SUMMARY OF PRODUCT CHARACTERISTICS

(SmPC)

DANZEL-200 TABLETS

Albendazole USP 200mg

1. Name of the Medicinal Product

Danzel Albendazole Tablets 200 mg

Albendazole Tablets USP 200 mg

1. Qualitative and Quantitative Composition

Each uncoated chewable tablet contains:

Albendazole USP 400 mg

Excipients……...……...Q.S.

Colour : Sunset Yellow FCF

2. Pharmaceutical Form

Uncoated Chewable Tablets.

Light orange colored caplet shaped uncoated tablet having a beak line on one side and other side plain of each tablet.

3. Clinical Particulars

4.1 Therapeutic Indications

Albendazole is indicated for the treatment of parasitic worm infestations (Single or mixed) due to: Enterobius vermicularis(Pin worms), Trichuris trichuira (Whipworms), Ascaris lumbricoides (large Roundworms), Ancylostoma duodenale(Hookworms), Necator americanus (Hookworms),Strongyloides stercoralis (Threadworms), Taenia spp (Tapeworms),Hymenolepis nana (Dwarf tapeworms), Taenia solium (Neurocysticercosis), Echinococcus granulosus (Hydatid cysts).

4.2 Posology and Method of Administration

The dose of Albendazole for adults and children above 2 years is one tablet or 10 mL of suspension (400 mg Albendazole) asa single dose in suspected or confirmed infestations with Pin worms, Whipworms, Large Roundworms, Hookworms.

In case of suspected or confirmed cases of Threadworms, Tapeworms, or Dwarf tapeworms,

Albendazole should be used ata dose of one tablet or 10 mL suspension once daily for 3 consecutive days. In case of Dwarf Tapeworms, retreatmentin 10 - 21 days is recommended.
Albendazole 400 mg twice daily for 3 consecutive days is effective in the treatment of patients with mixed worm infestationincluding infestation with Opisthorchis viverrini and Opisthorchis sinensis.

For hydatid cysts: 10 mg/kg of body weight / day for 4-8 weeks.

For neurocysticercosis: 400 mg twice a day for 30 days.

Symptoms of over dosage & its treatment:

If poisoning or excessive over dosage is suspected it is recommended, on general principles, that vomiting be inducedor gastric lavage be performed, and symptomatic supportive therapy be administered as appears indicated.

4.3 Contraindications

Albendazole is contraindicated in pregnancy and in patients with known hypersensitivity to albendazole.

4.4 Special Warnings and Precautions for use

General:

It has been noted that leucopaenia has occurred when used for periods longer than recommended. Patients beingtreated for neurocysticercosis should receive appropriate steroid and anticonvulsant therapy as required. Cysticercosismay, in rare cases, involve the retina. If retinal lesions are visualized, the need for anticysticeral therapy should beweighed against the possibility of retinal damage caused by albendazole-induced changes to the retinal lesion.

For use in special populations:

Pediatrics:

During albendazole therapy, because of the possibility of harm to the bone marrow, routine (every 2 weeks) monitoringof blood counts and liver function tests place. Albendazole should be taken with food.

Pregnancy: Refer to contra-indications.

Lactation: Because of inadequate data breast feeding should be discontinued during & minimum 5 days after thetreatment.

4.5 Interactions with other medicinal products and other forms of interactions

Praziquantel, Cimetidine & Dexamethasone increases the drug level of Albendazole. Theoretical risk of interaction with thetheophylline, anticonvulsants, oral contraceptives and oral hypoglycaemics increases.

4.6 Fertility, Pregnancy and Lactation

Albendazole is a pregnancy class D drug in Australia and pregnancy class C in the United States. It is contraindicated in the first trimester of pregnancy, and should not be avoided up to one month before conception. While studies in pregnant rats and rabbits have shown albendazole to be teratogenic, albendazole has been found to be safe in humans during the second and third trimesters. It can, however, possibly cause infantile eczema when given during pregnancy.

In pregnant dogs, albendazole use has lead to puppies with reduced weight and with cleft palates. Birds have lower rates of laying eggs and hatching when given albendazole.

Albendazole sulfoxide is secreted into breast milk at around 1.5% of the maternal dose, though oral absorption is poor enough that it is unlikely to affect nursing infants.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable Effects

Use of large doses of Albendazole can cause adverse effects like allergic reactions, raised liver enzyme values, alopecia, bonemarrow depression etc.

Side effects of Albendazole include transient abdominal pain and diarrhea, dizziness, nausea, constipation, dry mouth etc.

4.9 Overdose

None

5.Pharmacological Properties

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Anthelmentic

ATC code: P02CA03.

Albendazole selectively blocks the glucose uptake by adult helminthes in the intestine & their tissue dwelling larvae.Inhibition of glucose uptake leads to endogenous depletion of glycogen stored within the parasite. This in tum causes adecrease in the formation of adenosine triphosphate. By this mechanism, the drug slowly depletes the energy levels ofthe susceptible parasites.

5.2 Pharmacokinetic Properties

Absorption Oral absorption is low Plasma half-life 8.5 hrs. Mean plasma peak concentration 0.46 to 1.58 mcg/mLElimination Via bile.

5.3 Pre Clinical Safety Data

There are no preclinical data of relevance.

6.Pharmaceutical Particulars

6.1 List of Excipients

Lactose
Mannitol
Sugar
Maize starch
Maize starch
Maize starch
Gelatin

Sodium Benzoate

Colour: Sunset yellow supra

Purified water

Magnessium Stearate

Talcum

Orange flavour

Sodium saccharin

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

3 years

6.4 Special precautions for Storage

Do not store above 25 °C. Store in the original package.

6.5 Nature and contents of Container : A blister pack of 1 tablets packed in an monocarton along with insert.

6.6 Special precautions for disposal

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

7. REGISTRANT

8. MANUFACTURER

AR Lifesciences 819/B Rakanpur Indl area , Tal . kalol Dist . Ganhinagar , Gujarat .

9. DATE OF REVISION OF THE TEXT

Applicable once the registration is obtained.