Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Mebendazole Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Mebendazole 100 mg.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Chewable tablet
Mottled, pale orange, round tablets, shallow, concave with a breakline.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of threadworm (enterobiasis) infestation.

4.2 Posology and method of administration

Adults, the elderly and children over two years old:

One tablet to be chewed or swallowed whole. The efficacy in threadworm infestations is such that treatment failure will be rare. However, the possibility of re-infection means that some patients may require a second tablet after two weeks, if re-infected.

It is strongly recommended that all members of the family are treated at the same time.

Not recommended for children under two years of age.

4.3 Contraindications

Pregnancy: Mebendazole has not been studied extensively in children under two years of age - for this reason it is not currently recommended for children under two years of age.

4.4 Special warnings and precautions for use

1. Not to be taken during pregnancy, or whilst breast feeding.
2. Not recommended for children under two years.
3. Keep out of the reach and sight of children.
4. If after two weeks you need to take a second tablet following which your symptoms persist, then consult your doctor.

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6 Pregnancy and lactation

Mebendazole has shown embryotoxic and teratogenic activity in rats at single oral doses. No such findings have been seen in the rabbit, dog, sheep or horse. Since there is a risk that Mebendazole could produce foetal damage if taken during pregnancy, it is contra-indicated in pregnant women. No information on secretion into breast milk is available so mothers taking the drug should not breast feed.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Side effects reported have been minor. Transient abdominal pain and diarrhoea have been reported only rarely in cases of massive infestation and expulsion of worms. (Slight headache and dizziness have occasionally been reported).

4.9 Overdose

No cases of overdose have so far been reported with Mebendazole, but gastric lavage and/or supportive measures would be recommended. Symptoms of acute overdose would be expected to include gastro-intestinal disturbances, abdominal pain, headache, dizziness, pyrexia, and convulsions.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mebendazole is an anthelmintic.

5.2 Pharmacokinetic properties

Mebendazole is poorly absorbed from the gastrointestinal tract (5-10%) and undergoes extensive first pass elimination, being metabolised in the liver, eliminated in the bile as unchanged drug and metabolites, and excreted in the faeces. Only about 2% of the drug is excreted unchanged or as metabolites in the urine. Mebendazole is highly protein bound.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol
Jaffa orange 61001E
Magnesium stearate
Povidone
Maize starch
Croscarmellose sodium
Sodium saccharin

6.2 Incompatibilities

None stated.

6.3 Shelf Life

Three years.

6.4 Special precautions for storage

Store below 25^{o}C.

6.5 Nature and contents of container

250 micron white, opaque, rigid, uPVC 20µ Aluminium Foil Blisters in cardboard cartons in packs of two, four or eight tablets.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Cupal Limited
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8 MARKETING AUTHORISATION NUMBER

PA 0258/046/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 05 September 2003