#### **Consumer Medicine Information**

### What is in this leaflet

This leaflet answers some of the common questions about VERMOX. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits.

If you have any concerns about using VERMOX, ask your doctor or pharmacist.

 $\label{lem:conditional} \textbf{Keep this leaflet with your VERMOX.}$ 

You may need to read it again.

### What VERMOX is used for

VERMOX is used for the treatment of threadworm in adults and children over 2 yrs old.

VERMOX can also be used under medical supervision for the treatment of infestations with other type of worms such as roundworm, hookworm and whipworm.

In addition to taking VERMOX you can help prevent worm reinfestation as well as infestation in other people, by understanding a few simple facts about worms.

#### THREADWORM

Threadworm is an intestinal infestation caused by Enterobius vermicularis. This is the most commonly occurring worm in Australia and New Zealand. The infestation is acquired by swallowing the eggs.

Threadworms look like tiny white threads and live in the bowel, attached to the lining. Two weeks after infestation, the female worm may begin producing eggs. Usually at night, the worms travel to the anus where they lay their eggs. The worms are often observed around the anal region early in the morning. They sometimes cause itching. This is why restless sleep is a frequent sign of threadworms, especially in children. Scratching will cause threadworm eggs to stick to the fingers. Reinfestation will result if the fingers are placed in the mouth.

The eggs, which are too small to see, stick to whatever they come in contact with e.g. bedcloths, underwear, hands and food touched by contaminated hands. Even eggs floating in the air can be swallowed and cause infestation.

Threadworms are easily transmitted and frequently the whole family becomes infested. When a family member becomes infested by threadworm the entire family should receive treatment. Even the cleanest and most careful people can become infested.

### HOOKWORM, WHIPWORM AND ROUNDWORM

These worms are rare in most areas of Australia and New Zealand where effective sewerage systems have reduced the risk of infestation. Symptoms are generally more serious than with threadworm. If you suspect a rare worm infestation you should see your doctor.

Ask your doctor or pharmacist if you have any questions about this medicine.

### Before you take VERMOX

Evidence of worm infestation should be present before treating.

When you must not take it

Do not take VERMOX if you know you are allergic to it or any other medicines containing mebendazole or similar medicines or any of the ingredients listed at the end of the leaflet.

Symptoms of an allergic reaction may include:

- · rash, itching or hives on the skin
- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body

Do not use VERMOX in children under 2 years of age, unless directed by your doctor.

Do not take VERMOX if the packaging is torn or shows signs of tampering.

Do not take VERMOX after the expiry date (month and year) printed on the pack has passed. If you take this medicine after the expiry date it may not work as well.

Before you start to take it

### Tell your doctor or pharmacist if you are pregnant or breast-feeding.

Your doctor or pharmacist will advise whether you should take VERMOX.

#### Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may interfere with VERMOX. These include:

- cimetidine, a medicine used to treat stomach ulcers;
- metronidazole, a medicine used to treat infections.

These medicines may be affected by VERMOX, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

### How to take VERMOX

### How much to take

### For treatment of threadworm

Adults and children of 2 years and over: Tablet: A single dose of 1 tablet (100 mg)

or

Suspension: 1 x 5 mL measuring spoon (100mg) of the oral suspension as a single dose.

It can take up to 3 days for the dead worms to pass through the system. If reinfestation occurs after this time, take 1 tablet (100 mg) or 1 measuring spoon (5 mL) of the oral suspension again after 2 to 4 weeks.

### For treatment of hookworm, whipworm and roundworm (use only under medical advice)

Adults and children of 2 years and over:

Tablet: A single dose of 1 tablet (100 mg)

or

Suspension:  $1 \times 5 \text{ mL}$  measuring spoon (100mg) of the oral suspension in the morning and evening for three consecutive days.

#### How to take it

Use of suspension is recommended in young children or people having difficulty swallowing tablets.

VERMOX tablets and suspension are to be taken by mouth.

VERMOX tablets may be swallowed whole with liquid, chewed or crushed and mixed with food or juice for children.

Shake the suspension well before use.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (numbers below) for advice, or go to Accident and Emergency at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep telephone numbers for these places handy.

Poisons Information Centre telephone numbers:

Australia: 13 11 26

#### New Zealand: 0800 POISON or 0800 764 766

If you take too much VERMOX, you may experience abdominal cramps, nausea, vomiting or diarrhoea.

If you are not sure what to do, contact your doctor or pharmacist.

### While you are taking VERMOX

### Things you and other members of your family should do that may help prevent reinfestation

- Take a daily bath and shower
- Wash hands and fingernails with soap frequently during the day, especially before eating and after using the toilet;
- Change underwear daily. Snug fitting underpants worn day and night help to prevent scratching;
- Keep nails short, avoid scratching anal area and nail biting;
- Clean the bedroom floor thoroughly for 3 days after treatment, by vacuuming or damp mopping. Avoid dry sweeping as this may stir up dust;
- After treatment, wash bed linen and night clothes (don't shake them);
- Keep toilet seats clean.

### Side Effects

# Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using VERMOX.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some side effects.

VERMOX may have some unwanted side effects in a few people, even though it is usually well tolerated at the recommended dose.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

### Tell your doctor or pharmacist if you experience any of the following:

- nausea or vomiting
- · stomach pain
- diarrhoea

## Tell your doctor or pharmacist immediately if you notice the following and do not take your next dose of VERMOX:

- · shortness of breath or wheezing
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- sudden or severe blisters, itching, skin rash, hives
- · flaking or peeling of skin

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

Other side effects not listed above may also occur in some people. Tell your doctor if you feel unwell when you are taking, or soon after you have finished taking VERMOX.

### After using VERMOX

### Storage

Keep VERMOX in a cool dry place where the temperature stays below  $30\ deg\ C.$ 

Do not store VERMOX or any other medicines in a bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

### Keep VERMOX where young children cannot reach it.

A locked cupboard at least one-and-a-half metres (1.5m) above the ground is a good place to store medicines.

#### Disposal

Once you have finished using VERMOX, or your medicine has passed its expiry date, ask your pharmacist what to do with any that is left.

### **Product Description**

### What it looks like

VERMOX tablet is a slightly orange, circular, flat, bevel-edged, half-scored tablet with the inscription "JANSSEN" on one side and "Me/100" on the other side, with an orange flavour.

VERMOX suspension is a white, banana-flavoured suspension.

### Ingredients

Each VERMOX tablet contains:

- 100 mg of mebendazole as the active ingredient.
- Cellulose microcrystalline, sodium starch glycollate, talc-purified, starch-maize, saccharin-sodium, cottonseed oil hydrogenated, magnesium stearate, orange flavour, silica - colloidal anhydrous, sodium lauryl sulphate and sunset yellow SCF (orange yellow S (E110)),.

Each 5mL of VERMOX suspensions contains:

- 100 mg of mebendazole as the active ingredient.
- Cellulose microcrystalline, carmellose sodium (carboxymethylcellulose sodium), methylcellulose, sucrose, sodium lauryl sulphate, methyl hydroxybenzoate, propyl hydroxybenzoate, banana flavour 51452t, citric acid monohydrate and water-purified.

### Sponsor

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### The Australian Registration Number

Tablet - AUST R 125654 Suspension - AUST R 54703

This leaflet was prepared in September 2006.