

PERMETHRIN (Topical)

Category

Pediculicide 7, 9; Scabicide 11, 12.

Indications

Accepted

Pediculosis capitis (treatment)¼Permethrin 1% is indicated for the treatment of infestation caused by *Pediculus humanus var. capitis* (head louse) and its ova. 1, 8, 9

Scabies (treatment)¼Permethrin 5% is indicated for the treatment of scabies infestation caused by *Sarcoptes var. scabiei* (mites). 11, 12

Pharmacology/Pharmacokinetics

Physicochemical characteristics:

Source¼Permethrin is a mixture of the cis and trans isomers of a synthetic pyrethroid. 1 Permethrin is the first pyrethroid formulated for human use. 3

Molecular weight¼391.29 5

Mechanism of action/Effect:

Permethrin acts on the nerve cell membrane of the louse or mite to disrupt the sodium channel current that regulates the polarization of the membrane. This leads to delayed repolarization and subsequent paralysis of the louse or mite. 1, 11, 12

Other actions/effects:

Pharmacologically active against lice, ticks, mites, and fleas. 1

Absorption:

Absorption studies indicate that 2% or less of the amount applied is absorbed systemically. 1, 11, 12

Permethrin is detectable in residual amounts on the hair for at least 10 days following a treatment. 1

Biotransformation:

Rapidly metabolized by ester hydrolysis to inactive metabolites. 1

Duration of action:

14 days. 2

Elimination:

Primarily in the urine. 1

Precautions to Consider

Cross-sensitivity and/or related problems

Patients sensitive to veterinary insecticides containing permethrin will be sensitive to permethrin cream or lotion. In addition, patients sensitive to other synthetic pyrethroids, such as those found in household insecticides, 6 or sensitive to pyrethrins or chrysanthemums may be sensitive to this medication also. 1, 4

Carcinogenicity/Tumorigenicity

Carcinogenicity bioassays with permethrin were evaluated using 3 rat studies and 3 mice studies. In the 3 mice studies, there were increases in pulmonary adenomas. In addition, in the females in one of the mice studies, there was increased incidence of pulmonary alveolar-cell carcinomas and benign

liver adenomas when the mice were given permethrin at 5000 ppm in their food. No tumorigenicity was evident in the rat studies. 1, 11, 12

Mutagenicity

Permethrin showed no evidence of mutagenic potential in a battery of in vitro and in vivo genetic toxicity studies in rodents. 1, 11, 12

Pregnancy/Reproduction

Fertility In a 3-generation rat study, permethrin did not have any adverse effect on reproductive function at an oral dose of 180 mg per kg of body weight (mg/kg) per day. In addition, reproductive studies performed in mice, rats, and rabbits given oral doses of 200 to 400 mg of permethrin per kg of body weight per day revealed no evidence of impaired fertility. 1

Pregnancy There are no adequate and well-controlled studies in pregnant women.

Reproductive studies performed in mice, rats, and rabbits given oral doses of 200 to 400 mg of permethrin per kg of body weight per day revealed no evidence of harm to the fetus.

FDA Pregnancy Category B. 1, 11, 12

Breast-feeding

Problems in humans have not been documented. Although it is not known whether permethrin is distributed into human milk, permethrin has been shown to have tumorigenic potential in some animal studies. 1

Pediatrics

Appropriate studies on the relationship of age to the effects of permethrin have not been performed in the pediatric population. However, no pediatrics-specific problems have been documented to date.

Geriatrics

Appropriate studies on the relationship of age to the effects of permethrin have not been performed in the geriatric population. However, no geriatrics-specific problems have been documented to date.

Medical considerations/Contraindications

The medical considerations/contraindications included have been selected on the basis of their potential clinical significance (reasons given in parentheses where appropriate)^{3/4} not necessarily inclusive (>> = major clinical significance).

Risk-benefit should be considered when the following medical problems exist

Inflammation of the scalp, acute

(condition may be exacerbated) 6

Sensitivity to permethrin

Side/Adverse Effects

The following side/adverse effects have been selected on the basis of their potential clinical significance (possible signs and symptoms in parentheses where appropriate)^{3/4}not necessarily inclusive:

Those indicating need for medical attention only if they continue or are bothersome

Incidence less frequent or rare

Burning, itching, numbness, rash, redness, stinging, swelling, or tingling of the scalp

Note: Itching, redness, and swelling often accompany lice infestations; the use of permethrin may temporarily increase this discomfort. 1, 9

Patient Consultation

As an aid to patient consultation, refer to .Advice for the Patient, Permethrin (Topical).

In providing consultation, consider emphasizing the following selected information (>> = major clinical significance):

Before using this medication

>> Conditions affecting use, especially:

Sensitivity to permethrin; to other synthetic pyrethroids, such as those found in household insecticides; to pyrethrins or chrysanthemums; or to veterinary insecticides containing permethrin

Breast-feeding³/4Animal studies have shown that permethrin can cause tumors

Proper use of this medication

>> Avoiding contact with the eyes; flushing eyes thoroughly with water if medication accidentally gets in eyes

Container usually holds one treatment; using as much as needed and disposing of the remainder

Proper administration

For lice (1% permethrin)

Shampooing the hair and scalp first using regular shampoo

Thoroughly rinsing and towel drying hair and scalp

Shaking lotion well before applying

Thoroughly wetting hair and scalp with lotion; covering the areas behind the ears and on the nape of the neck also; allowing lotion to remain in place for 10 minutes

Rinsing hair and scalp thoroughly and drying with clean towel

If desired, using fine-toothed comb to remove dead lice and eggs

For scabies (5% permethrin)

Reading package directions carefully before using

Massaging cream into the skin from the head to the toes, including the soles of feet

Leaving permethrin on skin for 8 to 14 hours

Removing cream by washing thoroughly (shower or bath)

11, 12

>> Importance of having household members examined for infestation and treated if infested

>> Proper dosing

>> Proper storage

Precautions while using this medication

Using hygienic measures to control reinfestation or spread of infestation:¾Machine washing all clothing (including hats, scarves, and coats), bedding, towels, and washcloths in very hot water and drying them by using hot cycle of dryer for at least 20 minutes; for clothing or bedding that are not washable, dry cleaning or sealing in an airtight plastic bag for 2 weeks

Shampooing all wigs and hairpieces

Washing hairbrushes and combs in very hot soapy water (at least 130 °F) for 5 to 10 minutes; not sharing them with other people

Cleaning house or room by thoroughly vacuuming upholstered furniture, rugs, and floors

Washing all toys in very hot soapy water (at least 130 °F) for 5 to 10 minutes or sealing in an airtight plastic bag for 2 weeks; especially important for stuffed toys used on the bed 9

General Dosing Information

For pediculosis

Permethrin is used as a single-application treatment. Less than 1% of patients will require an additional treatment. If live lice are observed after 7 or more days following initial treatment, a second treatment may be administered. 1

Shampoo, rinse, and dry hair and scalp before application of permethrin. 1

The lotion should be worked into dry hair until the hair and scalp are thoroughly wet. The lotion should be allowed to remain in place for 10 minutes. Then the hair and scalp should be rinsed thoroughly and dried with a clean towel. 1

Although not necessary for the success of the treatment, when the hair is dry after the treatment, the patient may use a fine-toothed comb to remove any remaining nits or nit shells. 1

After treatment, a residual amount of permethrin remains on the hair providing protection against reinfestation for approximately 2 weeks. This protection is unaffected by regular shampooing. 2

For scabies

Scabies rarely infests the scalp of adults, although the hairline, neck, temple, and forehead may be infested in geriatric patients and in infants. Infants should be treated on the scalp, temple, and forehead. The cream should be massaged into the skin from the head to the soles of the feet. Usually 30 grams is sufficient for an average adult. The medication should be left on for 8 to 14 hours, then removed by thorough washing (shower or bath). 11, 12

Persistent pruritus may be experienced after treatment. This is rarely a sign of treatment failure and is not an indication for re-treatment. Demonstrable living mites after 14 days indicate that re-treatment is necessary. 11, 12

Topical Dosage Forms

PERMETHRIN LOTION

Usual adult and adolescent dose

Pediculosis capitis^{3/4}

Topical, to the hair and scalp, for one application. 1, 9

Usual pediatric dose

Pediculosis capitis^{3/4}

Children up to 2 years of age: Dosage has not been established. 1, 9

Children 2 years of age and older: See Usual adult and adolescent dose. 1, 9

Strength(s) usually available

U.S.^{3/4}1% (OTC)[Nix Cream Rinse (isopropyl alcohol 20%)] 9, 10

Canada^{3/4}1% (OTC)[Nix Cream Rinse (isopropyl alcohol 20%)] 8

Packaging and storage:

Store between 15 and 25 °C (59 and 77 °F), unless otherwise specified by manufacturer. 1, 9, 11, 12
Protect from freezing.

Auxiliary labeling:

- Shake well. 1, 9
- For external use only. 9

PERMETHRIN CREAM

Usual adult and adolescent dose

Sarcoptes scabiei^{3/4}

Topical, to the skin as a 5% cream, for one application. 11, 12

Usual pediatric dose

Sarcoptes scabiei ¼

Children up to 2 months of age: Dosage has not been established. 11, 12

Children 2 months of age and older: See Usual adult and adolescent dose. 11, 12

Strength(s) usually available

U.S. ¼ 5% (Rx)[Acticin Cream] 11

5% (Rx)[Elimite Cream] 12

Packaging and storage:

Store between 15 and 25 °C (59 and 77 °F), unless otherwise specified by manufacturer. 11, 12
Protect from freezing.

Auxiliary labeling:

- For external use only. 9