

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S1

WORMSTOP® SUSPENSION

WORMSTOP® 100 (TABLETS)

(Mebendazole)

WORMSTOP® SUSPENSION: Contains sugar: Sorbitol solution (70 % non-crystallising) 2 g/
5 ml

WORMSTOP® 100 (TABLETS): Sugar free, Artificially sweetened: Sodium saccharin 2 mg/
tablet

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

WORMSTOP® is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use WORMSTOP® carefully to get the best results from it.

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

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

The name of your medicine is WORMSTOP® SUSPENSION or

WORMSTOP® 100 (referred to as WORMSTOP® in this leaflet). WORMSTOP® contains a medicine called mebendazole. It is one of a group of medicines called 'anthelmintics'.

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

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

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

You or your child has been advised to take WORMSTOP® 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®

Do not take WORMSTOP®

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

Warnings and precautions

Take special care with WORMSTOP®:

- 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® should only be given to children under 1 year of age if your doctor has specifically prescribed it.

Other medicines and WORMSTOP®

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

If you are taking WORMSTOP® 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.

WORMSTOP® contains a sugar: sorbitol 70 % solution

This may cause gastrointestinal discomfort and have a mild laxative effect.

3. How to take WORMSTOP®

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

Always take WORMSTOP® 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 Round Worm; Pinworm; *Ternidens Deminutus*;
Infestations by *Moniliformis moniliformis*:

Tablets

One tablet (100 mg) twice daily (morning and evening) for three consecutive days. This standard dosage applies to adults, children and infants over the age of 1 year.

Suspension

One medicine measure (5 ml) twice daily (morning and evening) for three consecutive days. This standard dosage applies to adults, children and infants over the age of 1 year.

Tapeworm (*Taenia spp*):

Tablets

One tablet (100 mg) twice daily (morning and evening) for six consecutive days. This standard dosage applies to adults, children and infants.

Suspension

One medicine measure (5 ml) twice daily (morning and evening) for six consecutive days. This standard dosage applies to adults, children and infants.

Threadworm (*Strongyloides stercoralis*):

Tablets

Adults: Two tablets (200 mg) twice daily (morning and evening) for three consecutive days.

Children: One tablet (100 mg) twice daily (morning and evening) for three consecutive days.

Suspension

Adults: Two medicine measures (10 ml) twice daily (morning and evening) for three consecutive days.

Children: One medicine measure (5 ml) twice daily (morning and evening) for three consecutive days.

Tablets: WORMSTOP® is easily accepted even by children but may be crushed and given with some liquid.

If you take more WORMSTOP® 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®

- 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®

Do not stop taking your medicine without consulting your doctor.

4. Possible side effects

WORMSTOP® can have side effects.

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

If any of the following happens, stop taking WORMSTOP® 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®. 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®**.

5. How to store WORMSTOP®

- Store all medicines out of reach of children.
- Do not use this medicine after the expiry date which is stated on the label, carton and blister.
The expiry date refers to the last day of that month.
- Store at or below 25 °C.

- WORMSTOP® 100 (TABLETS): 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® contains

The active substance is mebendazole.

WORMSTOP® SUSPENSION

Each 5 ml contains: Mebendazole 100 mg

The other ingredients are:

Citric acid monohydrate, methyl hydroxybenzoate, propylene glycol, propyl hydroxybenzoate, polyoxyl 40 hydrogenated castor oil, mix fruit BUS29900S flavour, polysorbate-80, simethicone, sodium benzoate, sodium citrate, sorbitol solution (70 % non-crystallising), xanthan gum.

PRESERVATIVES

Methylparaben 0,18 % *m/v*

Propylparaben 0,02 % *m/v*

Sodium benzoate 0,2 % *m/v*

WORMSTOP® 100 (TABLETS)

Each tablet contains: Mebendazole 100 mg

The other ingredients are:

Date of Submission: 24 August 2021

Calcium hydrogen phosphate, gelatin, maize starch, magnesium stearate, orange DC116 flavour, purified talc, sodium lauryl sulphate, sodium saccharin, sunset yellow colour index No. 15985, vanillin.

What WORMSTOP® looks like and contents of the pack

WORMSTOP® SUSPENSION: A white to off-white, opaque, viscous suspension with characteristic fruit smell.

WORMSTOP® 100 TABLETS: Light orange coloured, orange flavoured, smooth, round, flat uncoated tablets with bevelled edges on both sides.

WORMSTOP® SUSPENSION:

Amber glass bottles containing 30 ml WORMSTOP® SUSPENSION.

WORMSTOP® 100 (TABLETS):

Blister packs of 6, 10 x 6, 24 x 6 and 40 x 6 tablets.

Holder of Certificate of Registration

RANBAXY PHARMACEUTICALS (PTY) LTD

14 Lautre Road,

Stormill, Ext.1,

Roodepoort, 1724

South Africa

This leaflet was last revised in

30 October 2021

Registration Number

WORMSTOP® SUSPENSION : 31 / 12 / 0248

S2	Bot 0500756 (Botswana)
NS2	04/12/1631 (Namibia)

Ranbaxy Pharmaceuticals (Pty) Ltd
WORMSTOP SUSPENSION (31/12/0248)
WORMSTOP 100 (31/12/0526)

(Mebendazole)
Suspension, 100mg/5ml
Tablets, 100 mg

Date of Submission: 24 August 2021

WORMSTOP ® 100: 31 / 12 / 0526

S2	Bot 0500778 (Botswana)
NS2	04/12/1632 (Namibia)

Access to the corresponding Professional information

To follow