# 1. Name of product

Emzor Mebendazole 500 Chewable Tablet

# 2. Qualitative and quantitative composition

Each tablet contains 500 mg mebendazole.

Excipient(s) with known effects:

Each tablet contains 48.0 mg of lactose monohydrate

For the full list of excipients, see section 6.1

# 3. Pharmaceutical form

Chewable Tablet

# 4. Clinical particulars

**4.1 Therapeutic indication:**

Emzor Mebendazole is very specifically indicated for the treatment of Trichuris trichiura (whipworm), Enterobius vermicularis (pinworm), Ascaris lumbricoides (roundworm), Ancylostoma duodenale (common hookworm), Necator americanus (American hookworm) and Strongyloides stercoralis (threadworm) in single and / or mixed infestations in adults and children. Efficacy varies in function of such factors as pre-existing diarrhea and gastrointestinal transit time, degree of infestation and helminth strains.

**4.2 Posology and method of administration:**

The same dosage applies to adults and children above 2 years of age.

Chew 1 tablet as a single dose. Repeated if required after 2 to 3 weeks.

Method of Administration: Oral

**4.3 Contraindication:**

Emzor Mebendazole is contraindicated in pregnant women and in children under two years of age, and in persons who have shown hypersensitivity to the drug.

**4.4 Special warnings and special precautions for use:**

Emzor Mebendazole has not been extensively studied in children under 2 years of age. Therefore, in the treatment of children under 2 years of age, the relative benefit / risk should be considered.

**4.5 Interaction with other FPPs and other forms of interaction:**

Metabolism of mebendazole possibly inhibited by cimetidine, causing increased plasma-mebendazole concentration.

**4.6 Pregnancy and lactation:**

Emzor Mebendazole has been shown embryotoxic and teratogenic activity in pregnant rats at single oral dosage of as low as 10mg/kg. Since Emzor Mebendazole may have a risk on fetus if administered during pregnancy, it is contraindicated in pregnant women.

Emzor Mebendazole is distributed in serum, cyst fluid, liver, omental fat and pelvis, pulmonary and hepatic cysts; highest concentration found in liver; relatively high concentration are found in muscle encysted trichinella spiralis larvae; crosses the placenta, also.

**4.7 Effects on ability to drive and use machines:**

No information available.

**4.8 Undesirable effects:**

Transient symptoms of abdominal pain and diarrhea may occur in cases of massive infestation and expulsion of worms.

**4.9 Overdose:**

In the event of accidental overdosage, gastrointestinal complaint lasting up to a few hours may occur.

Vomiting and purging should be induced.

## 5. Pharmacological properties

**5.1 Pharmacodynamic properties:**

Emzor Mebendazole exerts its anthelmintic effect by interfering (or inhibiting) with the uptake of exogenous glucose by the susceptible helminths, leading to glycogen depletion and reduced generation of ATP required for survival. As a result, the parasites die or are immobilized only slowly, and their clearance from the gastrointestinal tract may not be complete until the third day after treatment. Only an insignificant amount of Emzor Mebendazole is excreted in the urine within three days, either as metabolites or unchanged drug. Emzor Mebendazole can be used against all the stages of helminths' life-cycle, including mature and immature forms, even the egg stage.

**5.2 Pharmacokinetic properties:**

1) Emzor Mebendazole is a broad spectrum anthelmintic. It is useful in the treatment of ascariasis, enterobiasis, trichuriasis, uncinariasis and multiple helminthes infections.

2) Emzor Mebendazole is not significantly absorbed from the gastrointestinal tract; only about 2% of a dose is excreted unchanged or as a metabolite in the urine.

3) Emzor Mebendazole is distributed in serum, cyst fluid, liver, omental fat and pelvis, pulmonary and hepatic cysts; highest concentration found in liver; relatively high concentration are found in muscle-encysted trichinella spiralis larvae; crosses the placenta, also.

4) It is approximately 95% excreted unchanged or as the primary metabolite (2-amino derivatives) in faeces and it is approximately 2 to 5% excreted unchanged as the primary metabolite in urine.

**5.3 Preclinical safety data**:

No information available.

## 6. Pharmaceutical particulars

**6.1 List of excipients:**

Sodium Saccharin

Sodium Starch Glycolate

Lactose Monohydrate

Chocolate Flavour Powder

Potato Starch

Magnesium Stearate

Milk Flavour Powder

**6.2 Incompatibilities:**

No information available.

**6.3 Shelf life:**

3 years

**6.4 Special precautions for storage:**

Store at temperature below 30°C. Protect from light and moisture.

**6.5 Nature and contents of container:**

Strip Pack of 1's

**6.6 Instructions for use and handling <and disposal:**

None has been mentioned.

## 7. Marketing authorization holder

Emzor Pharmaceutical Industries Limited.

Sagamu/Benin Expressway, Makun, Sagamu Local Govt, Ogun state.

## 8. Marketing authorization number(s)

N/A

## 9. Date of first authorization/renewal of authorization

N/A

## 10. Date of revision of text

N/A