

#### **Drugs and Supplements**

# Mebendazole (Oral Route)

## **Description and Brand Names**

Drug information provided by: IBM Micromedex

#### **US Brand Name**

## **Vermox Descriptions**

Mebendazole is used to treat:

- Common roundworms (ascariasis).
- Hookworms (ancylostomiasis, necatoriasis, uncinariasis).
- Pinworms (enterobiasis, oxyuriasis).
- Whipworms (trichuriasis).

Mebendazole is used to treat infections caused by worms. It works by keeping the worm from absorbing sugar (glucose), so that the worm loses energy and dies.

This medicine is available only with your doctor's prescription.

This product is available in the following dosage forms:

Tablet, Chewable

## **Before Using**

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 this medicine, the following should be considered:

## **Allergies**

Tell your doctor if you have ever had any unusual or allergic reaction to this medicine or any

other medicines. Also tell your health care professional if you have any other types of allergies, such as to foods, dyes, preservatives, or animals. For non-prescription products, read the label or package ingredients carefully.

#### **Pediatric**

Appropriate studies performed to date have not demonstrated pediatric-specific problems that would limit the usefulness of Vermox<sup>™</sup> Chewable tablets in children. However, safety and efficacy have not been established in children younger than 1 year of age.

Appropriate studies have not been performed on the relationship of age to the effects of Emverm<sup>™</sup> chewable tablets in children younger than 2 years of age. Safety and efficacy have not been established.

#### **Geriatric**

No information is available on the relationship of age to the effects of mebendazole in geriatric patients.

## **Pregnancy**

	Pregnancy Category	Explanation
All Trimesters	С	Animal studies have shown an adverse effect and there are no adequate studies in pregnant women OR no animal studies have been conducted and there are no adequate studies in pregnant women.

## **Breastfeeding**

There are no adequate studies in women for determining infant risk when using this medication during breastfeeding. Weigh the potential benefits against the potential risks before taking this medication while breastfeeding.

## **Drug Interactions**

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 this medicine, it is especially important that your healthcare professional know if you are taking any of the medicines listed below. The following interactions have been selected on the basis of their potential significance and are not necessarily all-inclusive.

Using this medicine with any of the following medicines is usually not recommended, but may

be required in some cases. If both medicines are prescribed together, your doctor may change the dose or how often you use one or both of the medicines.

Metronidazole

#### Other Interactions

Certain medicines should not be used at or around the time of eating food or eating certain types of food since interactions may occur. Using alcohol or tobacco with certain medicines may also cause interactions to occur. Discuss with your healthcare professional the use of your medicine with food, alcohol, or tobacco.

#### Other Medical Problems

The presence of other medical problems may affect the use of this medicine. Make sure you tell your doctor if you have any other medical problems, especially:

- Bone marrow problems (eg, agranulocytosis, neutropenia)—Use with caution. May make these conditions worse.
- Liver disease—Use with caution. May increase risk for more serious side effects.

## **Proper Use**

Use this medicine exactly as directed by your doctor. Do not use more of it, do not use it more often, and do not use it for a longer time than your doctor ordered. To do so may increase the chance of side effects.

This medicine usually comes with patient directions. Read the instructions carefully and ask your doctor if you have any questions.

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

You may chew or swallow Emverm<sup>™</sup> chewable tablet whole, or crush it and mix with food.

If you are using Vermox™ Chewable tablet:

- You may take this medicine with or without food.
- Chew it completely before swallowing. Do not swallow the tablet whole.
- If you have trouble chewing the tablet, place it in a spoon and add 2 to 3 mL of drinking water by using a dosing syringe.
- The tablet will absorb the water within 2 minutes and turns into a soft mass with semi-solid consistency, which you can swallow it.

To help clear up your infection completely, take this medicine exactly as directed by your doctor for the full time of treatment. In some patients, additional treatments with this medicine may be needed at 3-week intervals to clear up the infection completely. Do not miss any doses.

For patients taking mebendazole for infections in which high doses are needed:

Mebendazole is best taken with meals, especially fatty ones (eg, meals that include whole
milk or ice cream). This helps to clear up the infection by helping your body absorb the
medicine better. However, if you are on a low-fat diet, check with your doctor.

## Dosing

The dose of this medicine 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 this medicine. If your dose is different, do not change it unless your doctor tells you to do so.

The amount of 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 using the medicine.

- For oral dosage form (Emverm<sup>™</sup> chewable tablets):
  - For common roundworms, hookworms, and whipworms:
    - Adults and children 2 years of age and older—100 milligrams (mg) two times a day, morning and evening, for 3 consecutive days. Treatment may need to be repeated in 3 weeks.
    - Children younger than 2 years of age—Use and dose must be determined by your doctor.
  - o For pinworms:
    - Adults and children 2 years of age and older—100 milligrams (mg) once a day for 1 day. Treatment may need to be repeated in 3 weeks.
    - Children younger than 2 years of age—Use and dose must be determined by your doctor.
- For oral dosage form (Vermox<sup>™</sup> chewable tablets):
  - o For roundworms and whipworms:
    - Adults and children 1 year of age and older—500 milligrams (mg) once a day for 1 day.
    - Children younger than 1 year of age—Use and dose must be determined by your doctor.

### **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**

Keep out of the reach of children.

Do not keep outdated medicine or medicine no longer needed.

Ask your healthcare professional how you should dispose of any medicine you do not use.

Store the medicine in a closed container at room temperature, away from heat, moisture, and direct light. Keep from freezing.

Keep the bottle tightly closed. Throw away any unused Vermox™ Chewable tablets 1 month after the bottle is first opened.

## **Precautions**

It is important that your doctor check your progress at regular visits, especially in infections in which high doses are needed. This is to make sure that the infection is cleared up completely, and to allow your doctor to check for any unwanted effects. Blood tests may be needed.

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.

Mebendazole can temporarily lower the number of white blood cells in your blood, increasing the chance of getting an infection. If you can, avoid people with infections. Check with your doctor immediately if you think you are getting an infection or if you get a fever or chills, cough or hoarseness, lower back or side pain, or painful or difficult urination.

It is important to tell your doctor if you are pregnant before taking this medicine.

For patients taking mebendazole 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 infection or reinfection.
- Some doctors may also recommend other measures to help keep your infection from returning. If you have any questions about this, check with your doctor.

For patients taking mebendazole for hookworms or whipworms:

- In hookworm and whipworm infections, anemia may occur. Therefore, your doctor may want you to take iron supplements to help clear up the anemia.
- It is important to take iron every day during treatment and for 6 months after you stop taking mebendazole. Do not miss any doses. If you have any questions about this, check with your doctor.

In some patients, infections may return after treatment with mebendazole. To help prevent the infection from coming back:

- Wash hands and fingernails often, especially before eating and after using the toilet.
- Wash all fruits and vegetables thoroughly. Cook them well.
- Clean the bedroom floor by vacuuming or damp mopping for several days after treatment

with this medicine. Avoid dry sweeping that may stir up the dust.

- Wash (not shake) all beddings and nightclothes (pajamas).
- Wear tight underpants both day and night. Change them daily. Also, wear shoes.
- Use the bathroom and keep the toilet seats clean.

This medicine may cause serious skin reactions when taken together with metronidazole. Check with your doctor right away if you have blistering, peeling, or loose skin, red skin lesions, severe acne or skin rash, sores or ulcers on the skin, or fever or chills while you are using this medicine.

Do not take other medicines unless they have been discussed with your doctor. This includes prescription or nonprescription (over-the-counter [OTC]) medicines and herbal or vitamin supplements.

## Side Effects

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

- · Black, tarry stools
- chills
- convulsions
- · cough or hoarseness
- dark urine
- fever with or without chills
- general feeling of tiredness or weakness
- hives or welts, itching, or skin rash
- large, hive-like swelling on the face, eyelids, lips, tongue, throat, hands, legs, feet, or sex organs
- light-colored stools
- lower back or side pain
- nausea and vomiting
- painful or difficult urination
- pale skin
- redness of the skin
- sore throat

- sores, ulcers, or white spots on the lips or in the mouth
- unusual bleeding or bruising
- unusual tiredness or weakness
- upper right abdominal or stomach pain
- yellow eyes and skin

#### Incidence not known

- Blistering, peeling, or loosening of the skin
- diarrhea
- difficulty with swallowing
- dizziness
- fast heartbeat
- · joint or muscle pain
- red skin lesions, often with a purple center
- red, irritated eyes
- tightness in the chest

Some 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. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects. Check with your health care professional if any of the following side effects continue or are bothersome or if you have any questions about them:

#### Rare

Abdominal or stomach pain or upset

#### Incidence not known

- Bloated
- · excess air or gas in the stomach or intestines
- full feeling
- hair loss or thinning of the hair
- loss of appetite
- passing gas
- weight loss

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

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

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