FINAL PACKAGE INSERT

S1

VERMOX®
500 mg tablet

SCHEDULING STATUS

Schedule 1

PROPRIETARY NAME (and dosage form)

VERMOX® 500 mg tablet

COMPOSITION

Each tablet contains 500 mg Mebendazole polymorph C and 34 mg Lactose.

PHARMACOLOGICAL CLASSIFICATION

A.12 Anthelmintics, Bilharzia medicines, Filaricides, etc.

PHARMACOLOGICAL ACTION

Mebendazole is a broad-spectrum anthelmintic.

Mebendazole acts locally in the lumen of the gut by interfering with cellular tubulin formation in the intestines of worms. Mebendazole binds specifically to tubulin and causes ultrastructural degenerative changes in the intestine. As a result, the glucose uptake and the digestive functions of the worm are disrupted to such an extent that an autolytic process occurs

INDICATIONS

VERMOX® is indicated for the treatment of single and mixed helminth gastrointestinal infestations caused by:

- **Nematodes such as**:
- Trichuris trichiura (whipworm)

- Ancylostoma duodenale (hookworm)
- Necator americanus (hookworm)
- Ascaris lumbricoides (large roundworm)
- Enterobius vermicularis (pinworm)

CONTRA-INDICATIONS

VERMOX® should not be used in children below the age of 1 year.

VERMOX® is contraindicated in persons with a known hypersensitivity to the medicine or its components.

VERMOX® should not be given during pregnancy, as it is teratogenic in animals. (SEE PREGNANCY AND LACTATION)

Concomitant use of mebendazole and metronidazole should be avoided.

WARNINGS

There have been reports of reversible liver function disturbances, hepatitis, neutropenia and glomerulonephritis described in patients who were treated with dosages substantially above those recommended for prolonged periods of time.

[See “Known Symptoms of Overdosage and Particulars of Its Treatment”.]

INTERACTIONS

Concomitant treatment with cimetidine may inhibit the metabolism of mebendazole in the liver, resulting in increased plasma concentrations of VERMOX® especially during prolonged treatment.

Concomitant use of VERMOX® and metronidazole should be avoided.

PREGNANCY AND LACTATION

VERMOX® is contra-indicated during pregnancy and lactation. (See Contra-Indications).

Mebendazole has shown embryotoxic and teratogenic activity in rats and in mice at single oral doses.

It is not known whether mebendazole is excreted in human breast milk.

DOSAGE AND DIRECTIONS FOR USE

Whipworm; Hookworm; Large Roundworm; Pinworm:

Adults and children older than 1 year: One tablet (500 mg) given as a single dose. The tablets may be crushed and given with some liquid for children.

A single dose of VERMOX® 500 mg may not be sufficient to cure infestations with hookworm and whipworm (Trichuris) although a substantial reduction in egg count can be expected.

A second course of treatment should be given to those patients who are still infected three to four weeks after the first course.

In worm-eradication campaigns the standard course should be administered every quarter during the first year.

The efficacy of VERMOX® is dependent upon the duration of physical contact between drug and parasite.

For infants under 1 year of age, see "Contra-indications and “Special Precautions".

SIDE-EFFECTS AND SPECIAL PRECAUTIONS

There have been reports of reversible liver function disturbances, hepatitis and neutropenia described in patients who were treated with mebendazole at standard doses for indicated conditions.

These events, along with glomerulonephritis, have also been reported with dosages substantially above those recommended and with treatment for prolonged periods of time. Results from a case control study investigating an outbreak of Stevens Johnson Syndrome/toxic epidermal necrolysis (SJS/TEN) indicated a possible relationship between SJS/TEN and the concomitant use of VERMOX® and metronidazole. Further data on interactions are not available. Therefore, concomitant use of VERMOX® and metronidazole should be avoided.

Patients with high parasitic burdens when treated with VERMOX® have manifested diarrhoea and abdominal pain.

Clinical Trial Data

The safety of VERMOX® was evaluated in 6276 subjects who participated in 39 clinical trials for the treatment of single or mixed parasitic infestations of the gastrointestinal tract. In these 39 clinical trials, no adverse drug reactions (ADRs) occurred in ≥ 1% of VERMOX®-treated subjects. ADRs occurring in ≤ 1% of of VERMOX®-treated subjects are shown in Table 1.

Table 1. Adverse Drug Reactions Reported by < 1% of VERMOX®-Treated Subjects in 39 Clinical Trials

System/Organ Class
Adverse Reaction
Gastrointestinal Disorders
Abdominal Discomfort
Diarrhoea
Flatulence

Skin and Subcutaneous Tissue Disorders

Rash

Postmarketing Experience

Adverse drug reactions first identified during post-marketing experience with VERMOX® (mebendazole) are included below.

System/Organ Class	Adverse Reaction

Blood and lymphatic system disorders

Neutropenia

Immune System Disorders

Hypersensitivity including anaphylactic reaction and anaphylactoid reaction

Nervous System Disorders

Convulsions

Gastrointestinal Disorders

Abdominal pain

Hepatobiliary Disorders

Hepatitis, Abnormal liver function tests

Skin and subcutaneous Tissue Disorders

Toxic epidermal necrolysis, Stevens Johnson syndrome, Exanthema, Angioedema, Urticaria, Alopecia

Special Precautions

Convulsions in children, including in infants below one year of age, have been reported during post-marketing experience with VERMOX®. VERMOX® should not be given to children below 1 year of age. VERMOX® 500 mg or VERMOX® SD should not be used and VERMOX® 100 mg Tablets or VERMOX® 20mg/ml should only be given to very young children if their worm infections interfere significantly with the nutritional status and the physical development.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

In patients treated at dosages substantially higher than recommended or for prolonged periods of time, the following adverse reactions have been reported; liver function disturbances, hepatitis, neutropenia and glomerulonephritis. With the exception of glomerulonephritis, these also have been reported in patients who were treated with mebendazole at standard dosages.

In the event of accidental overdose, abdominal cramps, nausea, vomiting and diarrhoea may occur. If poisoning or excessive overdosage is suspected it is recommended, on general principles, that vomiting be induced or gastric lavage be performed, and such symptomatic supportive therapy be administered as appears indicated. Activated charcoal may be given.

IDENTIFICATION

A white to faintly cream-coloured, bevel-edged tablet with $\frac{"Me"}{500}$ inscription on the one side and "JANSSEN" on the other side.

PRESENTATION

Carton containing one blister pack of 1 tablet.

STORAGE INSTRUCTIONS

Store at or below 25ºC.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

W/12/42

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Johnson & Johnson (Pty) Ltd.

241 Main Road

RETREAT

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South Africa

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