

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Vermox (mebendazole) 500 mg

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse .

In this leaflet:

1. What Vermox is and what it is used for
2. Before you use Vermox
3. How to use Vermox
4. Possible side effects
5. How to store Vermox
6. Contents of the pack and other information

1. WHAT VERMOX IS AND WHAT IT IS USED FOR

What Vermox is and used for

Vermox contains the active substance ‘mebendazole’. It is a medicine to treat worms, such as:

- pinworm (*Enterobius vermicularis*);
- whipworm (*Trichuris trichiura*);
- roundworm (*Ascaris lumbricoides*);
- hookworm (*Ancylostoma duodenale*; *Necator americanus*);
- ‘trichinella’ (*Trichinella spiralis*);
- dog tapeworm (*Echinococcus granulosus* or *cystic echinococcosis* or ‘Hydatid disease’);
- fox tapeworm (*Echinococcus multilocularis* or *alveolar echinococcosis*) for adults only.

2. BEFORE YOU ARE GIVEN VERMOX

Ask your doctor or nurse for advice before taking any medicine.

Do not use Vermox :

- For **children under 1 year of age**
- If you are **allergic (hypersensitive)** to it

Do not use this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before using Vermox tablets.

What special precautions should you take when taking Vermox 500 mg

Pregnancy

If you are pregnant, or think you may be, you should inform your doctor, who will decide if you can take Vermox 500 mg.

Breast-Feeding

If you are breast-feeding, you should talk to your doctor first, who will decide if you can take Vermox 500 mg.

Driving or operating machinery

Vermox 500 mg does not affect your alertness or driving ability.

Other medicines

Inform your doctor if you are taking cimetidine (medicine used for acid in the stomach). If you have to take more than 1 tablet of Vermox 500 mg, the doctor might have to change the dose. Tell your doctor if you are taking metronidazole (a medicine to treat bacterial and protozoan infections) so that they can decide if you should take Vermox.

3. HOW TO TAKE VERMOX AND HOW MUCH

Vermox 500 mg comes in the form of tablets to be taken by the mouth. (For young children or other patients who are unable to swallow the tablets use of the liquid form of this medicine may be appropriate. Ask your doctor or pharmacist about this.)

Tablets may be chewed or swallowed whole. Crush the tablet before giving it to a young child. Always supervise a child while they are taking this medicine. Take the tablets with some liquid.

You do not have to take Vermox 500 mg with food. You do not have to follow a special diet or take products which stimulate the stools.

Children above 1 year of age and adults usually take 1 tablet of Vermox 500 mg in one intake. Do not change this amount, unless your doctor tells you.

In regions where worm infections are frequent, children over 1 year and adults may take 1 tablet of Vermox 500 mg 1 to 2 times a year. In this way, worm infestations can be kept at a low level in the whole population.

Infestation with 'trichinella' or dog tapeworm or fox tapeworm:

Follow the dose and instructions given by your doctor.

4. POSSIBLE SIDE EFFECTS

The following undesired effects have been reported and may occur during treatment with Vermox 500mg:

- Dizziness
- Stomach aches and pains, intestinal gas, diarrhea, nausea, and vomiting
- Skin rash
- Hives
- Hair loss, which in some cases may be permanent
- Blood and liver disorders
- Inflammatory kidney disease and severely decreased number of white blood cells can occur with prolonged use of Vermox 500mg at doses substantially above those recommended (much more than is normally prescribed).

If any of the following symptoms occur, contact your doctor immediately:

- A severe skin disorder consisting of skin rashes, blisters on the skin and sores in the mouth, eyes, or anogenital region, along with fever
- A reaction that occurs soon after administration and is recognized by skin rash, itching, shortness of breath, and/or swollen face
- A severe hypersensitivity reaction that occurs soon after administration that may be characterized by hives, itching, flushing, fainting, and difficulty breathing among other possible symptoms
- Convulsions (seizures) have been reported, including in infants. Vermox 500 mg should not be given to children under 1 year of age.

Do not hesitate to report these or any other undesired effects to your doctor or pharmacist.

Overdose

If amounts higher than recommended are taken, or if Vermox is taken for long periods of time, blood, kidney, and liver disorders, some of which may be serious, may occur. Hair loss, which in some cases may be permanent may also occur. Therefore, long treatments should only take place under close medical surveillance.

If you have taken too much Vermox 500 mg, you might suffer from stomach cramps, nausea, vomiting and diarrhoea. If this is the case, consult your doctor.

5. HOW TO STORE VERMOX

- Store Between 15°C And 30°C.
- This medicine can be kept for only a limited period. Do not use Vermox 500 mg after the date printed after "EXP" (month and year), even if it has been stored properly.

6. CONTENT OF THE PACK AND OTHER INFORMATION

What Vermox contains

- The active substance is Mebendazole. The tablet contains 500 mg of mebendazole
- The other ingredients are lactose monohydrate, methylcellulose, sodium starch glycolate, microcrystalline cellulose, maize starch, magnesium stearate and colloidal anhydrous silica.

What Vermox looks like and contents of the pack

It's white, round tablets: one tablet contains 500 milligrams of mebendazole (on the tablet itself is marked: Me/500)

Vermox tablets are available in blister packs of 1 tablet.

Not all pack sizes and concentrations may be marketed.

To contact us, go to www.janssen.com/contact-us

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This leaflet was last revised on 13 January 2024.

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament. The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children

Council of Arab Health Ministers, Union of Arab Pharmacists