SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of finished pharmaceutical product:
DISWORM
(Albendazole Oral Suspension 200 mg)

1.1. Composition: Each
5ml contains:
Albendazole USP 200mg

1.2. Pharmaceutical dosage form:
Suspension
2. QUALITATIVE AND QUANTITATIVE COMPOSITIONS

2.1 Qualitative Declaration:

S.No	Ingredients
1.	Albendazole (Micronised)
2.	Sucrose
3.	Xanthum gum
4.	Methyl Hydroxybenzoate
5.	Propyl Hydroxybenzoate
6.	Sodium Benzoate
7.	Glycerol
8.	Polysorbate
9.	Disodium Edetate
10.	Citric Acid
11.	Aspartame
12.	Erythrosine Supra
13.	Raspberry
14.	Mixed Fruit
15.	Purified water

3. PHARMACEUTICAL FORM

Rose colour suspension having uniform consistency and free from gritty particles.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

This medication is used to treat certain tapeworm infections (e.g., neurocysticercosis). This drug may also be used to treat other types of worm infections.

4.2 Posology and method of administration

Age 12 to 24 months: 200 mg as a single dose

Adults & children (over two years): 10 ml suspension as a single dose in cases of Enterobius vermicularis, Trichuris trichiura, Ascaris lumbricoides, Ancylostoma duodenale and Necator americanus.

In cases of strongyloidiasis or taeniasis, 400 mg or 10 ml suspension as a single dose should be given for three consecutive days.

Giardiasis: 400 mg or 10 ml suspension once daily for five days.

Albendazole is given by mouth with meals in a dose of 400 mg twice daily for 28 days for patients weighing over 60 kg. A dose of 15 mg/kg body weight daily in two divided doses (to a maximum total daily dose of 800 mg) is used for patients weighing less than 60 kg. For cystic echinococcosis the 28- days course may be repeated after 14 days without treatment to a total of three treatment cycles. For alveolar echinococcosis, cycles of 28 days of treatment followed by 14 days without treatment may need to continue for months or years. When three courses of therapy have been given in the pre or post surgical setting, optimal killing of cyst contents is achieved.

4.3 Contraindications

Hypersensitivity to the benzimidazole class of compounds. Albendazole is known to be teratogenic and embryotoxic in animals. The safety of albendazole during pregnancy has not been established, and should not be taken by pregnant women at any stage of their pregnancy or by women who are likely to become pregnant, during or shortly after the course of therapy. It is contra-indicated in patients with a known history of hypersensitivity to Albendazole or constituents.

4.4 Special warnings and precautions for use

Before taking albendazole, check if you are allergic to it. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Before using this medication, tell your doctor or pharmacist your medical history, especially of: liver disease, biliary tract problems (e.g., blockage), and blood/bone marrow disorders. This medication may cause liver problems. Because drinking alcohol increases the risk of liver problems, limit alcoholic beverages while using this medication. During pregnancy, this medication should be used only when clearly needed. It may harm an unborn baby. Women of child-bearing age should have a negative pregnancy test before starting this medication. .It is not known if this medication passes into breast milk.

4.5 Interaction with other medicinal products and other forms of interaction

Antiepileptics

The drugs carbamazepine, phenytoin and phenobarbital lower the plasmatic concentration and the half life of Albendazole.

Antacids/histamine H2 antagonists

The drug cimetidine heightens serum Albendazole concentrations, and increases the half life of Albendazole.

This might be a helpful interaction on more severe cases, because it boosts the potency of Albendazole

4.6 Pregnancy and lactation

Pregnancy class D - contraindicated during pregnancy, and for one month prior to conception.

In order to avoid administering albendazole during early pregnancy, women of child bearing age should initiate treatment during the first week of menstruation or after a negative pregnancy test.

The use in human pregnancy has not been studied, but in animal studies it is teratogenic in more than one species. In animal studies oral treatment with maternotoxic doses of albendazole (30mg/kg/day) during the period of organogenesis was associated with multiple malformations in rats and ectrodactyly in rabbits. In one study in rats, an oral dose (10mg/kg/day) similar to the human therapeutic dose was not maternotoxic, but was associated with microphthalmia and microfetalis. The latter occurred alone and together with multiple malformations including cranioschisis, talipes and renal agenesis. There is no information on the possible effect of albendazole on the human foetus.

Use in Lactation: Adequate human and animal data on use during lactation are not available. Therefore breast feeding should be discontinued during and for a minimum of 5 days after treatment.

4.7 Effects on ability to drive and use machines

No information available

4.8 Undesirable effects

The following adverse events were observed during clinical studies. It should however be noted that causality has not necessarily been established for these events.

Common (≥1%)

Abdominal pain was the most frequently reported symptom (1%) during short term dosing, however this frequency was not significantly different from that in placebo-treated patients.

Uncommon (>0.1% and <1%)

Diarrhoea, nausea, vomiting, dizziness, itchiness and/or skin rashes were reported. There was no significant difference in the percentage of patients experiencing diarrhoea, compared to placebotreated patients.

Rare (< 0.1%)

Rarely reported events included bone pain, proteinuria, and low red cell count. Leucopenia and transiently raised hepatic enzymes were reported in studies with laboratory monitoring; however no definite relationship to the drug was shown

4.9 Overdose

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

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC classification:

Pharmacotherapeutic group: Anti helmentic drug, ATC code: P02CA03

Mode of action:

As a vermicidal, albendazole causes degenerative alterations in the tegument and intestinal cells of the worm by binding to the colchicine-sensitive site of tubulin, thus inhibiting its polymerization or assembly into microtubules. The loss of the cytoplasmic microtubules leads to impaired uptake of glucose by the larval and adult stages of the susceptible parasites, and depletes their glycogen stores. Degenerative changes in the endoplasmic reticulum, the mitochondria of the germinal layer, and the subsequent release of lysosomes result in decreased production of adenosine triphosphate (ATP), which is the energy required for the survival of the helminth. Due to diminished energy production, the parasite is immobilized and eventually dies.

Albendazole also has been shown to inhibit the enzyme fumarate reductase, which is helminthspecific.

This action may be considered secondary to the effect on the microtubules due to the decreased absorption of glucose. This action occurs in the presence of reduced amounts of nicotinamide-adenine dinucleotide in reduced form (NADH), which is a coenzyme involved in many cellular oxidation-reduction reactions.

Albendazole has larvicidal effects in necatoriasis and ovicidal effects in ascariasis, ancylostomiasis, and trichinosis.

5.2 Pharmacokinetic properties

Absorption

Albendazole is poorly absorbed from the GI tract; however, it is rapidly converted to its primary active metabolite, albendazole sulfoxide, prior to reaching systemic circulation.

Fatty meals enhance bioavailability, as indicated by up to a 5-fold increase in plasma concentration in albendazole sulfoxide. Albendazole sulfoxide plasma concentrations are dose-dependent. C max is achieved in 2 to 5 h and ranges from 0.46 to 1.58 mcg/mL, when given with a fatty meal.

Distribution

Albendazole sulfoxide is 70% protein bound and widely distributed throughout the body.

Metabolism

After metabolism in the liver to albendazole sulfoxide, it is further metabolized to albendazole sulfone and other oxidative metabolites.

Elimination

Albendazole sulfoxide elimination half-life is 8 to 12 h. biliary elimination of albendazole sulfoxide results in biliary concentrations similar to plasma concentration. Urinary excretion is a minor elimination pathway (less than 1%).

Special Populations

Renal Function Impairment

Pharmacokinetics has not been studied in patients with renal impairment, but it is unlikely that clearance of albendazole and albendazole sulfoxide would be affected, given the negligible renal elimination.

Hepatic Function Impairment

Systemic availability of albendazole sulfoxide is increased in patients with extrahepatic obstruction.

Elderly

Data suggest pharmacokinetics is similar to those in younger, healthy subjects.

Children

Albendazole sulfoxide pharmacokinetics are similar to those observed in adults.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

S. No	Name of Excipients
1	Sucrose
2	Xanthum gum
3	Methyl Hydroxybenzoate
4	Propyl Hydroxybenzoate
5	Sodium Benzoate
6	Glycerol
7	Polysorbate
8	Disodium Edetate
9	Citric Acid
10	Aspartame
11	Erythrosine Supra
12	Raspberry
13	Mixed Fruit
14	Purified water

6.2 Incompatibilities

None.

6.3 Shelf life

24 months

6.4 Special precautions for storage

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

6.5 Nature and contents of container

a) Type of package

Amber coloured glass bottle

b) Nature and packaging material

10ml Amber coloured glass bottle

6.6 Instructions for use handling for disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

MADRAS PHARMACEUTICALS

8. NUMBER(S) IN THE NATIONAL REGISTER OF FINISHED PHARMACEUTICALPRODUCTS

MAD/IND/405
07649/08396/REN/2022

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Aug 8, 2022

10. 10 DATE OF REVISION OF THE TEXT –

18.02.2022