

PART III: CONSUMER INFORMATION

PrVERMOX®

Mebendazole Tablets, House Std.

This leaflet is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about VERMOX®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

VERMOX® is a drug used to **treat infestations of the intestine** with one or several of the following **parasitic worms**:

- pinworm (*Enterobius vermicularis*);
- roundworm (*Ascaris lumbricoides*);
- whipworm (*Trichuris trichiura*);
- hookworm (*Ancylostoma duodenale*; *Necator americanus*);
- threadworm (*Strongyloides stercoralis*);
- tapeworm (*Taenia solium*).

What it does:

VERMOX® is believed to disrupt the intestinal function of the parasitic worms, which helps end the worm infestation.

When it should not be used:

You should not take VERMOX® if you are allergic to mebendazole, or to any of the non-medicinal ingredients in the product (see **What the non-medicinal ingredients are**).

What the medicinal ingredient is:

Mebendazole

What the non-medicinal ingredients are:

Colloidal anhydrous silica, cotton seed oil hydrogenated, corn starch, FD&C Yellow #6 (orange yellow S), magnesium stearate, microcrystalline cellulose, orange flavour, saccharin sodium, sodium lauryl sulphate, sodium starch glycolate and talc.

What dosage forms it comes in:

100 mg tablets

WARNINGS AND PRECAUTIONS

BEFORE you use VERMOX® talk to your doctor or pharmacist if:

- you are pregnant, or think you may be;
- you are breast-feeding or planning to breastfeed;
- you are taking cimetidine (medicine used for acid in the stomach);
- you are taking metronidazole (medicine used to treat bacterial and protozoan infections);

- you are taking any other medications, including prescription, over-the-counter, herbal or natural health products (See **INTERACTIONS WITH THIS MEDICATION**).

INTERACTIONS WITH THIS MEDICATION

Inform your doctor if you are taking cimetidine (medicine used for acid in the stomach). If so, your VERMOX® dosage might have to be adapted. The use of VERMOX® with metronidazole (medicine used to treat bacterial and protozoan infections) should be avoided.

PROPER USE OF THIS MEDICATION

Take the tablets with some liquid. You do not have to take VERMOX® with food. You do not have to follow a special diet or take products which stimulate the stools. The amount of VERMOX® you have to take will depend on the type of worm you are infected with. If in doubt, consult your doctor or pharmacist.

Tablets may be chewed or swallowed whole. For children 1 to 6 years old who have difficulty in swallowing tablets, crush the tablet before giving. Always supervise a child while they are taking this medicine.

Usual dose: Adults and Children over 2 years of age

Infestation with pinworm: Take 1 tablet as a single dose. After 2 and 4 weeks, take 1 tablet again. This is necessary to completely get rid of the infestation. The first treatment killed off the worms, but not their eggs. Those eggs might cause another infestation.

Infestation with whipworm, roundworm, hookworm, threadworm, tapeworm or with several worm species: Take 1 tablet in the morning and in the evening, for 3 days in a row.

If infestation continues after 3 weeks, contact your doctor.

Overdose:

If amounts higher than recommended are taken, blood, kidney, and liver disorders, some of which may be serious, may occur. Hair loss, which in some cases may be permanent, may also occur.

If you have taken too much VERMOX®, you might suffer from stomach cramps, nausea, vomiting and diarrhea. If this is the case, you should consult your doctor.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The following undesired effects have been reported and may occur during treatment with VERMOX®:

- dizziness;
- stomach aches and pains, intestinal gas, diarrhea, nausea and vomiting;
- skin rash;
- hives;
- hair loss, which in some cases may be permanent;
- blood and liver disorders;
- Inflammatory kidney disease and severely decreased number of white blood cells can occur with prolonged use of VERMOX® at doses substantially higher than recommended (much more than normally prescribed).

If any of the following symptoms occur, **contact your doctor immediately**:

- A severe skin disorder consisting of skin rashes, blisters on the skin and sores in the mouth, or on the eyes, anus or genitals region, along with fever;
- A severe hypersensitivity (allergic) reaction occurs after administration with symptoms such as swollen mouth, throat, extremities, difficulty breathing, shortness of breath, skin rash, itching, hives, flushing or fainting.
- Convulsions (seizures) have been reported, including in infants.

This is not a complete list of side effects. For any unexpected effects while taking VERMOX®, contact your doctor or pharmacist.

HOW TO STORE IT

VERMOX® tablets should be stored at room temperature (15–30°C) and protected from light.

Keep out of the sight and reach of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect® Canada website at: www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada
NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full Product Monograph, prepared for health professionals can be found at:
<http://www.janssen.com/canada> or by contacting the sponsor, Janssen Inc. at: 1-800-567-3331 or 1-800-387-8781.

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