PACKAGE LEAFLET: INFORMATION FOR THE USER

Vermox[®] 100 mg/5 ml oral suspension

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

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1. What Vermox suspension is and what it is used for

The name of your medicine is Vermox 100 mg/5 ml oral suspension (referred to as Vermox suspension in this leaflet). It contains a medicine called mebendazole. It is one of a group of medicines called 'anthelmintics'. Vermox suspension 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 aged over 2 years. You or your child has been advised to take Vermox 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. Before you use Vermox suspension

Do not use Vermox suspension if:

- You are allergic to anything in Vermox suspension (listed in section 6 below)
- You are pregnant

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 suspension.

Warnings and precautions

- Vermox suspension should not be given to children under 2 years of age
- Vermox should only be given to younger children if your doctor has specifically prescribed it. Your doctor will decide whether Vermox is suitable for your child. You must follow the doctor's instructions carefully.
- Convulsions (seizures) have been reported, including in infants. Vermox should only be given to children under 2 year of age if your doctor has specifically prescribed it.

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 suspension if you are taking any of these medicines.

Pregnancy and breast-feeding

- Do not take Vermox suspension 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

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 suspension

Vermox suspension contains

- Sucrose. If your doctor has told you that you are intolerant of 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 suspension
- This medicine contains less than 1 mmol sodium (23 mg) per mL, that is to say essentially 'sodium-free'.

3. How to use Vermox suspension

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

Using this medicine

- Take this medicine by mouth
- The dose will depend on which type of worm you have
- Always shake the bottle thoroughly before use
- Use the 5 ml cup in the pack to measure the dose
- Always supervise a child if they are taking this medicine
- You do not need to use a laxative or change your diet
- Consider using Vermox oral suspension for patients such as young children who are unable to swallow the tablet
- Vermox should only be given to children under 2 year of age if your doctor has specifically prescribed it.

How much you should take

Adults and children over 2 years old

For threadworms (pinworms):

• one 5 ml measuring cup (or spoonful) of suspension

A single dose of Vermox suspension will kill threadworms. Your doctor may tell you to take a second dose after 2 weeks in case of re-infection.

For other common worm infections:

 one 5 ml measuring cup (or spoonful) of suspension two times a day (morning and evening) for three consecutive days or as directed by your doctor

Directions for opening the bottle:

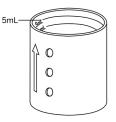
The bottle comes with a child-proof cap, and should be opened as follows:

push the plastic screw cap down, while turning it counter clockwise.



How to use the measuring cup:

Use the measuring cup just as it sits on the bottle. Make sure that the side with the graduation (the side that holds less) is uppermost; that is the side you have to fill. When the arrow on the side points up, the correct side is uppermost. Fill the dosing cup until the 5 mL line is reached.



If you take more Vermox suspension than you should

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

If you forget to take Vermox suspension

- 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 suspension can cause side effects, although not everybody gets them.

Stop using Vermox suspension 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
- Feeling sick (nausea) or being sick (vomiting)

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

- Rash
- Inflammation of the liver
- Changes in liver enzymes (shown in blood tests)
- Inflammation of the kidneys (when treated for dog tapeworm or fox tapeworm)
- Reduction in white blood cells (shown in blood tests). You may get more infections (when treated for dog tapeworm or fox tapeworm)
- Unusual hair loss
- Dizziness

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: <u>www.mhra.gov.uk/yellowcard</u> or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Vermox suspension

- Keep out of the sight and reach of children
- Shake well before use
- Do not use Vermox suspension 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 suspension to your pharmacist

6. Further information

The active substance in Vermox suspension is mebendazole. Each millilitre (ml) contains 20 mg of mebendazole.

The other ingredients are sucrose, microcrystalline cellulose and carmellose sodium, methylcellulose, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), sodium laurilsulfate, banana flavour, citric acid monohydrate and purified water.

What Vermox suspension looks like and contents of the pack

Vermox suspension is a white banana flavoured liquid supplied in 30 ml bottles with a measuring cup marked for 2.5 ml and 5 ml.

The product licence is held by:

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

Vermox suspension is made by:

Janssen Pharmaceutica NV, Turnhoutseweg 30, B-2340 Beerse, Belgium 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 revised in February 2024.

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.