PACKAGE LEAFLET: INFORMATION FOR THE USER

Vermox[®] 100 mg tablets

Mebendazole

Vermox is a registered trademark

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor or pharmacist
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- If you get side effects and they become serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

In this leaflet

- 1. What Vermox tablets are and what they are used for
- 2. Before you use Vermox tablets
- 3. How to use Vermox tablets
- 4. Possible side effects
- 5. How to store Vermox tablets
- **6.** Further information
- 7. Further advice regarding worms

1. What Vermox tablets are and what they are used for

The name of your medicine is Vermox 100 mg tablets (referred to as Vermox tablets in this leaflet). Vermox tablets contain a medicine called mebendazole. It is one of a group of medicines called 'anthelmintics'.

Vermox tablets are used to treat worm infections of the gut such as:

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

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

2. Before you use Vermox tablets

Do not use Vermox tablets if:

- You are allergic to anything in Vermox tablets (listed in section 6 below)
- Your child is under 2 years old

Do not use this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before using Vermox tablets.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription, herbal medicines, dietary supplements or vitamins.

In particular tell your doctor or pharmacist if you are taking:

- Metronidazole for certain infections
- Cimetidine for excess stomach acidity

Talk to your doctor before using Vermox tablets if you are taking any of these medicines.

Pregnancy and breast-feeding

- Do not take Vermox tablets if you are pregnant, think you may be pregnant or might become pregnant
- Ask your doctor or pharmacist for advice if you are breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

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

Important information about some of the ingredients of Vermox

This medicine contains 0.06 mg of sunset yellow (E110). This ingredient may cause allergic reactions.

3. How to use Vermox tablets

Always use Vermox tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth
- The dose will depend on which type of worm you have
- Crush the tablet before giving it to your child. Always supervise a child if they are taking this medicine
- Chew the tablets or swallow them whole
- You do not need to use a laxative or change your diet

How much you should take

Adults and children over 2 years old

For threadworms (pinworms):

one tablet

A single Vermox tablet will kill threadworms. Your doctor may tell you to take a second tablet after two weeks in case of re-infection.

For other common worm infections:

 one tablet two times a day (morning and evening) for three consecutive days or as directed by your doctor.

If you take more Vermox tablets than you should

If you take more Vermox tablets than you should, talk to a doctor or go to the nearest hospital casualty department straight away.

If you forget to take Vermox tablets

- 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 have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Vermox tablets can cause side effects, although not everybody gets them.

Stop using Vermox tablets and tell your doctor straight away if you notice or suspect the following serious side effects. You may need urgent medical treatment.

- 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)

Tell your doctor or pharmacist if you notice any of the following side effects:

Common (affects less than 1 in 10 people)

Stomach pain

Uncommon (affects less than 1 in 100 people)

- Stomach discomfort
- Diarrhoea
- Wind

Rare (affects less than 1 in 1,000 people)

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

If you get side effects and they become serious or if you notice any other side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Vermox tablets

- Keep out of the reach and sight of children
- Do not use Vermox tablets after the expiry date which is stated on the label. The expiry date refers to the last day of that month
- There are no special storage conditions

Medicines should not be disposed of via wastewater or household waste.
These measures will help protect the environment. Return any leftover
Vermox tablets to your pharmacist

6. Further information

The active substance in Vermox tablets is mebendazole. The tablets contain 100 mg of mebendazole.

The other ingredients are microcrystalline cellulose, sodium starch glycolate, talc, maize starch, sodium saccharin, magnesium stearate, cottonseed oil hydrogenated, orange flavour, colloidal anhydrous silica, sodium laurilsulfate, sunset yellow (E110).

What Vermox tablets look like and contents of the pack

Vermox tablets are flat, circular, pale orange tablets with "Me/100" on one side and "JANSSEN" on the other.

Vermox tablets are available in blister packs containing 6 tablets.

The product licence is held by:

JANSSEN-CILAG LTD, 50-100 Holmers Farm Way, High Wycombe, Buckinghamshire HP12 4EG, UK

Vermox tablets are made by:

Janssen-Cilag SpA, Via C Janssen, 04010 Borgo San Michele, Latina, Italy OR

McGregor Cory Limited, Middleton Close, Banbury, Oxfordshire, OX16 4RS, UK

For information in large print, tape, CD or Braille, telephone 0800 7318450.

This leaflet was last approved in March 2011.

7. Further advice regarding worms

Threadworms (pinworms) produce large numbers of tiny eggs. They may be present in house dust and can stick to clothing, carpets, towels and bed linen. They can also be picked up by contact with someone who already has worms. Because the eggs are so small, it is very easy for them to be swallowed. Then they pass into the bowel where they grow into worms. The female lays her eggs at night around the bottom. It is this that causes the "itchy bottom" and leads to scratching. The eggs are then transferred to the fingers and finger nails, and can easily get into the mouth by finger sucking or nail biting. The life cycle of an adult worm can be as long as six weeks.

To stop you and your family infecting others or re-infecting yourselves, follow the advice below for at least 6 weeks:

- Keep nails short
- Discourage nail biting or finger sucking

- Wear pyjamas or underclothes in bed
- Each morning, 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.