

**WHO-PQ RECOMMENDED
PATIENT INFORMATION LEAFLET**

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

VERMOX™ CHEWABLE* 500 mg chewable tablets Mebendazole

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your health care provider.
- 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 health care provider.

In this leaflet:

1. What Vermox Chewable is and what it is used for
2. Before you take Vermox Chewable
3. How to take Vermox Chewable
4. Possible side effects
5. How to store Vermox Chewable
6. Further information

1. WHAT VERMOX CHEWABLE IS AND WHAT IT IS USED FOR

What is Vermox Chewable?

Vermox Chewable contains the active substance mebendazole. It is a medicine used in the treatment of worm infections of the gut. It belongs to a group of medicines called 'anthelmintics'.

What it is used for?

Vermox Chewable is used to treat adults and children of 1 years of age and above with worm infections of the gut caused by roundworm, whipworm or hookworms. Vermox Chewable is used for mass drug administration in communities affected by intestinal worms. You are being given these tablets under a mass drug administration programme in which this medicine is administered depending on the risk of infection in your community. Mass drug administration works by reducing the number of people in the community who are heavily infected with intestinal worms.

2. BEFORE YOU TAKE VERMOX CHEWABLE

Do not take Vermox Chewable

- if you are **allergic** (hypersensitive) to mebendazole, or other ingredients of Vermox Chewable.

Do not give Vermox Chewable to children under 1 year of age.

Warnings and precautions

Take special care with Vermox Chewable

- Fits (convulsions/ seizures) have been reported in infants below the age of 1 year.
- For long-term therapy, the blood count and liver and kidney function tests should be checked regularly.

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only

Taking other medicines

Vermox Chewable might interact with other medicines. Please tell your health care provider if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Vermox Chewable is not recommend to be taken with metronidazole (a drug used to treat bacterial and protozoan infections) as a serious skin reaction can rarely occur.

Taking Vermox Chewable with food and drink

See section 3 'How to take Vermox Chewable.'

Pregnancy and breast-feeding

Tell your health care provider if you are pregnant, think you may be pregnant or if you are breast-feeding. Your health care provider will decide whether you are allowed to take Vermox Chewable while you are pregnant or breast-feeding.

Driving and using machines

This medicine is unlikely to affect your alertness or ability to drive.

3. HOW TO TAKE VERMOX CHEWABLE

Always use Vermox Chewable exactly as your health care provider has told you. You must check with your health care provider if you are not sure.

Taking this medicine:

- Take this medicine by mouth.
- This medicine is a single-tablet dose.
- The tablet must be chewed completely before swallowing.
- If you have difficulty chewing the tablet:
 - add approximately 2 mL to 3 mL of drinking water to a suitably sized spoon
 - place the Vermox Chewable tablet into the water
 - wait for two minutes
 - by then the tablet has turned into a soft mass with semi-solid consistency.It will now be easier to swallow.

If you take more Vermox Chewable than you should

Talk to a health care provider immediately. Take the medicine and this leaflet with you. You might suffer from symptoms that include stomach cramps, nausea, vomiting or diarrhoea.

If you have any further questions on the use of this product, ask your health care provider.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Vermox Chewable can cause side effects, although not everybody gets them.

Tell your health care provider immediately if you notice or suspect the following serious side effects. You may need urgent medical treatment.

- Fits (seizures/convulsions)
- Severe allergic reaction that may include:
 - a swollen face, lips, mouth, tongue or throat
 - difficulty swallowing or breathing
 - itchy rash (hives)

- Life-threatening rash with blisters and peeling skin over much of the body (toxic epidermal necrolysis)
- Severe rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome)

Other side effects.

- Loss of appetite
- Stomach pain
- Diarrhoea
- Passing gas
- Nausea
- Vomiting
- Low number of a type of white blood cell (neutrophils)
- Feeling dizzy
- Inflamed liver
- Changes that show up in blood tests of the liver
- Inflammation of the kidney
- Skin rash over a wide area
- Hives
- Hair loss

Talk to your health care provider if you have any concerns about these side effects.

5. HOW TO STORE VERMOX CHEWABLE

Keep out of the reach and sight of children.

Do not use Vermox Chewable after the expiry date which is stated on the bottle after 'Expiry'. The expiry date refers to the last day of that month.

Unused tablets should be discarded three (3) months after the bottle is first opened.

When the bottle is first opened this date (Date opened) should be written on the bottle label in the space provided.

Do not store above 30°C. Keep container tightly closed.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Vermox Chewable contains

- The active substance is mebendazole. Each tablet contains 500 mg of mebendazole.
- The other ingredients are crospovidone, magnesium stearate, microcrystalline cellulose, povidone, strawberry flavour, sucralose.

What Vermox Chewable looks like and contents of the pack

Chewable tablet: Round, flat radius-edged white to yellowish chewable tablet that is debossed with "M" over "500" on one side and "J" on the other side. 200 tablets in a plastic bottle.

Supplier and Manufacturer

Supplier

Janssen-Cilag International NV
Turnhoutseweg 30
B-2340 Beerse
Belgium
Phone: +32 (0)800 933 77
Email: janssen@jacbe.jnj.com

Manufacturer

Lusomedicamenta Sociedade Técnica
Farmacêutica S.A.
Estrada Consiglieri Pedroso, 69 – B
Queluz de Baixo
2730-055 Barcarena
Portugal
Phone: +351 21 434000
Fax: +351 21 4340099

For any information about this medicinal product, please contact the supplier.

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Detailed information on this medicine is available on the WHO Prequalification web site:
<https://extranet.who.int/prequal/>.