOR IF

side effects occur.

breathing difficulty occurs

eye irritation occurs

- skin or scalp irritation continues or infection occurs

PREGNANCY OR BREAST FEEDING

If pregnant or breast-feeding, ask a health professional before use.

KEEP OUT OF REACH OF CHILDREN

If swallowed, get medical help or contact a Poison Control Center right away.

DIRECTIONS

Inspect

- all household members should be checked by another person for lice and/or nits (eggs)
- use a magnifying glass in bright light to help you see the lice and nits (eggs)
- use a tool, such as a comb or two unsharpened pencils to lift and part the hair
- look for tiny nits near the scalp, beginning at the back of the neck and behind the ears
- small sections of hair (1-2 inches wide) should be examined at a time
- unlike dandruff, nits stick to the hair. Dandruff should move when lightly touched.
- if either lice or nits (eggs) are found, treat with Permethrin Lotion 1%

Treat

- wash hair with a shampoo without conditioner. Do not use a shampoo that contains a conditioner or a conditioner alone since this may decrease the activity of Permethrin Lotion 1%. Rinse with water.
- towel dry hair so it is damp but not wet
- shake the bottle of Permethrin Lotion 1% well
- completely saturate the hair and scalp with Permethrin Lotion 1%. Begin to apply Permethrin Lotion 1% behind the ears and at the back of the neck.
- keep Permethrin Lotion 1% out of the eyes. Protect the eyes with a washcloth or towel.
- leave Permethrin Lotion 1% on the hair for 10 minutes, but no longer
- rinse with warm water
- towel dry hair and comb out tangles
- if live lice are seen seven days or more after the first treatment, a second treatment should be given

Remove Lice/Nits

- remove nits by combing the hair with the special small tooth comb provided. Remaining nits may be removed by hand (using a throw-away glove), or cutting the nits out.
- use the nit comb provided and make sure the hair remains slightly damp while removing nits
- if the hair dries during combing, dampen it slightly with water
- part the hair into 4 sections. Work on one section at a time. Longer hair may take more time (1-2 hours).
- start at the top of the head on the section you have picked
- with one hand, lift a 1-2 inch wide strand of hair. Get the teeth of the comb as close to the scalp as possible and comb with a firm, even motion away from the scalp to the end of the hair.
- use clips to pin back each strand of hair after you have combed out the nits
- clean the comb completely as you go. Wipe the nits from the comb with a tissue and throw away the tissue in a sealed plastic bag to prevent the lice from coming back.
- after combing, recheck the entire head for nits and repeat combing if necessary
- check the affected head daily to remove any nits that you might have missed

Other information

- read all the directions in the Consumer Information Insert and warnings before use. Keep the carton. It contains important information.
- store at 20° to 25°C (68° to 77°F)

INACTIVE INGREDIENTS

Balsam fir canada, cetyl alcohol, citric acid, FD&C yellow #6, fragrance, hydrolyzed animal protein, hydroxyethylcellulose, isopropyl alcohol, methylparaben, polyoxyethylene 10 cetyl ether, propylene glycol, propylparaben, purified water, stearylalkonium chloride

QUESTIONS?

1-800-432-8534 (select option # 2) between 9 am and 4 pm EST, Monday – Friday.

Patient Information

Single Application

Lice Treatment

Permethrin Lotion 1%

With A Single Application:

- Kills Lice & Their Eggs
 - Prevents Reinfestation for 14 Days
- Creme Rinse With Nit Removal Comb
2 FL OZ (59 mL)

Information for Patients

Consumer Information Insert

Permethrin Lotion 1%

Lice Treatment

Please read all information before using Permethrin Lotion 1%.

If you or a member of your household has lice, don't panic. Keep calm.

Anyone can get head lice – **it has nothing to do with cleanliness or poor hygiene.** Head lice are treatable and very rarely cause serious health problems.

What are head lice?

- head lice are small insects that live and feed on the human scalp
- they may get as big as sesame seeds and are brown
- lice do not fly or jump from one person to another. They can only crawl.

What are nits?

- nits are lice eggs laid on the hair near the scalp. One louse may lay over 100 nits.
- nits are oval shaped, tiny and greyish-white
- they are attached to hair with a waterproof glue-like substance that cannot be washed out or blown away

Because nits (eggs) hatch in about one week, all nits must be removed to stop lice.

How do head lice spread?

- head lice spread easily from close head-to-head or hand-to-head contact with persons who have lice
- they may also spread by sharing hats, helmets, scarves, headphones, brushes, combs, bedding and clothing

How do you know if you have lice?

- itching is the most common symptom
- scratching behind the ears or the back of the neck is a sign that you should check for head lice
- scabs or blood spots may be seen

How do you prevent the spread of lice?

- do not share or borrow personal items like combs, brushes, or headbands
- do not share or borrow hats, sweaters, coats, scarves, helmets, headphones, pillows or stuffed animals
- store hats in coat sleeves and hang coats separately, so that they do not touch other people's hats and coats
- wash under fingernails when you first see lice or nits (eggs)
- check your child's head daily when you hear of a lice outbreak in day care or school

How to use Permethrin Lotion 1%

1. Inspect

If you suspect head lice – check. Head lice may be hard to locate because they avoid light. Nits are easier to see.

- all household members should be checked by another person for lice and/or nits (eggs)
- use a magnifying glass in bright light to help you see the lice and nits (eggs)
- use a tool, such as a comb or two unsharpened pencils to lift and part the hair
- look for tiny nits near the scalp, beginning at the back of the neck and behind the ears
- small sections of hair (1-2 inches wide) should be examined at a time
- unlike dandruff, nits stick to the hair. Dandruff should move when lightly touched.



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PICTURE OF MOTHER CHECKING FOR LICE

- if either lice or nits (eggs) are found, treat with Permethrin Lotion 1%
 1. **Treat**
 - wash hair with a shampoo without conditioner. Do not use a shampoo that contains a conditioner or a conditioner alone since this may decrease the activity of Permethrin Lotion 1%. Rinse with water.
 - towel dry hair so it is damp but not wet
 - shake the bottle of Permethrin Lotion 1% well
 - completely saturate the hair and scalp with Permethrin Lotion 1%. Begin to apply Permethrin Lotion 1% behind the ears and at the back of the neck.
 - keep Permethrin Lotion 1% out of the eyes. Protect the eyes with a washcloth or towel.
 - leave Permethrin Lotion 1% on the hair for 10 minutes, but no longer
 - rinse with warm water
 - towel dry hair and comb out tangles

- if live lice are seen seven days or more after the first treatment, a second treatment should be given



PICTURE OF CHILD WITH SHAMPOO ON HAIR

- **1. Remove Lice/Nits**

Treatment kills lice but does not remove the nits.

- remove nits by combing the hair with the special small tooth comb provided. Remaining nits may be removed by hand (using a throw-away glove), or cutting the nits out.
- use the nit comb provided and make sure the hair remains slightly damp while removing nits
- if the hair dries during combing, dampen it slightly with water
- part the hair into 4 sections. Work on one section at a time. Longer hair may take more time (1-2 hours).
- start at the top of the head on the section you have picked
- with one hand, lift a 1-2 inch wide strand of hair. Get the teeth of the comb as close to the scalp as possible and comb with a firm, even motion away from the scalp to the end of the hair.
- use clips to pin back each strand of hair after you have combed out the nits
- clean the comb completely as you go. Wipe the nits from the comb with a tissue and throw away the tissue in a sealed plastic bag to prevent the lice from coming back.
- after combing, recheck the entire head for nits and repeat combing if necessary
- check the affected head daily to remove any nits that you might have missed



PICTURE SHOWING HOW TO COMB HAIR

- **1. Clean home and personal items**

After using Permethrin Lotion 1%, it is very important to clean personal items and your home to prevent the spread of lice. Nits may live away from the human head for about 7-12 days. Lice may live away from the human head for about 1 day.

- all personal head gear (hats, hair ribbons, etc.), scarves, coats, towels and bed linens should be washed in hot water (above 130°F), then dried in the dryer using the hottest cycle for at least 20 minutes
- personal combs, including nit combs, and brushes should be soaked in hot water (above 130°F) for at least 10 minutes

- personal articles such as clothing, bedspreads, blankets, pillows or stuffed animals that cannot be washed should be dry-cleaned or sealed tightly in a plastic bag for a period of at least 4 weeks. Items should be taken out of the plastic bag outdoors and shaken out very hard before using again.
- for anything you cannot wash, dry-clean or store in a plastic bag, spray with a product that kills lice
- vacuum everywhere. Vacuum all carpets, mattresses, upholstered furniture and car seats that may have been used by infested household members.



PICTURE OF MOTHER CLEANING

- **WARNINGS**

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on children under 2 months of age

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 - inside the nose, ear, mouth, or vagina
 - on lice in eyebrows or eyelashes. See your doctor.
- Ask a doctor before use if you are**
- allergic to ragweed. May cause breathing difficulty or an asthmatic episode.

When using this product

- keep eyes tightly closed and protect eyes with a washcloth or towel
- if product gets into the eyes, immediately flush with large amounts of water
- scalp itching or redness may occur

Stop use and see a doctor if

- breathing difficulty occurs
- eye irritation occurs
- skin or scalp irritation continues or infection occurs

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Questions? 1-800-432-8534 (select option # 2).

Form No. 5242-PI

Rev. 8/08

VC 3202

PRINCIPAL DISPLAY PANEL

The image shows a rectangular label for a lice treatment product. At the top, there are four tabs labeled "Peel". The central logo reads "PHYSICIAN PARTNER" with a tagline "A DIVISION OF BAXTER INTERNATIONAL CORP." Below the logo, the product name "Lice Treatment (Permethrin Lotion) 1%" is prominently displayed. To the right of the name is the NDC number "NDC 42254-065-60". The quantity and application instructions "2oz (60ml) Single Application" are listed below the name. A barcode is present on the right side with the number "SP006560" printed vertically. The text "Each Fluid Ounce contains: Permethrin 280mg (1%) Lice treatment" and "See box." are also included. On the left and right sides, there are vertical columns of text providing lot numbers, expiration dates, and AWP prices. At the bottom, a red banner contains distribution information, storage instructions, and a warning to keep medication out of children's reach.

PHYSICIAN PARTNER
A DIVISION OF BAXTER INTERNATIONAL CORP.

Lice Treatment (Permethrin Lotion) 1% NDC 42254-065-60

2oz (60ml) Single Application

Each Fluid Ounce contains: Permethrin 280mg (1%) Lice treatment

See box.

Product ID: SP006560

RX#Master Mfr. By: Actavis Mid Atlantic LLC 1877 Kawai Road Lincolnton, NC 28092 USA

Distributed by: Physician Partner, Thousand Oaks, CA 91320 www.physicianpartner.com
Store at controlled room temperature 15°-30°C (59°-86°F) Keep medication out of the reach of children.

LICE TREATMENT

permethrin lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42254-065(NDC:0472-5242)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PERMETHRIN (UNII: 509F88P9SZ) (PERMETHRIN - UNII:509F88P9SZ)	PERMETHRIN	1 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CANADA BALSAM (UNII: K304VI98I3)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

ISOPROPYL ALCOHOL (UNII: ND2M416302)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
CETETH-10 (UNII: LF9X1PN3XJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
STEARALKONIUM CHLORIDE (UNII: 0OUO26BB88)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42254-065-60	1 in 1 CARTON		
1		59 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075014	03/28/2010	

Labeler - Rebel Distributors Corp (118802834)

Establishment

Name	Address	ID/FEI	Business Operations
Rebel Distributors Corp		118802834	RELABEL, REPACK

Revised: 12/2011

Rebel Distributors Corp