

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Vermox™ 100mg tablets (Mebendazole)

- This medicine is used to treat threadworm and other common worm infections of the gut.
- This medicine is for use by adults and children aged over 2 years.
- Do not use this medicine:**
  - There are some people who should not use this medicine. *To find out if you are one of them see section 2.*
  - If you have ever had a **bad reaction** to any of the ingredients. *To view the list of ingredients see section 6.*
- Speak to your doctor:**
  - If you are taking any other medicines. *See section 2.*
  - Follow the dosage instructions carefully.** These are shown in the dosage table. *See section 3.*

**Now read this whole leaflet carefully before you use this medicine.** Keep the leaflet: you might need it again.

#### 1. What the medicine is for

Vermox Tablets is a medicine which is used to treat threadworms (sometimes known as pinworms) and other common worm infections e.g. whipworm, roundworm, hookworm. The tablets contain mebendazole, which is one of a group of medicines called 'anthelmintics'.

This medicine is for use in adults and children aged over 2 years.

#### 2. Before taking this medicine

This medicine is suitable for most adults and children, but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist.

##### Do not use this medicine...

- If you are **hypersensitive** (allergic) to any of the ingredients.
- If it is for a **child under 2 years**.
- If you are **pregnant or think you are pregnant**.
- If you are **breast-feeding**.

If any of these apply to you, **get advice from a doctor or pharmacist before using Vermox Tablets.**

##### Talk to your doctor or pharmacist...

- If you are taking any **other medicines, including:**
  - Metronidazole* (a drug used to treat **bacterial and protozoan infections**) as a serious skin reaction can rarely occur.
  - Cimetidine* (a medicine used to treat excess **stomach acidity**).

If you are not sure about any of the medicines you are taking, show the bottle or the pack to your pharmacist.

If any of the bullet points apply to you now or in the past, **talk to a doctor or pharmacist.**

##### If you are pregnant or breast-feeding

Do not take this medicine if you are pregnant or breast-feeding.

##### Special warnings about this medicine

Since threadworms can spread very easily, it is strongly recommended that all the family (except pregnant, breast-feeding women or children under 2) are treated at the same time and that suitable hygiene precautions are followed to prevent re-infection (see Section 7 of this leaflet for more advice).

##### Some of the ingredients can cause problems.

- Sunset yellow FCF (E110) may cause allergic reactions.

#### 3. How to take this medicine

##### Check the table below to see how much medicine to take

- Do not take more than the stated dose shown below.
- For oral use only.
- The tablets may be either chewed or swallowed whole. Crush the tablet before giving it to a young child.
- Always supervise a child if they are taking this medicine.

##### Children under 2 years old

This medicine is not recommended for children aged under 2 years old.

##### Adults and children aged 2 years and older

| Threadworm infection ( <i>Enterobiasis</i> )   |  |
|--|--|
| Age  | Dose   |
| Adults and children aged 2 years and over  | Take one tablet. After two to four weeks take another tablet.  |
| • If symptoms do not disappear within a few days, speak to your doctor.                          |  |
| Common worm infections ( <i>Ascariasis, trichuriasis, ancylostomiasis and mixed infections</i> ) |  |
| Age  | Dose   |
| Adults and children aged 2 years and over  | Take one tablet twice daily (i.e. morning and evening) for three consecutive days or as directed by your doctor. |

| Other worm infections ( <i>Taeniasis and strongyloidiasis</i> ) |   |
|---|---|
| Age   | Dose  |
| Adults  | Take two tablets twice daily (morning and evening) for three consecutive days.  |
| Children 2 years and over                                       | Take one tablet twice daily (i.e. morning and evening) for three consecutive days.<br>Your doctor will advise the appropriate dose depending on the type of worm infection. |

##### If anyone takes too much

If anyone takes too many Vermox Tablets, contact a doctor or your nearest Accident & Emergency department taking this leaflet and pack with you.

#### 4. Possible side-effects

Vermox Tablets can have side-effects, like all medicines, although these don't affect everyone and are usually mild.

##### If you experience any of the following, stop using the medicine and seek immediate medical help:

**Rarely:** (less than 1 in 1,000 people are affected)

- Convulsions (seizure/fit) in infants.
- Allergic reactions including unexplained wheezing, shortness of breath, sudden swelling of your face or throat and hives (also known as 'nettle rash' or 'urticaria').
- Skin rashes (which may be severe and include blistering or peeling of the skin) and itching, and may be accompanied by a high temperature.

##### If you experience any of the following, stop using the medicine and talk to your doctor:

**Commonly:** (fewer than 1 in 10 people are affected)

- Stomach pain.

**Uncommonly:** (fewer than 1 in 100 people are affected)

- Stomach discomfort.
- Diarrhoea.
- Wind.

##### Other effects which may occur include:

**Rarely:** (fewer than 1 in 1,000 people are affected)

- Dizziness.
- Inflammation of the kidneys or liver or abnormal liver function.
- Reduction in white blood cells (which reduces the body's defences against infections).
- Unusual hair loss.

##### 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

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

E-mail: medsafety@hpra.ie

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

#### 5. Storing this medicine

- Do not store above 25°C.
- Keep the blister in the outer carton in order to protect from light.
- Keep this medicine out of the sight and reach of children.**
- Do not use this medicine after the expiry date (Exp) which is marked on the carton and blister strips. This refers to the last day of that month.
- Do not use this medicine if you notice discoloration, damage or any other signs of deterioration.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

#### 6. Further information

##### What's in this medicine?

**The active ingredient in Vermox Tablets is:** Mebendazole 100mg per tablet.

**Other ingredients:** microcrystalline cellulose, sodium starch glycollate, talc, maize starch, saccharin sodium, magnesium stearate, hydrogenated vegetable oil, tetraorange, colloidal dioxide silica, sodium laurylsulfate and Sunset Yellow (E110).

##### What the medicine looks like

Each flat, circular, pale orange tablet is inscribed with 'Me/100' on one side and 'JANSSEN' on the other, and contains 100mg of mebendazole. The tablets are supplied to the pharmacist in packs of 6 tablets.

Vermox is manufactured by:  
FAMAR SA (LAB B), Anthousas Ave, 153 44 Anthousa, Athens, Greece.

Procured from within the EU and repackaged by:  
Doncaster Pharmaceuticals Group Ltd, Kirk Sandall, Doncaster, DN3 1QR, UK.

PPA holder: Imbat Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

Distributed by: Eurodrug Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

PPA No: 1151/145/2

Leaflet revision and issue date (Ref): 15.02.17

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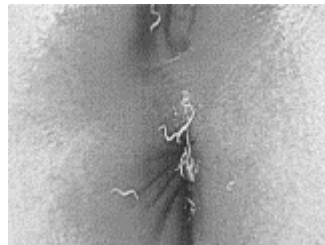
## 7. Further advice regarding threadworms

### What are threadworms?

Threadworms (*Enterobius vermicularis*) are tiny white parasitic worms that live in the bowel. They are approximately half an inch long and resemble threads of white cotton – hence the name threadworms.

### How common are threadworms?

Threadworms are extremely common, especially in children. It is estimated that up to 40% of children under ten years in the UK may be affected at any one time. Once a child has threadworms, it is very easy for the rest of the family to get them.



### How do they spread?

Threadworms spread by producing large numbers of tiny eggs. These eggs are so small that they cannot be seen with the naked eye. When swallowed, the eggs pass into the bowel where they hatch into worms. When mature, the female threadworm lays her eggs at night around the anal area, which causes an "itchy bottom". The resulting irritation can cause intense scratching, which may lead to further infections if the skin becomes sore or broken. Scratching also allows transfer of the eggs to the fingers and nails. Eggs can then be easily transferred to the mouth by finger sucking or nail biting, causing re-infection, and spread to other members of the family by direct contact or via food, towels and bed linen etc.

Threadworm eggs are present in house dust; they stick to clothing, carpets, towels and bed linen; they can also be picked up in garden soil, or on unwashed vegetables and salads. Because the eggs are so small and so widespread, it is very easy for them to be swallowed.

### Lifecycle of threadworms

#### 2 – 6 weeks.

1. Scratching the bottom transfers eggs to fingers and from there back to the mouth or to others either by direct contact or via food, bed linen etc.
2. Eggs swallowed.
3. Female worms migrate to the anal area to lay eggs at night.



### Are they harmful?

Threadworms do not cause serious damage but they are an irritating problem. Besides the intense itching, which can be distressing and embarrassing for the sufferer, they can also lead to disturbed sleep, tummy aches, irritable crying, loss of appetite or an unusually large appetite. Sometimes, threadworms can be transferred to the vagina and urinary passage. This can result in vaginal irritation and discharge, symptoms of cystitis or bed wetting.

### Who gets threadworms?

Anyone, although they are more common in children. It does not mean that your family or your home are not clean. Because threadworms are passed on very easily it is a wise precaution to treat everyone in the family at the same time.

### How can you tell if someone has threadworms?

The most obvious sign of threadworms is intense itching in the anal area, especially at night, although this does not affect everyone. If your children frequently scratch their bottoms, suffer from disturbed sleep or become irritable, it is worth checking their motions and the anal area for tiny white threads. If one member of the family has threadworms, the rest of the family may already have picked up the infection, even if they do not have obvious symptoms. Important note: Threadworms only affect humans, they do not affect pets.

### General advice

To ensure that you and your family do not infect others or re-infect yourselves, you should also follow the hygiene measures listed 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 thoroughly around the bottom.
- Provide a towel for the exclusive use of each member of the household.
- Change clothes regularly.
- Regularly wash and iron bed linen.
- Thoroughly wash hands and nails after using the toilet and before each meal.



### Do you need to keep your children off school?

No. As long as the children are treated and the general hygiene measures outlined above are followed, there is no reason to keep them off school.

### How can you stop the problem coming back?

Threadworms are easily treated but unless the following precautions are taken the problem may recur:

- Follow the general advice above.
- Make sure everyone in the family is treated at the same time.

## Blind or partially sighted?

Is this leaflet hard to see or read?

Call 00 44 1302 365000 (Regulatory)

Please be ready to give the following information:

Product name: Vermox 100mg tablets

Reference No: 1151/145/2