

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS****S1****VERMOX® SD suspension****Mebendazole****Contains sugar (150 mg sucrose per mL).****Read all of this leaflet carefully because it contains important information for you.**

VERMOX® SD suspension is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to take VERMOX® SD suspension 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® SD suspension is and what it is used for.
2. What you need to know before you take VERMOX® SD suspension.
3. How to take VERMOX® SD suspension.
4. Possible side effects.
5. How to store VERMOX® SD suspension.
6. Contents of the pack and other information.

1. What VERMOX® SD suspension is and what it is used for

VERMOX® SD suspension 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*);

This medicine is for use in adults and children (see section 2).

You or your child has been advised to take VERMOX® SD suspension 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® SD suspension

Do not take VERMOX® SD suspension:

- If you are hypersensitive (allergic) to mebendazole or any of the other ingredients of VERMOX® SD suspension (see **What VERMOX® SD suspension contains**).
- If you are pregnant (see **Pregnancy, breastfeeding and fertility**).
- If you are taking metronidazole (antibiotics used to treat bacterial infections).

VERMOX® SD suspension should not be used in children below the age of 1 year.

Warnings and precautions

Take special care with VERMOX® SD suspension:

- VERMOX® SD suspension should only be given to younger children if your doctor has specifically prescribed it. Your doctor will decide whether VERMOX® SD suspension is suitable for your child. You must follow the doctor's instructions carefully. VERMOX® SD suspension should not be given to children under the age of 1 year.

Other medicines and VERMOX® SD suspension

Always tell your health care provider if you 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 bacterial infections).

VERMOX® SD suspension with food, drink and alcohol

See section 3.

Pregnancy, breastfeeding and fertility

- Do not take VERMOX® SD suspension if you are pregnant, think you may be pregnant or might become pregnant.
- Ask your doctor or pharmacist for advice if you are breastfeeding.
- VERMOX® SD suspension is not recommended during breastfeeding.

Driving and using machines

VERMOX® SD suspension 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® SD suspension affects you.

Important information about some of the ingredients of VERMOX® SD suspension

VERMOX® SD suspension contains

- Sucrose. If your doctor has told you that you are intolerant to some sugars, contact them before taking this medicine.
- Methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216). This may cause an allergic reaction. This reaction may happen some time after you have taken VERMOX® SD suspension.
- This medicine contains less than 1 mmol sodium (23 mg) per mL, that is to say essentially 'sodium-free'.

3. How to take VERMOX® SD suspension

Do not share medicines with any other person.

VERMOX® SD suspension comes in the form of a suspension and should be taken by mouth.

VERMOX® SD suspension can be taken with or without food.

The amount of VERMOX® SD suspension you have to take will depend on the worm species you are infected with. If in doubt, consult with your doctor or pharmacist.

Children above the age of 1 year and adults take the same dose of VERMOX® SD suspension.

For common worm infections (whipworm; hookworm; large roundworm; pinworm)

Adults and children over the age of 1 year:

The usual dose is two medicine measures (10 mL) given as a single dose.

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® SD suspension 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® SD suspension is too strong or too weak, tell your doctor or pharmacist.

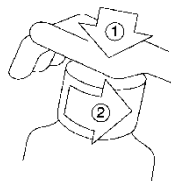
Instructions for use of VERMOX® SD

suspension:

Shake the bottle before use.

The bottle comes with a child-proof cap, and should be opened as follows:

1. Push the plastic screw cap down
2. While pressing down, turn the cap counterclockwise.



If you take more VERMOX® SD suspension than you should

If you have taken too much VERMOX® SD suspension, 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® SD suspension with you so the doctor will know what you have taken.

If you forget to take VERMOX® SD suspension

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

4. Possible side effects

VERMOX® SD suspension can have side effects.

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

If any of the following happens, stop taking VERMOX® SD suspension 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 or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to VERMOX® SD suspension. 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), 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® SD suspension.

5. How to store VERMOX® SD suspension

- Store at or below 25 °C.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the label / 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® SD suspension contains

Each bottle (10 mL) contains 500 mg mebendazole.

The other ingredients are chocolate flavour, citric acid (E330), ethanol 96 %, methylcellulose (E461), methylparaben (E218), microcrystalline cellulose (E460(i)), polysorbate 20 (E432), propylparaben (E216), purified water, sodium carmellose and tetrarome orange flavour.

What VERMOX® SD suspension looks like and contents of the pack

White to off-white suspension with a chocolate flavour.

15 mL amber glass bottles containing 10 mL VERMOX® SD suspension.

Holder of certificate of registration

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For further information please contact the Johnson & Johnson Call Centre at telephone

0860 410032

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