

Proposed patient information leaflet for VERMOX® 500 mg tablets**PATIENT INFORMATION LEAFLET****SCHEDULING STATUS****S1****VERMOX® 500 mg tablets****Mebendazole****Contains sugar (34 mg lactose monohydrate per tablet).****Read all of this leaflet carefully because it contains important information for you.**

VERMOX® 500 mg is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to take VERMOX® 500 mg carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

1. What VERMOX® 500 mg is and what it is used for.
2. What you need to know before you take VERMOX® 500 mg.
3. How to take VERMOX® 500 mg.
4. Possible side effects.
5. How to store VERMOX® 500 mg.
6. Contents of the pack and other information.

1. What VERMOX® 500 mg is and what it is used for

VERMOX® 500 mg belongs to a group of medicines known as anthelmintics. It is used to treat worm infections of the gut, such as:

- Pinworm (*Enterobius vermicularis*);
- Whipworm (*Trichuris trichiura*);
- Roundworm (*Ascaris lumbricoides*);
- Hookworm (*Ancylostoma duodenale*; *Necator americanus*);

VERMOX® 500 mg is for use in adults and children (see section 2). You or your child has been advised to take VERMOX® 500 mg because you have a worm infection. Worms can infect anyone. It does not necessarily mean that your hygiene is poor.

To stop you and your family infecting others or re-infecting yourselves follow the advice below for at least six weeks:

- Keep nails short;
- Discourage nail biting or finger sucking;
- Wear pyjamas or underclothes in bed;
- In the mornings, wash your bottom thoroughly;
- Use a separate towel for each person in the house;
- Change clothes regularly;
- Wash and iron bed linen regularly;
- Wash hands and nails well after using the toilet and before meals.

2. What you need to know before you take VERMOX® 500 mg

Do not take VERMOX® 500 mg:

- If you or your child are hypersensitive (allergic) to mebendazole or any of the other ingredients of VERMOX® 500 mg (see **What VERMOX® 500 mg contains**).

- If you are pregnant (see **Pregnancy, breastfeeding and fertility**).

Warnings and precautions

Take special care with VERMOX® 500 mg:

- If your child is very young and they are unable to swallow tablets. VERMOX® 500 mg should only be given to younger children if your doctor has specifically prescribed it. Your doctor will decide whether VERMOX® 500 mg is suitable for your child. You must follow the doctor's instructions carefully. VERMOX® 500 mg should not be given to children under the age of 1 year.
- If you or your child are taking a medicine called metronidazole (see "**Other medicines and Vermox® 500 mg**").

Other medicines and VERMOX® 500 mg

Always tell your health care provider if you or your child are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor or pharmacist if you are currently using:

- cimetidine (used to treat heartburn);
- metronidazole (an antibiotic used to treat infections).

VERMOX® 500 mg with food, drink and alcohol

See section 3.

Pregnancy, breastfeeding and fertility

Do not use VERMOX® 500 mg if you are pregnant, think you may be pregnant or might become pregnant.

Please consult your doctor, pharmacist or other health care provider for advice if you are breastfeeding.

Driving and using machines

VERMOX® 500 mg can cause side effects, such as dizziness. Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how VERMOX® 500 mg affects you.

VERMOX® 500 mg contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, consult your doctor before VERMOX® 500 mg.

3. How to take VERMOX® 500 mg

Do not share medicines with any other person.

VERMOX® 500 mg comes in the form of tablets and should be taken by mouth.

Take the tablets with some liquid.

You may crush the tablet and mix it with some water before giving it to your child. Always supervise your child when they take VERMOX® 500 mg.

VERMOX® 500 mg can be taken with or without food.

For Whipworm; Hookworm; Large Roundworm; Pinworm

Adults and children over the age of 1 year: Take one tablet (500 mg) once a day.

You might have to take a second course of treatment if you are still infected three to four weeks after the first course.

Do not exceed the recommended dosage. Always take VERMOX® 500 mg exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

If you have the impression that the effect of VERMOX® 500 mg is too strong or too weak, tell your doctor or pharmacist.

If you take more VERMOX® 500 mg than you should

If you have taken too much VERMOX® 500 mg, you might experience stomach cramps, nausea, vomiting and diarrhoea.

In the event of an overdose, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison centre.

Take this leaflet and the rest of the remaining VERMOX® 500 mg with you so the doctor will know what you have taken.

If you forget to take VERMOX® 500 mg

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

VERMOX® 500 mg can have side effects.

Not all side effects reported for VERMOX® 500 mg are included in this leaflet. Should your or your child's general health worsen or if you experience any untoward effects while taking VERMOX® 500 mg, please consult your health care provider for advice.

If any of the following happens, stop taking VERMOX® 500 mg and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;

- rash, hives (also known as nettle rash or urticaria), severe irritation, reddening or blistering of your skin;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to VERMOX® 500 mg. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- frequent infections such as fever, severe chills, sore throat or mouth ulcers;
- fits (seizures);
- yellowing of your skin and eyes, dark urine, and tiredness which may be symptoms of liver problems;
- painful, blistering or peeling skin rash, such as Stevens-Johnson syndrome or toxic epidermal necrolysis;
- glomerulonephritis (kidney disease in which the part of your kidneys that helps filter waste and fluids from the blood is damaged causing puffiness in your face in the morning, blood in your urine, urinating less than usual).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- abdominal pain.

Less frequent side effects:

- dizziness;

- nausea (feeling sick), vomiting (being sick), upset stomach, diarrhoea, flatulence (excess wind);
- hair loss (temporary).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reactions Reporting Form**”, found online under SAHPRA’s publications: <http://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of VERMOX® 500 mg.

5. How to store VERMOX® 500 mg

- Store at or below 25 °C.
- Keep in the original container until required for use.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the blister / carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What VERMOX® 500 mg contains

Each tablet contains 500 mg mebendazole.

The other ingredients are corn starch, magnesium stearate (E572), methylcellulose, microcrystalline cellulose (E460(i)), silicon dioxide (E551) and sodium starch glycolate.

What VERMOX® 500 mg looks like and contents of the pack

A white to faintly cream-coloured, bevel-edged tablet with $\frac{Me}{500}$ inscription on the one side and "JANSSEN" on the other side.

Carton containing one blister pack of 1 tablet.

Holder of certificate of registration

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South Africa

For further information please contact the Johnson & Johnson Call

Centre at telephone

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