

DENZOL 200mg Film Coated Tablet

DENZOL 20mg/ml Suspension

Albendazole

Product Description

DENZOL Film Coated Tablet: White, round, biconvex smooth film coated tablets, engraved E1A3 from one side.

DENZOL Suspension: Homogenous syrupy suspension, white to off white colour with a banana like odour. Each 1ml contains Albendazole 20 mg.

Composition

DENZOL Film Coated Tablet: Each tablet contains Albendazole 200 mg.

DENZOL Suspension: Each 1ml contains Albendazole 20 mg.

Pharmacodynamics

Albendazole is a broad spectrum antihelminthic with activity against most nematodes and some cestodes. Albendazole acts by destruction of cytoplasmic microtubules in the worm's intestinal or absorptive cells and inhibition of glucose uptake and other nutrients in susceptible helminthes, resulting in death of the worm.

Pharmacokinetics

Albendazole is poorly absorbed from GI tract, and is rapidly metabolized in the liver to the active albendazole sulphoxide, which is approximately 70% bound to the plasma protein. Peak plasma concentrations occur in 2-5 hours after dosing. It has a plasma half-life of about 8.5 hours and is primarily eliminated in the bile.

Indication

Albendazole is use in patient with Enterobiasis, Ascariasis, Ancylostomiasis, trichuriasis, Strongyloidiasis, Taeniasis, Capillariasis, Neurocysticercosis, Trichostrongyliasis, Hydatid Disease (*Echinococcus granulosus*), and Filariasis, in combination with other Anthelmintics.

Recommended Dosage

DENZOL is for oral administration and should be taken with meals.

Enterobiasis, ascariasis, ancylostomiasis, or trichuriasis:

Adults & children above 2 years of age: 400 mg as a single.

Children up to 2 years of age: 200 mg as a single dose.

The dose may be repeated in 3 weeks.

Taeniasis, strongyloidiasis: 400 mg /day for 3 days.

Capillariasis: 400 /day for 10 days.

Neurocysticercosis: 15 mg /kg/day for 30 days.

Trichostrongyliasis: 400 mg single dose

Hydatid disease:

Patients over 60 kg body weight: 400 mg twice daily for 28 days followed by 2 weeks drug free interval. Dose may be repeated for 2-3 cycles and if the case is inoperable, up to 5 cycles.

Patients under 60 kg body weight: 10 - 15 mg/kg/day for 28 days.

Filariasis: 400 mg with diethyl carbamazine 6 mg /kg given once. This regimen is given every year for 4 - 6 years.

Contraindications

DENZOL must not be used in patient known hypersensitivity to the product and in pregnancy.

Warnings and Precautions

Patients receiving high doses of Albendazole should be supervised closely with blood counts and liver function being monitored.

Interactions with Other Medicaments

Plasma concentrations of Albendazole sulphoxide have been increased by concomitant administration of dexamethasone, praziquantel or cimetidine.

Pregnancy and Lactation

Should not be administered during confirmed or suspected pregnancy.

In pregnancy albendazole was found to have embryotoxic and teratogenic effects.

Side Effects

Transient abdominal pain, diarrhea, headache, dizziness, elevated transaminases, leucopenia and thrombocytopenia.

Symptoms and Treatment of Overdose

Symptoms of an albendazole overdose are not known.

Presentation

DENZOL Film Coated Tablet is available in 1 blister of 2 tablets each per box and 100 blisters of 2 tablets each per box. .

DENZOL Suspension is available in an amber bottle of 20ml each per box.

Storage conditions

DENZOL Film Coated Tablet: Store at temperature below 30°C. Protect from light and keep out of reach of children.

DENZOL Suspension: Store at temperature below 30°C. Protect from light and keep out of reach of children.

Shelf Life

36 months from the date of manufacture if kept as recommended.

Registration Number

DENZOL 200mg Film Coated Tablet - MAL09020980XZ

DENZOL 20mg/ml Suspension – MAL10080070XZ

Name and Address of Manufacturer

Egyptian International Pharmaceutical Industries Co. (EIPICO)

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Product Registration Holder

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