

Package leaflet VERMOX

Read the entire package leaflet carefully because it contains important information for you. This medicine is available without a prescription. However, to achieve the best possible treatment success, VERMOX must be used as directed.

Keep the package leaflet. You may want to read it again later.

Ask your pharmacist if you need more information or advice.

If your symptoms worsen or do not improve after a few days, you must see a doctor.

This package leaflet includes:

1. What is VERMOX and what is it used for?
2. What do you need to know before taking VERMOX?
3. How to take VERMOX?
4. What side effects are possible?
5. How to store VERMOX?
6. Further information

Name of the medicinal product

VERMOX 100 mg tablets

VERMOX 20 mg/ml oral suspension

The active substance is mebendazole.

VERMOX tablets contain 100 mg of mebendazole (R 17 635) per tablet.

Other ingredients: microcrystalline cellulose, talc, corn starch, sodium carboxymethyl starch, sodium saccharin, magnesium stearate, hydrogenated cottonseed oil, orange peel oil, silicon dioxide, sodium lauryl sulfate, sunset yellow FCF (E 110).

VERMOX oral suspension contains 20 mg mebendazole (R 17 635) per ml of suspension.

Other ingredients: microcrystalline cellulose, methylcellulose, sodium carboxymethylcellulose, sucrose, sodium lauryl sulfate, methylparahydroxybenzoate, propylparahydroxybenzoate, banana flavor, citric acid, purified water.

Marketing Authorization Holder

Janssen-Cilag n.v.

Roderveldlaan 1

B-2600 Berchem

Belgium

Manufacturer

Tablets

Janssen-Cilag S.p.A.

Via C. Janssen

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Latina – Italy

Oral suspension

Janssen Pharmaceutica N.V.

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Belgium

Marketing Authorization Number
VERMOX tablets: 1028 IS 162 F 3
VERMOX oral suspension: 2 S 260 F 11

1. What is VERMOX and what is it used for?

Tablets for oral administration:

The tablets are available in a blister pack containing 6 tablets.

Oral suspension:

The oral suspension is available in a bottle with 30 ml of drinking solution (with a plastic dosing cap for 5 ml).

VERMOX is an anti-worm medication

VERMOX is indicated for the treatment of infections caused by one or more types of worms:

- Pinworm (*Enterobius vermicularis*);
- Roundworm (*Ascaris lumbricoides*);
- Whipworm (*Trichuris trichuria*);
- Hookworm (*Ancylostoma duodenale*, *Necator americanus*);
- Tapeworm (*Taenia* spp.);
- Threadworm (*Strongyloides stercoralis*).

2. What should you consider before taking VERMOX?

VERMOX must not be taken,

- if you are hypersensitive (allergic) to mebendazole or any of the other components of VERMOX. This hypersensitivity may manifest as a rash, itching, shortness of breath, and/or a swollen face. In this case, discontinue treatment and consult your doctor.

Special caution is required when taking VERMOX,

- when administered to children under 2 years of age. VERMOX should only be given to toddlers under 2 years if the worm infection significantly affects the child's nutritional status and physical development. In any case, consult your doctor for advice first.
- if you are taking other medications. Please also read the section "Taking VERMOX with other medications".

Taking VERMOX with food and drinks

Not applicable

Pregnancy

Especially in the first three months of pregnancy, it is necessary to weigh the benefits of VERMOX against the possible risks.

Consult your doctor or pharmacist before taking any medications.

Breastfeeding

During breastfeeding, you must be cautious with the use of VERMOX.

Consult your doctor or pharmacist before taking any medications.

Driving and using machines

VERMOX has no effect on the ability to drive or use machines.

Important information about certain other ingredients of VERMOX

Not applicable

Taking VERMOX with other medications

Please inform your doctor or pharmacist if you are taking other medications or have recently taken them, even if they are non-prescription medications.

- If you are taking Cimetidine (a medication for stomach acid) at the same time, you must inform your doctor. He will take appropriate measures and make necessary dose adjustments.
- The simultaneous use of VERMOX and Metronidazole (a medication for bacterial and protozoal infections) should be avoided.

3. How to take VERMOX?

Please follow these instructions exactly, unless your doctor has prescribed otherwise. Please consult your doctor or pharmacist if you are not completely sure.

How much VERMOX you need to take depends on the type of worm you are infected with. If you have any doubts, please ask your doctor for advice.

1. Pinworms (*Enterobius vermicularis*):

1 single tablet or 5 ml (= 1 dosing cap) oral suspension.

All family members must be treated at the same time and this treatment must be repeated after 2 to 4 weeks (all family members take 1 tablet or 5 ml oral suspension again). This is necessary for effective treatment: the first dose kills all worms, but not their eggs, which can cause reinfection.

The dosage applies to both children and adults.

2. Roundworms, whipworms, hookworms, and mixed infections: 1 tablet or 5 ml (= 1 dosing cap) oral suspension in the morning and evening for three consecutive days.

The dosage applies to both children and adults.

3. Tapeworms and threadworms:

* Adults:

2 to 3 tablets or 10 to 15 ml (= 2 to 3 dosing caps) oral suspension in the morning and evening for three consecutive days.

* Children over 2 years:

1 tablet or 5 ml (= 1 dosing cap) oral suspension in the morning and evening for three consecutive days.

Children under 2 years: see section "Special precautions for taking VERMOX".

When undergoing treatment with VERMOX, you should not follow a special diet or take laxatives.

Take the tablet(s) with some water. Shake the suspension before use. The bottle is opened as follows: press the plastic screw cap down and simultaneously turn counterclockwise (see illustration).

If you forget to take VERMOX

Not applicable

If you have stopped taking VERMOX

Not applicable

If you have taken more VERMOX than you should If you have taken too much VERMOX, please contact your doctor, pharmacist, or the poison control center (070/245.245) immediately. Taking too much VERMOX does not pose significant dangers. At worst, intestinal cramps, vomiting, diarrhea, headaches, and dizziness may occur. Prolonged intake of large amounts may lead to liver function disturbances.

If any of these symptoms occur, you must inform your doctor. The administration of activated charcoal may be beneficial.

4. What side effects are possible?

Like all medicines, VERMOX can have side effects.

VERMOX is well tolerated, and when taken in the prescribed amounts, side effects are hardly expected. However, the following side effects may occasionally occur:

- Short-lasting stomach pain and diarrhea may occasionally occur, especially if you have a severe worm infection. In this case, you can continue taking VERMOX as directed.
- Hypersensitivity to VERMOX is very rare. This can manifest as a rash, itching, shortness of breath, and a swollen face. If any of these symptoms occur, stop taking VERMOX and contact your doctor.
- In very rare cases, a serious skin condition with rash, blisters on the skin, and ulcers in the mouth, eyes, and genital and anal areas, along with fever, has been reported. If you notice these symptoms, contact your doctor immediately.
- Very rarely, convulsions (seizures) may occur in infants. VERMOX should only be administered to children under 1 year if prescribed by your doctor.
- Very rarely, prolonged intake of VERMOX in doses significantly higher than recommended (i.e., much higher than normally prescribed) may cause problems related to blood, liver, and kidneys.

Inform your doctor or pharmacist if you notice side effects not listed in this leaflet and that you consider serious.

5. How to store VERMOX

VERMOX is stored at room temperature (15-30°C) and protected from light. Keep VERMOX out of reach of children.

Expiry date

The abbreviation "exp." on the packaging means that the medicine expires on the last day of the month indicated after the abbreviation (month and year).

6. Further information

If you have further questions on the use of this medicine, please ask your doctor or pharmacist.

Dispensing

VERMOX tablets and oral suspension are available without prescription.

This package leaflet was last revised in October 2004

Approval date of this package leaflet: July 2006

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