

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S1

WORMSTOP® 500 (TABLETS)

(Mebendazole)

Sugar free, Artificially sweetened: Sodium saccharin 10 mg / tablet

Read all of this leaflet carefully because it contains important information for you

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

Nevertheless, you still need to use WORMSTOP® 500 carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share WORMSTOP® 500 with any other person.
- Ask your health care provider or 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 WORMSTOP® 500 is and what it is used for
2. What you need to know before you take WORMSTOP® 500
3. How to take WORMSTOP® 500
4. Possible side effects
5. How to store WORMSTOP® 500
6. Contents of the pack and other information

1. What WORMSTOP® 500 is and what it is used for

The name of your medicine is WORMSTOP® 500.

WORMSTOP® 500 contains a medicine called mebendazole. It is one of a group of medicines called 'anthelmintics'.

WORMSTOP® 500 is used to treat worm infections of the gut such as:

- threadworms (pinworms)

- other common worm infections (such as whipworm, roundworm, hookworm)

This medicine is for use in adults and children over 1 year.

You or your child has been advised to take WORMSTOP® 500 because you have a worm infection. Worms can infect anyone. It does not necessarily mean that your hygiene is poor.

2. What you need to know before you take WORMSTOP® 500

Do not take WORMSTOP® 500

- If you are hypersensitive (allergic) to mebendazole or any of the other ingredients of WORMSTOP® 500 (listed in section 6).
- If your child is younger than 1 year
- If you are pregnant
- If you are taking metronidazole used for certain infections.

Warnings and precautions

Take special care with WORMSTOP® 500:

- If you have inflammation of the liver
- If you have changes in liver enzymes (shown in blood tests)
- If you have inflammation of the kidneys
- If you have a reduction in white blood cells (shown in blood tests). You may get more infections.
- If your child has convulsions (seizures). WORMSTOP® 500 should only be given to children under 1 year of age if your doctor has specifically prescribed it.

Other medicines and WORMSTOP® 500

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

If you are taking WORMSTOP® 500 do not take following medicines:

- Metronidazole - for certain infections
- Cimetidine - for excess stomach acidity

Ask your doctor for advice before taking any medicine.

Pregnancy and breast-feeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Ask your doctor or pharmacist if you are breast-feeding.

Driving and using machines

This medicine is not likely to affect you being able to drive or use any tools or machines.

3. How to take WORMSTOP® 500

Do not share medicines prescribed for you with any other person.

Always take **WORMSTOP® 500** exactly as prescribed in this leaflet or as your doctor or pharmacist or nurse has told you. Check with your doctor or pharmacist or nurse if you are not sure.

The usual dose is:

Whipworm; Hookworm; Large Roundworm; Pinworm:

Adults and children older than 1 year: One tablet (500 mg) given as a single dose. The tablets may be crushed and given with some liquid for children.

WORMSTOP® 500 is easily accepted even by children. The tablet may be crushed and given with some liquid.

If you take more WORMSTOP® 500 than you should

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

If you forget to take WORMSTOP® 500

- Do not take the missed dose
- Take your next dose at the usual time, and then keep taking your medicine as your doctor has told you
- Do not take a double dose to make up for a forgotten dose.

If you stop taking WORMSTOP® 500

Do not stop taking your medicine without consulting your doctor.

4. Possible side effects

WORMSTOP® 500 can have side effects.

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

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

- Sudden swelling of your face or throat. Hives (also known as nettle rash or urticaria), severe irritation, reddening or blistering of your skin. These may be signs of a severe allergic reaction
- Blistering of your skin, mouth, eyes and genitals
- Fits (convulsions)

These are all very serious side effects. If you have them, you may have had a serious reaction to WORMSTOP® 500. 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:

- Palpitations
- Increased heart rate.

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:

- Stomach pain

Less frequent side effects:

- Stomach discomfort
- Diarrhoea
- Wind
- Feeling sick (nausea) or being sick (vomiting)
- Rash
- Inflammation of the liver

- Changes in liver enzymes (shown in blood tests)
- Inflammation of the kidneys
- Reduction in white blood cells (shown in blood tests). You may get more infections
- Unusual hair loss
- Dizziness

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 or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of WORMSTOP® 500.

5. How to store WORMSTOP® 500

- Store all medicines out of reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month.
- Store at or below 25 °C.
- Keep the blisters in the outer carton in order to protect from light.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What WORMSTOP® 500 contains

The active substance is mebendazole.

The other ingredients are:

Calcium hydrogen phosphate, colour sunset yellow FCF (C.I.15985), flavour orange DC-116 PH, gelatin, magnesium stearate, maize starch, purified talc, sodium carboxy methyl cellulose, sodium lauryl sulphate, saccharin, vanillin.

What WORMSTOP® 500 looks like and contents of the pack

Light orange coloured, orange flavoured, smooth, capsule shaped biconvex uncoated tablets.

Cartons containing one strip pack of 1 tablet, 20 strip packs of 1 tablet.

Holder of Certificate of Registration

RANBAXY PHARMACEUTICALS (PTY) LTD

14 Lautre Road,

Stormill, Ext.1,

Roodepoort, 1724

South Africa

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REGISTRATION NUMBER(S)

31 / 12 / 0527 (S.A.)

S2	Bot 0500777 (Botswana)
NS2	04/12/1633 (Namibia)

**Ranbaxy Pharmaceuticals (Pty) Ltd
WORMSTOP 500 (31/12/0527)**

**Tablets, 500 mg
(Mebendazole)**

Date of Submission: 24 August 2021

Access to the corresponding Professional information

To follow