

Package leaflet: information for the patient

Vermox 100 mg tablets **Vermox 20 mg/mL oral suspension** mebendazole

Read all of this leaflet carefully before you start taking 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 pharmacist.
- This medicine has been prescribed for you only. Do not pass it to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Vermox is and what it is used for
2. What you need to know before you take Vermox
3. How to take 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

The active ingredient of Vermox is mebendazole, which belongs to a category of medicines called anthelmintics. These medicines cause the elimination or destruction of parasitic worms in humans (worms that live off the human body).

In particular, this medicine has strong activity against many parasitic worms in humans (helminths) belonging to the classes of the nematodes and cestodes.

Vermox is particularly active for infestations caused by:

- *Enterobius vermicularis* (pinworm): parasitic worm of the digestive tract
- *Ascaris lumbricoides* (large roundworm): parasitic worm of the intestine
- *Trichuris trichiura* (whipworm): parasitic worm of the cecum
- *Ancylostoma duodenale* (hookworm): parasitic worm of the small intestine
- *Necator Americanus* (hookworm): parasitic worm of the intestine
- *Strongyloides stercoralis* (threadworm): parasitic worm of the intestinal walls
- *Taenia spp.* (tapeworm): parasitic worm of the digestive tract.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Vermox

Do NOT take Vermox:

- if you are allergic to mebendazole or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Vermox.

Glomerulonephritis (inflammatory kidney disease) and agranulocytosis (severe decrease in the number of white blood cells) have been reported with dosages substantially higher than those recommended and for prolonged periods of treatment.

Children

Vermox can in rare cases induce seizures in children, including newborns.

Vermox must not be used in children under 1 year of age.

Vermox can only be given to children aged 1-2 years if the doctor has specifically prescribed it.

Vermox should only be used if there is no therapeutic alternative.

The doctor will prescribe Vermox to your child only in absence of alternative treatments.

To reduce the risk of suffocation, VERMOX 20mg / mL oral suspension should be considered for patients, such as young children, who have difficulty swallowing the tablets.

Other medicines and Vermox

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicine.

Avoid using the following medicine with Vermox:

- metronidazole (an antibiotic), because Stevens-Johnson syndrome/toxic epidermal necrolysis (SJS/TEN) (severe drug-induced reactions of the skin and/or mucous membranes) could occur.

Use Vermox with caution and warn your doctor or pharmacist if you are taking:

- cimetidine (medicine used for treating stomach ulcer): the use of this medicine with Vermox can increase its effect. Use Vermox with caution if you are being treated with cimetidine.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

A small amount of mebendazole is present in breast milk after oral administration. Therefore, caution should be exercised when VERMOX is administered to breastfeeding women.

Driving and using machines

No studies have been carried out on the ability to drive and use machines.

Vermox suspension contains methylparaben and propylparaben

Methylparaben and propylparaben may cause allergic reactions (possibly delayed).

Vermox suspension contains sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Vermox suspension contain sodium

This medicine contains less than 1 mmol sodium (23 mg) per mL, that is to say essentially 'sodium-free'.

Vermox tablets contain Sunset Yellow.

Sunset Yellow is an azo dye that may cause allergic reactions.

Vermox tablets contain sodium

This medicine contains 3.8 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 0.19% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take Vermox

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose varies depending on the parasite:

1. **Enterobiasis (parasitic infestation in the digestive tract):** the recommended dose is 100 mg (one tablet or one 5 mL measuring cup of suspension) to be taken by mouth. It is advisable to repeat the treatment after 2-4 weeks, since the risk of a new infestation is extremely high, particularly in large social groups.
2. **Ascariasis (parasitic infestation in the intestine), trichuriasis (parasitic infestation in the cecum), hookworm infestation (parasitic infestation in the small intestine) and mixed infestations:** the recommended dose is 100 mg (one tablet or one 5 mL measuring cup of suspension) by mouth, twice a day (in the morning and the evening), for three consecutive days, regardless of the patient's age and weight.
3. **Taeniasis (parasitic infestation of the digestive tract) and strongyloidiasis (parasitic infestation of the intestinal walls):**
 - **Adults:** the recommended dose is 200 mg (2 tablets or 2 5 mL measuring cups of suspension) by mouth, divided into two daily doses (in the morning and in the evening) for three consecutive days.
 - **Children:** the recommended dose is 100 mg (one tablet or one 5 mL measuring cup of suspension) by mouth twice a day (in the morning and the evening), for three consecutive days.For use in children, also see the section "Warnings and Precautions".

Method of administration

Vermox is available in the form of tablets and oral suspension. One 5 mL measuring cup of suspension contains the same amount of active ingredient as one 100 mg tablet.

- **Tablets**

The tablets can be swallowed with a small amount of water or chewed with a meal. The treatment does not require a particular diet, nor the use of laxatives.

- **Suspension**

Shake the bottle of suspension before use.

The correct dose for each indication allows complete elimination of the worms in over 90% of patients, even in cases of severe or mixed infestations.

VERMOX oral suspension should be considered for patients such as young children who have difficulty swallowing tablets.

If the doctor has specifically prescribed it, the tablet must be crushed before it is given to a young child. A child must always be supervised while they are taking Vermox.

Use in children and adolescents

For children below the age of one year, see section "Warning and Precautions".

VERMOX Should only be used in children and adolescents if the doctor has specifically prescribed it.

If you take more Vermox than you should

If you have accidentally taken/swallowed too much Vermox, inform your doctor immediately or go to the nearest hospital.

If you take higher amounts of Vermox than recommended, or if you take it for prolonged periods of time, the following problems could occur, and in some cases they could be serious:

- blood problems
- kidney problems
- liver problems
- hair loss, in some cases permanent

Long-term treatments must be carefully monitored by your doctor.

If you accidentally take/swallow an excessive amount of Vermox, you may experience abdominal cramps, nausea, vomiting and diarrhea. In this case, you must call your doctor, who, if appropriate, will administer activated charcoal (used to absorb the quantities of Vermox left in your stomach).

There is no specific antidote. You will be given activated charcoal if appropriate.

If you have any doubts on the use of this medicine, talk to your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Call your doctor immediately if you experience any of the following symptoms:

- A severe skin disorder consisting of skin rashes, blisters on the skin and mouth ulcers, inflammation in the eyes or in the ano-genital area, and fever.
- A reaction that occurs soon after administration and is characterized by skin rash (red blotches on the skin), itching, shortness of breath and/or swelling of the face.
- A serious hypersensitivity (allergy) reaction that occurs soon after administration that may be characterized by hives (skin rash), itching, hot flashes, fainting, and difficulty breathing.
- Convulsions have been reported, including in infants. Vermox may be given to children under 1 year of age only if your doctor has specifically prescribed it.

The following side effects have been reported with Vermox:

Common side effects (may affect up to 1 person in 10):

- Abdominal pain

Uncommon side effects (may affect up to 1 person in 100):

- Abdominal disorders
- Diarrhea
- Flatulence (gas in the stomach or intestines)
- Nausea
- Vomiting

Rare side effects (may affect up to 1 person in 1 000):

- Neutropenia (decrease in the number of white blood cells)
- Allergy (anaphylactic and anaphylactoid reaction)
- Convulsions
- Dizziness
- Hepatitis
- Abnormal liver function tests (changes in normal liver values)
- Skin rash (red blotches on the skin)
- Stevens-Johnson syndrome/toxic epidermal necrolysis (SJS/TEN) (serious drug-induced reaction of the skin and/or mucous membranes)
- Exanthema (skin rash with pustules, blisters and bullae)
- Angioedema (swelling of the face, mouth, lips and/or tongue)
- Urticaria (skin rash)
- Alopecia (hair loss, which in some cases could be permanent)

Very rare side effects (may affect up to 1 in 10 000 people):

- Inflammatory kidney disorder (glomerulonephritis) *
- Severe decrease in the number of white blood cells (agranulocytosis) *.

* could occur with prolonged use of Vermox at doses much higher than those prescribed.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Vermox

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the pack after Exp.. The expiry date refers to the last day of that month. The expiration date refers to the product kept unopened in its original packaging, properly stored.

Do not throw away any medicine via wastewater or household waste Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Storage

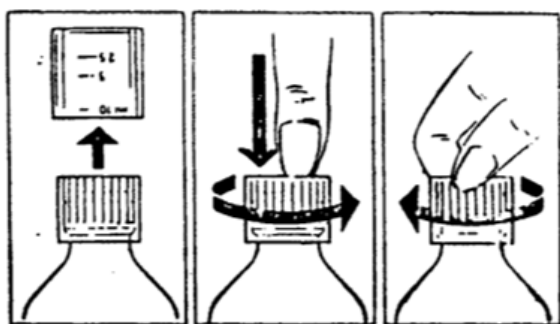
- Tablets and suspension: Store below 30 °C.

Child-proof cap: (tablets)

Opaque blister

Child-proof cap: (suspension)

Glass bottle with measuring cup

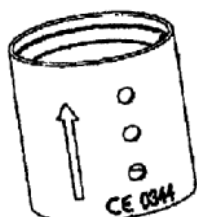


1. Before opening, remove the measuring cup inserted on top of the plastic cap of the bottle.

2. To open push the plastic cap firmly downwards, then unscrew.

3. To close after sampling screw tightly until the plastic cap turns freely.

Use of the measuring cup: pour the suspension into the hollow indicated by the arrow on the measuring cup (as shown in the drawing)



The holes on the measuring cup allow leakage of the suspension if it is poured from the side opposite to that indicated by the arrow by mistake.

6. Contents of the pack and other information

What Vermox contains

100 mg tablets:

- The active substance is mebendazole
- The other ingredients are: corn starch, **sodium** saccharin, **sodium** lauryl sulfate, **Sunset Yellow**, orange flavor, microcrystalline cellulose, colloidal silica, magnesium stearate, **sodium** starch glycolate, talc, hydrogenated cottonseed oil.

20 mg/mL oral suspension:

- The active substance is mebendazole
- The other ingredients are: microcrystalline cellulose and sodium carmellose, sodium lauryl sulfate, **methylparaben**, **propylparaben**, citric acid monohydrate, methylcellulose, banana flavor, **sucrose**, purified water.

What Vermox looks like and contents of the pack

- 100 mg tablets - 6 tablets in opaque blister
- 20 mg/mL oral suspension - 30 mL bottle

Not all pack sizes and concentrations may be marketed.

Marketing authorization holder

Janssen-Cilag SpA
Viale Fulvio Testi, 280/6
20126 Milano MI
Italy

Manufacturer

- **Tablets**
Lusomedicamenta Sociedade Técnica Farmacêutica, S.A.
Estrada Consiglieri Pedroso 69-B
Queluz de baxio
2730-055 Barcarena
Portugal
- **Suspension**
JANSSEN PHARMACEUTICA N.V.
Turnhoutseweg, 30
B-2340 Beerse (Belgium)

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

This leaflet was last revised or approved 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