

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**75014**

**DRAFT FINAL PRINTED LABELING**

FRONT

FORM 5242  
VC1587  
REV. 9/99

# Permethrin Lotion 1% Lice Treatment



# Permethrin Lotion 1% Lice Treatment

### DESCRIPTION

**EACH FLUID OUNCE CONTAINS:** Active Ingredient: Permethrin 280 mg (1%). Inactive Ingredients: Balsam fir canadensis, cetyl alcohol, citric acid, FD&C Yellow No. 6, fragrance, hydrolyzed animal protein, hydroxyethylcellulose, polyoxyethylene 10 cetyl ether, propylene glycol, stearylalkonium chloride, water, isopropyl alcohol 5.6 g (20%), methylparaben 56 mg (0.2%), and propylparaben 22 mg (0.08%).

Permethrin Lotion 1% kills lice and their unhatched eggs with usually only one application. Permethrin Lotion 1% protects against head lice reinfestation for 14 days. The creme rinse formula leaves hair manageable and easy to comb.

### INDICATIONS

For the treatment of head lice. For prophylactic use during head lice epidemics.

### WARNINGS

For external use only. Keep out of eyes when rinsing hair. Adults and children: Close eyes and do not open eyes until product is rinsed out. If product gets into the eyes, immediately flush with water. Do not use near the eyes or permit contact with mucous membranes, such as inside the nose, mouth, or vagina, as irritation may occur. Children: Also protect children's eyes with a washcloth, towel or other suitable material or method. This product should not be used on pediatric patients less than 2 months of age. Itching, redness, or swelling of the scalp may occur. If skin irritation persists or infection is present or develops, discontinue use and consult a doctor. Consult a doctor if infestation of eyebrows or eyelashes occurs. This product may cause breathing difficulty or an asthmatic episode in susceptible persons. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product. Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

### DOSAGE AND ADMINISTRATION TREATMENT

Permethrin Lotion 1% should be used after hair has been washed with patient's regular shampoo, rinsed with water and towel dried. A sufficient amount should be applied to saturate hair and scalp (especially behind the ears and on the nape of the neck). Leave on hair for 10 minutes but not longer. Rinse with water. A single application is usually sufficient. If live lice are observed seven days or more after the first application of this product, a second treatment should be given. For proper head lice management, remove nits with the nit comb provided.

Head lice live on the scalp and lay small white eggs (nits) on the hair shaft close to the scalp. The nits are most easily found on the nape of the neck or behind the ears. All personal headgear, scarfs, coats, and bed linen should be disinfected by machine washing in hot water and drying, using the hot cycle of a dryer for at least 20 minutes. Personal articles of clothing or bedding that cannot be washed may be dry-cleaned, sealed in a plastic bag for a period of about 2 weeks, or sprayed with a product specifically designed for this purpose. Personal combs and brushes may be disinfected by soaking in hot water (above 130°F) for 5 to 10 minutes. Thorough vacuuming of rooms inhabited by infected patients is recommended.

### PROPHYLAXIS

Prophylactic use of Permethrin Lotion 1% is only recommended for individuals exposed to head lice epidemics in which at least 20% of the population at an institution are infested and for immediate household members of infested individuals. Causal use is strongly discouraged.

The method of application of Permethrin Lotion 1% for prophylaxis is identical to that described above for treatment of a lice infestation except nit removal is not required.

### DIRECTIONS FOR USE

One application of Permethrin Lotion 1% has been shown to protect greater than 95% of patients against reinfestation for at least two weeks. In epidemic settings, a second prophylactic application is recommended two weeks after the first because the life cycle of a head louse is approximately four weeks.

### HOW SUPPLIED

Bottles of 2 fl. oz. (59 mL) with nit removal comb and Family Pack of 2 bottles, 2 fl. oz. (59 mL) each, with 2 nit removal combs.

Store at 15° to 25°C (59° to 77°F).

Manufactured by  
Alpharma USPD Inc.  
Baltimore, MD 21244

FORM NO. 5242

Rev. 9/99  
VC1587

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**Lice Treatment**

**Permethrin Lotion 1%**

ALPHARMA

**SHAKE WELL BEFORE USING**

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Manufactured by Alpharma USPD Inc., Baltimore, MD 21244

ALPHARMA NDC 0472-5242-67

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**Lice Treatment**

**With A Single Application:**

- Kills Lice & Their Eggs
- Prevents Reinfestation for 14 Days

**Creme Rinse With Nit Removal Comb**

2 FL OZ (59 mL)

Nit Removal Comb Included

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