



# ALBENDAZOLE (Systemic)†

Some commonly used brand names are:

In the U.S.—

- Albenza

† Not commercially available in Canada.

## Category

- Anthelmintic, systemic

## Description

Albendazole (al-BEN-da-zole) is used to treat infections caused by worms. Albendazole works by keeping the worm from absorbing sugar (glucose), so that the worm loses energy and dies.

Albendazole is used to treat:

- Hydatid disease (echinococcosis);
- Infection of the nervous system caused by pork tapeworms (neurocysticercosis).

Albendazole is available only with your doctor's prescription, in the following dosage forms:

- Oral*
- Tablets (U.S.)

## Before Using This Medicine

In deciding to use a medicine, the risks of taking the medicine must be weighed against the good it will do. This is a decision you and your doctor will make. For albendazole, the following should be considered:

**Allergies**—Tell your doctor if you have ever had any unusual or allergic reaction to albendazole. Also tell your health care professional if you are allergic to any other substances, such as foods, preservatives, or dyes.

**Pregnancy**—Albendazole has not been studied in pregnant women. However, studies in animals have shown that albendazole can cause birth defects or other problems. Before taking this medicine, make sure your doctor knows if you are pregnant or if you may become pregnant. Women of childbearing age should take the medicine within 7 days after the start of their period (menstrual cycle). After a negative pregnancy test, birth control must be used during treatment and for 1 month after stopping treatment with albendazole.

**Breast-feeding**—Albendazole passes into animal milk. It is not known whether albendazole passes into human breast milk. Although most medicines pass into breast milk in small amounts, many of them may be used safely while breast-feeding. Mothers who are taking this medicine and who wish to breast-feed should discuss this with their doctor.

**Children**—Although there is very little specific information comparing use of albendazole in children with use in other age groups, this medicine is not expected to cause different side effects or problems in children than it does in adults.

**Older adults**—Many medicines have not been studied specifically in older people. Therefore, it may not be known whether

they work exactly the same way they do in younger adults or if they cause different side effects or problems in older people. There is no specific information comparing use of albendazole in the elderly with use in other age groups.

**Other medicines**—Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, your doctor may want to change the dose, or other precautions may be necessary. When you are taking albendazole, it is especially important that your health care professional know if you are taking any of the following:

- Cimetidine (e.g., Tagamet, Tagamet HB) or
- Corticosteroids (cortisone-like medicines) or
- Praziquantel (e.g., Biltricide)—Use of these medicines with albendazole has been shown to increase the effects of albendazole

**Other medical problems**—The presence of other medical problems may affect the use of albendazole. Make sure you tell your doctor if you have any other medical problems, especially:

- Cysticercosis involving the eye—Patients who are being treated with albendazole for pork tapeworms of the nervous system (neurocysticercosis) should be examined for lesions in the eye; use of albendazole may increase the chance of side effects involving the eye
- Liver disease—Patients with liver disease may have an increased chance of side effects

## Proper Use of This Medicine

No special preparations (fasting, laxatives, or enemas) or other steps are necessary before, during, or immediately after treatment with albendazole.

Albendazole is best *taken with meals, especially with food containing fat*, to help your body absorb the medicine better.

For patients taking the *tablet form* of albendazole:

- Tablets should be swallowed whole with a small amount of liquid.

To help clear up your infection completely, *take this medicine exactly as directed by your doctor for the full time of treatment*. In some infections, additional treatments with this medicine may be needed at 2-week intervals to clear up the infection completely. *Do not miss any doses*.

**Dosing**—The dose of albendazole will be different for different patients. *Follow your doctor's orders or the directions on the label*. The following information includes only the average doses of albendazole. *If your dose is different, do not change it unless your doctor tells you to do so.*

*The number of doses you take each day, the time allowed between doses, and the length of time you take the medicine depend on the medical problem for which you are taking albendazole.*

- For *oral dosage form (tablets)*:
  - For hydatid disease:
    - Adults, teenagers, and children weighing 60 kilograms (132 pounds) and over—400 milligrams (mg) two times a day for twenty-eight days. Treatment may need to be repeated in fourteen days.
    - Adults, teenagers, and children weighing less than 60 kilograms (132 pounds)—15 mg per kilogram (6.8 milligrams per pound) of body weight per day divided into two doses and taken for twenty-eight days. Treatment may need to be repeated in fourteen days.
  - For infections of the nervous system caused by pork tapeworm (neurocysticercosis):
    - Adults, teenagers, and children weighing 60 kilograms (132 pounds) and over—400 milligrams (mg) two times a day for eight to thirty days.
    - For adults, teenagers, and children weighing less than 60 kilograms (132 pounds)—15 mg per kilogram (6.8 mg per pound) of body weight per day divided into two doses and taken for eight to thirty days.

**Missed dose**—If you miss a dose of this medicine, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

**Storage**—To store this medicine:

- Keep out of the reach of children.
- Store away from heat and direct light.
- Do not store in the bathroom, near the kitchen sink, or in other damp places. Heat or moisture may cause the medicine to break down.
- Keep the suspension form of this medicine from freezing.
- Do not keep outdated medicine or medicine no longer needed. Be sure that any discarded medicine is out of the reach of children.

## Precautions While Using This Medicine

It is important that your doctor check your progress after treatment. This is to make sure that the infection is cleared up completely, and to allow your doctor to check for any unwanted effects.

If your symptoms do not improve after you have taken this medicine for the full course of treatment, or if they become worse, check with your doctor.

For women of childbearing age, it is important that you use birth control while taking albendazole since this medicine can cause birth defects or other problems.

## Side Effects of This Medicine

Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor as soon as possible if any of the following side effects occur:

### *Rare*

Fever; skin rash or itching; sore throat; unusual tiredness and weakness

Other side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. However, check with your doctor if any of the following side effects continue or are bothersome:

### *Less common*

Abdominal pain; diarrhea; dizziness; headache; nausea; vomiting

### *Rare*

Thinning or loss of hair

Other side effects not listed above may also occur in some patients. If you notice any other effects, check with your doctor.

## Additional Information

Once a medicine has been approved for marketing for a certain use, experience may show that it is also useful for other medical problems. Although these uses are not included in product labeling in the U.S., albendazole is used in certain patients with the following infections:

- Capillariasis;
- Cutaneous larva migrans;
- Common roundworms (ascariasis);
- Hookworms (ancylostomiasis and necatoriasis);
- Pinworms (enterobiasis or oxyuriasis);
- Strongyloidiasis;
- Tapeworms (taeniasis);
- Trichostrongyliasis;

- Whipworms (trichuriasis).

For patients taking albendazole for *hookworms* :

- In hookworm infections, anemia may occur. Therefore, your doctor may want you to take iron supplements. If so, it is important to take iron every day while you are being treated for hookworm infection. Do not miss any doses. Your doctor may also want you to keep taking iron supplements for at least 3 to 6 months after you stop taking albendazole. If you have any questions about this, check with your doctor.

For patients taking albendazole for *pinworms* :

- In some patients, pinworms may return after treatment with albendazole. Wear pajamas and underwear to sleep, take a bath every day, and wash (not shake) all bedding and nightclothes (pajamas) after treatment to help prevent reinfection. Treatment may be repeated after 3 weeks.
- Pinworms may be easily passed from one person to another, especially among persons in the same household. Therefore, all household members may have to be treated at the same time to prevent their infection or reinfection.

Other than the above information, there is no additional information relating to proper use, precautions, or side effects for these uses.

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# PIPERAZINE (Systemic)

Some commonly used brand names are:

## In Canada—

- Entacyl

Generic name product may be available in the U.S.

## Category

- Anthelmintic, systemic

## Description

Piperazine (PI-per-a-zeen) belongs to the family of medicines called anthelmintics (ant-hel-MIN-tiks) . Anthelmintics are used in the treatment of worm infections.

Piperazine is used to treat:

- common roundworms (ascariasis) and
- pinworms (enterobiasis; oxyuriasis).

Piperazine works by paralyzing the worms. They are then passed in the stool.

Piperazine is available only with your doctor's prescription, in the following dosage forms:

### *Oral*

- Granules for oral solution (Canada)
- Oral suspension (Canada)
- Tablets (U.S.)

## Before Using This Medicine

In deciding to use a medicine, the risks of taking the medicine must be weighed against the good it will do. This is a decision you and your doctor will make. For piperazine, the following should be considered:

**Allergies**—Tell your doctor if you have ever had any unusual or allergic reaction to piperazine or ethylenediamine. Also tell your health care professional if you are allergic to any other substances, such as foods, preservatives, or dyes.

**Pregnancy**—Piperazine has not been studied in pregnant women. Piperazine has not been shown to cause birth defects or other problems in animal studies. However, piperazine, taken by mouth, may be changed within the body into a substance that may cause cancer. Before taking piperazine, make sure your doctor knows if you are pregnant or if you may become pregnant.

**Breast-feeding**—It is not known whether piperazine passes into breast milk. Although most medicines pass into breast milk in small amounts, many of them may be used safely while breast-feeding. Mothers who are taking this medicine and who wish to breast-feed should discuss this with their doctor.

**Children**—Children may be especially sensitive to the effects of piperazine. This may increase the chance of side effects

during treatment.

**Older adults**—Many medicines have not been studied specifically in older people. Therefore, it may not be known whether they work exactly the same way they do in younger adults or if they cause different side effects or problems in older people. There is no specific information comparing use of piperazine in the elderly with use in other age groups.

**Other medicines**—Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, your doctor may want to change the dose, or other precautions may be necessary. When you are taking piperazine, it is especially important that your health care professional know if you are taking any of the following:

- Phenothiazines (acetophenazine [e.g., Tindal], chlorpromazine [e.g., Thorazine], fluphenazine [e.g., Prolixin], mesoridazine [e.g., Serentil], perphenazine [e.g., Trilafon], prochlorperazine [e.g., Compazine], promazine [e.g., Sparine], promethazine [e.g., Phenergan], thioridazine [e.g., Mellaril], trifluoperazine [e.g., Stelazine], triflupromazine [e.g., Vesprin], trimeprazine [e.g., Temaril])—Taking piperazine and a phenothiazine together may increase the risk of convulsions (seizures)
- Pyrantel (e.g., Antiminth)—Taking piperazine and pyrantel together may decrease the effects of piperazine

**Other medical problems**—The presence of other medical problems may affect the use of piperazine. Make sure you tell your doctor if you have any other medical problems, especially:

- Kidney disease or
- Liver disease—Patients with kidney or liver disease may have an increased chance of side effects
- Seizure disorder, especially a history of epilepsy—Piperazine may make the condition worse

## Proper Use of This Medicine

No special preparations or other steps (for example, special diet, fasting, other medicines, laxatives, or enemas) are necessary before, during, or immediately after you take piperazine.

Piperazine may be taken with or without food or on a full or empty stomach. However, if your doctor tells you to take the medicine a certain way, take it exactly as directed.

For patients taking the *granules for oral solution form* of piperazine:

- Dissolve the contents of 1 packet of granules in 57 mL (about 2 ounces) of water, milk, or fruit juice.
- Be sure to drink all of the liquid to get the full dose of medicine.

*Take this medicine only as directed* . Do not take more of it and do not take it more often than your doctor ordered. To do so may increase the chance of serious side effects.

To help clear up your infection completely, *take this medicine in regularly spaced doses as ordered by your doctor* . In some infections, a second treatment with this medicine may be required to clear up the infection completely. *Do not miss any doses* .

For patients taking piperazine for *pinworms* :

- Pinworms may be easily passed from one person to another, especially among persons in the same household. Therefore, all household members may have to be treated at the same time to prevent their infection or reinfection.

**Dosing**—The dose of piperazine will be different for different patients. *Follow your doctor's orders or the directions on the label* . The following information includes only the average doses of piperazine. *If your dose is different, do not change it unless your doctor tells you to do so.*

The number of tablets or teaspoonfuls of solution or suspension of the medicine that you take depends on the strength of the medicine. Also, *the number of doses you take each day, the time allowed between doses, and the length of time you take the medicine depend on the medical problem for which you are taking piperazine* .

- For *granules for oral solution* dosage form:
  - For common roundworms or pinworms:
    - Adults and teenagers—2 grams three times a day for one day. Treatment may need to be repeated in two weeks.
    - Children—Dose is based on age and/or body weight. Treatment may need to be repeated in two weeks.
      - Up to 2 years of age: Dose must be determined by your doctor.
      - 2 to 8 years of age: 2 grams once a day for one day.
      - 8 to 14 years of age: 2 grams two times a day for one day.
- For *oral suspension* dosage form:
  - For common roundworms or pinworms:
    - Adults and teenagers—1.8 grams every four hours for a total of three doses in one day. Treatment may need to be repeated in two weeks.
    - Children—Dose is based on age. Treatment may need to be repeated in two weeks.
      - Up to 2 years of age: 600 milligrams (mg) every four hours for a total of three doses in one day.
      - 2 to 8 years of age: 1.2 grams every six hours for a total of two doses in one day.
      - 8 to 14 years of age: 1.2 grams every four hours for a total of three doses in one day.
- For *tablet* dosage form:
  - For common roundworms:
    - Adults and teenagers—3.5 grams (piperazine hexahydrate) per day for two days in a row. Treatment may need to be repeated in one week.
    - Children—Dose is based on body weight and must be determined by your doctor. However, the usual dose is 75 mg (piperazine hexahydrate) per kilogram (34 mg per pound) of body weight per day for two days in a row. Treatment may need to be repeated in one week.
  - For pinworms:
    - Adults and children—Dose is based on body weight and must be determined by your doctor. However, the usual dose is 65 mg (piperazine hexahydrate) per kilogram (29.5 mg per pound) of body weight per day for seven days in a row. Treatment may need to be repeated in one week.

**Missed dose**—If you miss a dose of this medicine, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

**Storage**—To store this medicine:

- Keep out of the reach of children. Overdose of piperazine is very dangerous in young children.
- Store away from heat and direct light.
- Do not store in the bathroom, near the kitchen sink, or in other damp places. Heat or moisture may cause the medicine to break down.
- Keep the liquid form of this medicine from freezing.
- Do not keep outdated medicine or medicine no longer needed. Be sure that any discarded medicine is out of the reach of children.

## Precautions While Using This Medicine

It is important that your doctor check your progress after treatment. This is to make sure that the infection is cleared up completely, and to allow your doctor to check for any unwanted effects.

If your symptoms do not improve after you have taken this medicine for the full course of treatment, or if they become worse, check with your doctor.

For patients taking piperazine for *pinworms* :

- In some patients, pinworms may return after treatment with piperazine. Washing (not shaking) all bedding and nightclothes (pajamas) after treatment may help to prevent this.

## Side Effects of This Medicine

Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor immediately if any of the following side effects occur:

Rare

Blurring of vision; clumsiness; crawling or tingling feeling of the skin; fever; irregular, twisting movement, especially of the face, arms, and legs; joint pain; skin rash or itching

Other side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. However, check with your doctor if any of the following side effects continue or are bothersome:

*Less common*

Abdominal or stomach cramps or pain; diarrhea; dizziness; drowsiness; headache; muscle weakness; nausea or vomiting; tremors

Other side effects not listed above may also occur in some patients. If you notice any other effects, check with your doctor.

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# Permethrin Lotion

**Generic Name:** Permethrin Lotion (per-METH-rin)

**Brand Name:** Generic only. No brands available.

## Permethrin Lotion is used for:

Treating head lice or preventing head lice during an outbreak. It may also be used for other conditions as determined by your doctor.

Permethrin Lotion is a pediculocide. It works by killing lice and their eggs.

## Do NOT use Permethrin Lotion if:

- you are allergic to any ingredient in Permethrin Lotion

Contact your doctor or health care provider right away if any of these apply to you.

## Before using Permethrin Lotion:

Some medical conditions may interact with Permethrin Lotion. Tell your doctor or pharmacist if you have any medical conditions, especially if any of the following apply to you:

- if you are pregnant, planning to become pregnant, or are breast-feeding
- if you are taking any prescription or nonprescription medicine, herbal preparation, or dietary supplement
- if you have allergies to medicines, foods, or other substances
- if you have irritation or an infection of the skin in the area to be treated with Permethrin Lotion
- if you have asthma or other breathing problems

Some MEDICINES MAY INTERACT with Permethrin Lotion. Because little, if any, of Permethrin Lotion is absorbed into the blood, the risk of it interacting with another medicine is low.

Ask your health care provider if Permethrin Lotion may interact with other medicines that you take. Check with your health care provider before you start, stop, or change the dose of any medicine.

## How to use Permethrin Lotion:

Use Permethrin Lotion as directed by your doctor. Check the label on the medicine for exact dosing instructions.

- Before using, wash hair with regular shampoo and towel dry.
- Permethrin Lotion is for external use only. Do not get Permethrin Lotion in the eyes. Keep eyes closed until Permethrin Lotion is rinsed out of the hair. If using Permethrin Lotion on a child, cover the eyes with a washcloth or towel.
- Apply enough of Permethrin Lotion to saturate hair and scalp, especially behind the ears and on the nape of the neck. Leave on hair for 10 minutes, but no longer. Rinse with water.
- If live lice are observed after 7 days or more after the first application, treat hair and scalp a second time.
- Head lice live on the scalp and lay small white eggs (nits) on the hair close to the scalp. For proper head lice management, remove eggs with the comb provided.
- All personal headgear, scarves, coats, and bed linen should be disinfected by machine washing in hot water and drying. Use the hot cycle of a dryer for at least 20 minutes.
- Personal articles of clothing or bedding that cannot be washed or dried by machine 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 degrees F (54 degrees C) for 5 to 10 minutes.
  - Thoroughly vacuum rooms, including furniture, of individuals infected with lice.
  - If you miss a dose of Permethrin Lotion, use it as soon as you remember. Continue to use it as directed by your doctor.

Ask your health care provider any questions you may have about how to use Permethrin Lotion.

## Important safety information:

- Permethrin Lotion is for external use only. Do not use it near the eyes or allow it to come into contact with the inside of the nose, mouth, or genitals. Irritation may occur if Permethrin Lotion comes into contact with these areas. If Permethrin Lotion gets in your eyes, flush with water immediately.
- If you have lice in the eyebrows or eyelashes, check with your doctor before using Permethrin Lotion.
- Permethrin Lotion should not be used in CHILDREN younger than 2 months old; safety and effectiveness in these children have not been confirmed.
- PREGNANCY and BREAST-FEEDING: If you become pregnant, contact your doctor. You will need to discuss the benefits and risks of using Permethrin Lotion while you are pregnant. It is not known if Permethrin Lotion is found in breast milk after topical use. If you are or will be breast-feeding while you use Permethrin Lotion, check with your doctor. Discuss any possible risks to your baby.

## Possible side effects of Permethrin Lotion:

All medicines may cause side effects, but many people have no, or minor, side effects. Check with your doctor if any of these most COMMON side effects persist or become bothersome:

Itching; mild burning or stinging; redness; swelling.

Seek medical attention right away if any of these SEVERE side effects occur:

Severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue); shortness of breath; skin irritation.

This is not a complete list of all side effects that may occur. If you have questions or need medical advice about side effects, contact your doctor or health care provider. You may report side effects to the FDA at 1-800-FDA-1088 (1-800-332-1088) or at <http://www.fda.gov/medwatch>.

## If OVERDOSE is suspected:

Contact 1-800-222-1222 (the American Association of Poison Control Centers), your local poison control center (<http://www.aapcc.org/findyour.htm>), or emergency room immediately. Permethrin Lotion may be harmful if swallowed. Symptoms may include dizziness; headache; loss of appetite; loss of consciousness; seizures; vomiting; weakness.

### Proper storage of Permethrin Lotion:

Store Permethrin Lotion at room temperature, between 59 and 77 degrees F (15 and 25 degrees C). Store away from heat, light, and moisture. Keep Permethrin Lotion out of the reach of children and away from pets.

## General information:

- If you have any questions about Permethrin Lotion, please talk with your doctor, pharmacist, or other health care provider.
- Permethrin Lotion is to be used only by the patient for whom it is prescribed. Do not share it with other people.
- If your symptoms do not improve or if they become worse, check with your doctor.

This information is a summary only. It does not contain all information about Permethrin Lotion. If you have questions about the medicine you are taking or would like more information, check with your doctor, pharmacist, or other health care provider.

# Permethrin

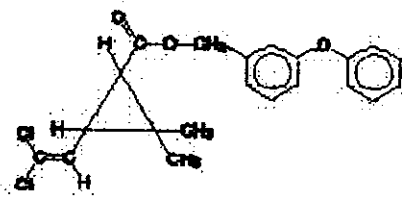
Dosage Form: Cream

## Permethrin Description

Permethrin Cream 5% is a topical scabicide agent for the treatment of infestation with *Sarcoptes scabiei* (scabies). It is available in a white to off-white, vanishing cream base.

Permethrin cream is for topical use only.

Structural Formula:



**Chemical Name:** The Permethrin used is an approximate 1:3 mixture of the cis and trans isomers of the pyrethroid 3-(2,2-dichloroethyl)- 2,2-dimethylcyclopropanecarboxylic acid, (3-phenoxyphenyl) methyl ester. Permethrin has a molecular formula of C<sub>21</sub>H<sub>20</sub>Cl<sub>2</sub>O<sub>3</sub> and a molecular weight of 391.29. It is a yellow to light orange-brown, low melting solid or viscous liquid.

Each gram contains Permethrin 50 mg (5%) and the inactive ingredients butylated hydroxytoluene, carbomer 934P, coconut oil, glycerin, glyceryl stearate, isopropyl myristate, lanolin alcohols, light mineral oil, polyoxyethylene cetyl ethers, purified water, and sodium hydroxide. Formaldehyde 1 mg (0.1%) is added as a preservative.

## Permethrin - Clinical Pharmacology

Permethrin, a pyrethroid, is active against a broad range of pests including lice, ticks, fleas, mites, and other arthropods. It acts on the nerve cell membrane to disrupt the sodium channel current by which the polarization of the membrane is regulated. Delayed repolarization and paralysis of the pests are the consequences of this disturbance.

Permethrin is rapidly metabolized by ester hydrolysis to inactive metabolites which are excreted primarily in the urine. Although the amount of Permethrin absorbed after a single application of the 5% cream has not been determined precisely, data from studies with <sup>14</sup>C-labeled Permethrin and absorption studies of the cream applied to patients with moderate to severe scabies indicate it is 2% or less of the amount applied.

## Indications and Usage for Permethrin

Permethrin cream is indicated for the treatment of infestation with *Sarcoptes scabiei* (scabies).

## Contraindications

Permethrin cream is contraindicated in patients with known hypersensitivity to any of its components, to any synthetic pyrethroid or pyrethrin.

## Warnings

If hypersensitivity to Permethrin cream occurs, discontinue use.

## Precautions

### General

Scabies infestation is often accompanied by pruritis, edema and erythema. Treatment with Permethrin cream may temporarily exacerbate these conditions.

### Information for Patients

Patients with scabies should be advised that itching, mild burning and/or stinging may occur after application of Permethrin cream. In clinical trials, approximately 75% of patients treated with Permethrin cream who continued to manifest pruritis at 2 weeks had cessation by 4 weeks. If irritation persists, they should consult their physician. Permethrin cream may be very mildly irritating to the eyes. Patients should be advised to avoid contact with eyes during application and to flush with water immediately if Permethrin cream gets in the eyes.

### Carcinogenesis, Mutagenesis, Impairment of Fertility

Six carcinogenicity bioassays were evaluated with Permethrin, three each in rats and mice. No tumorigenicity was seen in the rat studies. However, species-specific increases in pulmonary adenomas, a common benign tumor of mice of high spontaneous background incidence, were seen in the three mouse studies. In one of these studies there was an increased incidence of pulmonary alveolar-cell carcinomas and benign liver adenomas only in female mice when Permethrin was given in their food at a concentration of 5000 ppm. Mutagenicity assays, which give useful correlative data for interpreting results from carcinogenicity bioassays in rodents, were negative. Permethrin showed no evidence of mutagenic potential in a battery of in vitro and in vivo genetic toxicity studies.

Permethrin did not have any adverse effect on reproductive function at a dose of 180 mg/kg/day orally in a three-generation rat study.

### Pregnancy

#### Teratogenic Effects

Pregnancy category B: Reproduction studies have been performed in mice, rats, and rabbits (200 to 400 mg/kg/day orally) and have revealed no evidence of impaired fertility or harm to the fetus due to Permethrin. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

### Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the evidence for tumorigenic potential of Permethrin in animal studies, consideration should be given to discontinuing nursing temporarily or withholding the drug while the mother is nursing.

### Pediatric Use

Permethrin cream is safe and effective in pediatric patients two months of age and older. Safety and effectiveness in pediatric patients less than two months of age have not been established.

### Geriatric Use

Clinical studies of Permethrin cream did not identify sufficient numbers of subjects aged 65 and over to allow a definitive statement regarding whether elderly subjects respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. This drug is known to be substantially excreted by the kidney. However, since topical Permethrin is metabolized in the liver and excreted in the urine as inactive metabolites, there does not appear to be an increased risk of toxic reactions in patients with impaired renal function when used as labeled.

## Adverse Reactions

In clinical trials, generally mild and transient burning and stinging followed application with Permethrin cream in 10% of patients and was associated with the severity of infestation. Pruritis was reported in 7% of patients at various times post-application. Erythema, numbness, tingling, and rash were reported in 1 to 2% or less of patients (see PRECAUTIONS: General).

## Overdosage

No instance of accidental ingestion of Permethrin cream has been reported. If ingested, gastric lavage and general supportive measures should be employed.

## Permethrin Dosage and Administration

Adults and children: Thoroughly massage Permethrin cream into the skin from the head to the soles of the feet. Scabies rarely infests the scalp of adults, although the hairline, neck, temple, and forehead may be infested in infants and geriatric patients. Usually 30 grams is sufficient for an average adult. The cream should be removed by washing (shower or bath) after 8 to 14 hours. Infants should be treated on the scalp, temple and forehead. ONE APPLICATION IS GENERALLY CURATIVE.

Patients may experience persistent pruritus after treatment. This is rarely a sign of treatment failure and is not an indication for retreatment. Demonstrable living mites after 14 days indicate that retreatment is necessary.

## How is Permethrin Supplied

Permethrin Cream 5% (wt./wt.) is supplied in 60 g tubes.

Store at room temperature 15°-25°C (59°-77°F).

Manufactured by  
Actavis Mid Atlantic LLC  
1877 Kawai Road  
Lincolnton, NC 28092 USA

FORM NO. 0242  
Rev. 8/06  
VC2882

Permethrin (Permethrin)

### PRODUCT INFO

Product Code	0472-0242	Dosage Form	CREAM
Route Of Administration	TOPICAL	DEA Schedule	

### INGREDIENTS

Name (Active Moiety)	Type	Strength
Permethrin (Permethrin)	Active	50 MILLIGRAM In 1 GRAM
butylated hydroxytoluene	Inactive	

<b>carbomer934p</b>	Inactive
<b>coconut oil</b>	Inactive
<b>glycerin</b>	Inactive
<b>glyceryl stearate</b>	Inactive
<b>isopropyl myristate</b>	Inactive
<b>lanolin alcohols</b>	Inactive
<b>light mineral oil</b>	Inactive
<b>polyoxyethylene cetyl ethers</b>	Inactive
<b>water</b>	Inactive
<b>sodium hydroxide</b>	Inactive

**IMPRINT INFORMATION**

<b>Characteristic Appearance</b>	<b>Characteristic</b>	<b>Appearance</b>
Color	Score	
Shape	Symbol	
Imprint Code	Coating	
Size		

**PACKAGING**

<b># NDC</b>	<b>Package Description</b>	<b>Multilevel Packaging</b>
1 0472-0242-60	60 GRAM In 1 CARTON	None

Revised: 03/2007