

## MEBENDAZOLE TABLETS USP 100 mg

POM

### COMPOSITION:

Each uncoated tablet contains :  
Mebendazole USP 100 mg  
Excipients Q.S.

### THERAPEUTIC CLASS:

Broad-spectrum Anthelmintic

### PHARMACOLOGICAL ACTION:

Mebendazole inhibits the formation of worms microtubules and irreversibly blocks glucose uptake by the susceptible helminths, thereby depleting endogenous glycogen stored within the parasite that required for survival and reproduction of the helminth. Mebendazole does not affect blood glucose concentration in the host.

**Pharmacokinetics :** Mebendazole is poorly absorbed from the gastrointestinal tract. Peak plasma levels are reached in 2 to 4 hours. Mebendazole undergoes extensive first-pass elimination, being metabolised in the liver, eliminated in the bile as unchanged drug and metabolites and excreted in faeces. Only about 2% of a dose is excreted unchanged or as metabolites in the urine. Mebendazole is highly protein bound.

### INDICATIONS:

Mebendazole is indicated for the treatment of *Enterobius vermicularis* (pinworm), *Trichuris trichiura* (whipworm), *Ascaris lumbricoides* (common roundworm), *Ancylostoma duodenale* (common hookworm), *Necator americanus* (american hookworm) in single or mixed infections.

Efficacy varies as a function of such factors as pre-existing diarrhoea and gastrointestinal transit time, degree of infection, and helminth strains.

### CONTRAINDICATIONS:

Mebendazole is contraindicated in persons who have shown hypersensitivity to the drug.

### SPECIAL PRECAUTIONS & WARNINGS:

Patients receiving high doses of Mebendazole, such as those with echinococcosis, should be supervised closely with blood counts and liver function being monitored.

**Pregnancy :** During pregnancy, especially during the first trimester, Mebendazole should be used only if the potential benefit justifies the potential risk to the foetus.

**Nursing Mothers :** It is not known whether Mebendazole is excreted in human milk, though because many drugs are excreted in human milk, caution should be exercised when Mebendazole is administered to a nursing woman.

**Paediatric Use :** Safety and efficacy for use in children under two years have

not been established; therefore relative benefit/risk should be considered. There is no evidence that Mebendazole is effective for hydatid disease. There have been rare reports of neutropenia and liver function elevations, including hepatitis, when Mebendazole is taken for prolonged periods and at dosages substantially above those recommended. Keep all medicines out of reach of children.

### ADVERSE EFFECTS:

Transient symptoms of abdominal pain and diarrhoea have occurred in cases of massive infection and expulsion of worms. Hypersensitivity reactions such as rash, urticaria and angioedema have been observed on rare occasions. Very rare cases of convulsions have been reported.

### DOSE AND ADMINISTRATION:

The same dosage schedule applies to children and adults. The tablet may be chewed, swallowed, or crushed and mixed with food.

**Pinworm (enterobiasis) :** 1 tablet once

**Whipworm (trichuriasis), Common Roundworm (ascariasis), Hookworm :** 1 tablet morning and evening for 3 consecutive days.

If the patient is not cured after three weeks of treatment, a second course of treatment is advised. No special procedures, such as fasting or purging, are required.

### OVERDOSAGE:

GI complaints lasting up to a few hours may occur. Induce vomiting and purging. Activated charcoal may be given.

### DRUG INTERACTIONS:

Preliminary evidence suggests that cimetidine inhibits Mebendazole metabolism and may result in an increase in plasma concentrations of Mebendazole.

Carbamazepine and hydantoins may reduce the plasma levels of concomitant Mebendazole, possibly decreasing its therapeutic effect.

### PRESENTATION:

Blister pack / Jar pack.

### STORAGE CONDITION:

Store below 30°C. Protect from light & moisture.

Manufactured by :

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