

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed with a doctor's prescription only

Vermox[®] Suspension, Vermox[®] Tablets

Each 5 ml of suspension contain: Mebendazole 100 mg

Each tablet contains: Mebendazole 100 mg

For the list of inactive and allergenic ingredients in the preparation – see section 6 “Further Information” and section 2 “Important information about some of the ingredients in this medicine”.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

The medicine is not intended for children below the age of two, unless explicitly instructed by a doctor.

1. WHAT IS THE MEDICINE INTENDED FOR?

Vermox is intended for the treatment of infections caused by intestinal worms, such as:

- Threadworms (pinworms)
- Other common infections caused by worms

Therapeutic group:

Medicines for the treatment of worms (anthelmintics).

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient mebendazole or to any of the additional ingredients contained in the medicine. For a list of additional ingredients, see section 6 “Further Information”.

Special warnings regarding use of this medicine

- Before treatment with Vermox, tell the doctor:
 - About your medical condition, including if you are pregnant or plan to become pregnant.
 - If you are sensitive to any food or any medicine.
- Vermox is given to young children only if the doctor has specifically prescribed the medicine. The doctor will decide whether Vermox is suitable for your child. You must follow the doctor's instructions.
- Convulsions (seizures) have been reported, including in infants. Vermox Suspension should only be given to children under 2 years of age if the doctor

has explicitly prescribed it.

If you are taking, or have recently taken, other medicines, including non-prescription medicines or nutritional supplements, tell the doctor or pharmacist. In particular if you are taking:

- Cimetidine (for treatment of excess stomach acidity).
- Preparations containing metronidazole (for treatment of infections).

Use of the medicine and food

There is no need to take laxatives or to change the diet.

Pregnancy and breastfeeding

Before using the medicine, tell your doctor about your medical condition, including if you are pregnant or plan to become pregnant. It is not known if Vermox will harm your unborn baby.

If you are breastfeeding, consult with a doctor before using the medicine.

Driving and using machinery

The medicine almost certainly has no effect on alertness or the ability to drive or use machinery.

Important information about some of the ingredients in this medicine

Vermox Suspension contains sucrose. If you suffer from intolerance to certain sugars, inform the doctor before using the medicine.

In addition, Vermox Suspension contains methyl parahydroxybenzoate and propyl parahydroxybenzoate. These ingredients may cause an allergic reaction. The reaction may occur some time after taking the medicine.

Vermox suspension contains less than 1 mmol (23 mg) sodium per ml, that is to say it is essentially 'sodium-free'.

One Vermox tablet contains 0.06 mg sunset yellow (E110). This ingredient may cause an allergic reaction.

3. HOW SHOULD THE MEDICINE BE USED?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only.

The usual dosage generally depends on the type of infection. There are three possible dosages:

- 5 ml of suspension or one tablet taken on a one-off basis. It is recommended to repeat the treatment after two weeks and also after 4 weeks.
- 5 ml of suspension or one tablet, twice a day, in the morning and evening, for 3 consecutive days.

These dosages are suitable both for children over the age of two and for adults.

- An additional dosage for adults in accordance with the doctor's instructions: 10 ml of suspension or 2 tablets in one dose, twice a day, in the morning and

evening, for 3 consecutive days.

Consider using Vermox suspension for patients, e.g., children, who are unable to swallow Vermox tablets.

This medicine is not intended for children and infants below the age of two years, unless explicitly instructed by a doctor.

Do not exceed the recommended dosage.

5 ml suspension contain the same amount of active ingredient as one tablet.

Always supervise the child when taking the medicine. Crush the tablet before giving it to a child.

Method of administration

- Tablets:
The tablet may be swallowed with water. The tablet can be crushed/chewed. There is no information regarding halving.
- Suspension:
 - Shake the suspension well before use.
 - Use the measuring cup provided with the preparation to measure the correct amount of medicine. If no measuring utensil was provided with the package, consult the pharmacist. Do not use a household teaspoon to measure the amount of medicine. Household teaspoons vary in their size and you may not receive the correct amount of medicine.

Directions for opening the suspension bottle

The suspension bottle comes with a child-proof cap. Child-proof caps have significantly lowered the number of cases of poisoning caused each year by medicines. However, if you find it hard to open the bottle, you can ask the pharmacist to remove the cap’s safety mechanism and to turn it into a regular easy-to-open cap.

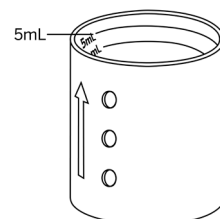


Open the cap as follows:

- Press down on the plastic cap while turning it counterclockwise.
- Remove the cap.

Directions for using the measuring cup

- a. The suspension comes with a clear plastic measuring cup on top of the bottle cap.
- b. Remove the measuring cup from the bottle.
- c. Measurement should be done by filling the concave, upper part of the measuring cup with the suspension; be sure that the arrow is pointing up; see markings on the attached sketch.
- d. The concave upper part of the measuring cup has “ring” markings of 2.5 ml and 5 ml.
- e. The bottom part of the measuring cup that has three



holes on both sides is only meant for gripping the measuring cup.

Do not use this part for measuring the amount of suspension.

- f. Measure the amount of suspension in accordance with the dosage determined by the doctor.

If you accidentally took a higher dosage or if your child has swallowed too high a dose of the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If taken in higher amounts than recommended or for a longer duration of time than recommended, side effects of blood disorders (agranulocytosis) and kidney disorders (glomerulonephritis) may occur.

If you take an overdose of Vermox, you might suffer from abdominal cramps, nausea, vomiting and diarrhea. If you experience any of the aforementioned effects, consult a doctor. He may recommend that you take activated charcoal designated to absorb the remaining medicine that is left in the stomach.

If you forgot to take Vermox at the required time, do not take the forgotten dose. Take the next dose at the usual time and consult the doctor. Do not take two doses together to make up for a forgotten dose.

Adhere to the treatment regimen as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor or pharmacist.

How can you contribute to the success of the treatment

Threadworms produce large numbers of tiny eggs. They may be present in dust and stick to clothing, carpets, towels and bed linen. They can also be transmitted by contact with someone who has worms. Because the eggs are very small, it is easy to swallow them. Then, they pass into the bowel, where they grow and turn into worms. The female lays her eggs at night in the anal area. This causes irritation of the bottom and thus itching. The eggs are thus transferred to the fingers and finger nails, and can easily be transferred into the mouth by finger sucking or nail biting. The lifespan of an adult worm is about 6 weeks.

In order to stop infecting others or re-infection of the same patient, follow the guidelines below for at least 6 weeks:

- Cut nails
- Avoid nail biting and finger sucking
- Wear pajamas in bed
- Wash your bottom thoroughly each morning
- Separate towel for each person in the home
- Change clothes regularly
- Wash and iron bed linen regularly
- Wash hands and nails thoroughly after using the toilet and before meals

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Vermox may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Stop the use of Vermox and refer to a doctor immediately if any of the following severe effects occur. You may need urgent medical treatment:

- Sudden swelling of the face and/or throat
- Urticaria (a rash manifesting as raised red and itchy lesions on the skin)
- Acute irritation, redness or blisters on the skin

All these may be signs of a severe allergic reaction

- Blisters on the skin, mouth, eyes and genitals
- Convulsions (seizures)

Additional side effects:

Common side effects – effects that occur in 1-10 in 100 users

- Abdominal pain

Uncommon side effects – effects that occur in 1-10 in 1,000 users

- Abdominal discomfort
- Diarrhea
- Flatulence
- Nausea or vomiting

Rare side effects – effects that occur in 1-10 in 10,000 users

- Rash
- Inflammation of the liver
- Change in liver enzymes (can be seen in blood tests)
- Inflammation of the kidneys (when administered to treat dog or fox tapeworms [Echinococcosis])
- Reduction in white blood cells (can be seen in blood tests) that may cause you to suffer from more infections (when administered to treat dog or fox tapeworms [Echinococcosis])
- Hair loss
- Dizziness

In extremely rare cases, convulsions may occur in small children who are taking the preparation. In such cases, refer to the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il/>

If one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Do not store Vermox Suspension above 25° C. The suspension is good for use for 28 days after first opening the bottle. Shake well before use.
- Do not store Vermox Tablets above 25° C.

6. FURTHER INFORMATION

- In addition to the active ingredient, Vermox Suspension also contains:
Sucrose 500 mg, Microcrystalline cellulose & carboxymethylcellulose sodium, Methylcellulose 15 mPa.s, Sodium lauryl sulfate 5 mg, Methyl parahydroxybenzoate, Propyl parahydroxybenzoate, Banana flavour 1, Citric acid monohydrate, Purified water.
Each 5 ml of suspension contain 500 mg sucrose.
- In addition to the active ingredient, Vermox Tablets also contain:
Microcrystalline cellulose, Sodium starch glycolate, Talc, Maize starch, Sodium saccharin 5 mg, Magnesium stearate, Cotton seed oil hydrogenated, Orange flavour, Colloidal anhydrous silica, Sodium lauryl sulfate 0.5 mg and Orange yellow S (E110).

What the medicine looks like and contents of the package

Vermox Suspension:

- A homogenous, white, banana- flavoured suspension.
- Vermox suspension is provided in a carton box that contains a 30 ml brown glass bottle and a measuring cup marked for 2.5 ml and 5 ml.

Vermox Tablets:

- A pale orange, round, flat, bevel-edged tablet with a score-line and with “JANSSEN” written on one side and “ME/100” on the other side.
- The package has 6 tablets packaged in a blister.

Registration holder: J-C Health Care Ltd., Kibbutz Shefayim 6099000, Israel.

Manufacturer:

- Vermox Suspension: Janssen Pharmaceutica, Beerse, Belgium.
- Vermox Tablets: Lusomedicamenta Sociedade Tecnica Farmaceutica, Portugal.

Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:

- Vermox Suspension: 106-69-21882-00
- Vermox Tablets: 130-12-30986-00

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