ALENDA 400
(ALBENDAZOLE TABLETS 400 mg)

COMPOSITION:

Each uncoated chewable tablet contains:
Albendazole USP …….400 mg
Excipients …….. q.s.

MECHANISM OF ACTION:

Albendazole is a benzimidazole anthelmintic drug. 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 turn causes a decrease in the formation of adenosine triphosphate. By this mechanism, the drug slowly depletes the energy levels of the susceptible parasites.

INDICATIONS:

ALENDA 400 is indicated for the treatment of the following infections:

- Neurocysticercosis:
- Albendazole is indicated for the treatment of parenchymal neurocysticercosis due to active lesions caused by larval forms of the pork tapeworm, Taenia solium.
- Lesions considered responsive to albendazole therapy appear as nonenhancing cysts with no surrounding edema on contrast enhanced computerized tomography. Clinical studies in patients with lesions of this type demonstrate a 74% to 88% reduction in number of cysts; 40% to 70% of albendazole-treated patients showed resolution of all active cysts.
- Hydatid disease.
- Albendazole is indicated for the treatment of cystic hydatid disease of the liver, lung, and peritoneum, caused by the larval form of the dog tapeworm, Echinococcus granulosus.

CONTRAINDICATIONS:

ALENDA 400 is contraindicated in patients with known hypersensitivity to the benzimidazole class of compounds or any components of Albendazole Tablets.

DOSAGE AND ADMINISTRATION:

Adults:
Usual Dose: 400 mg as a single dose.
Strongyloidosis, Taeniasis, H.nana Infestations: 400 mg once daily for 3 consecutive days.
Hydatid disease: 400 mg twice daily with meals for 28 days. The therapy may be repeated after 14 days interval for a total of 3 cycles.
Children:
(1-2 Years): 200 mg as a single dose.
Above 2 years: Same dose as adult.

PRECAUTIONS:

Hepatic and renal impairment, in neurocysticercosis patients should be received appropriate steroid and anticonvulsant therapy.

WARNINGS:

- Rare fatalities associated with the use of albendazole have been reported due to granulocytopenia or pancytopenia. Blood counts should be monitored at the beginning of each 28-day cycle of therapy, and every 2 weeks while on therapy with albendazole. Albendazole may be continued if the total white blood cell count and absolute neutrophil count decrease appear modest and do not progress.
- Albendazole should not be used in pregnant women except in clinical circumstances where no alternative management is appropriate. Patients should not become pregnant for at least 1 month following cessation of albendazole therapy. If a patient becomes pregnant while taking this drug, albendazole should be discontinued immediately. If pregnancy occurs while taking this drug, the patient should be apprised of the potential hazard to the fetus.

ADVERSE REACTIONS:

Side effects are generally restricted to gastrointestinal tract such as transient abdominal pain and diarrhea, dizziness, nausea, constipation, dry mouth.

Pregnancy:
Albendazole is known to be teratogenic and embryotoxic so should not be administered during pregnancy or in women though to be pregnant.

DRUG INTERACTIONS:

- Dexamethasone Steady-state trough concentrations of albendazole sulfoxide were about 56% higher when 8 mg dexamethasone was coadministered with each dose of albendazole (15 mg/kg/day) in eight neurocysticercosis patients.
- Praziquantel In the fed state, praziquantel (40 mg/kg) increased mean maximum plasma concentration and area under the curve of albendazole sulfoxide by about 50% in healthy subjects (n=10) compared with a separate group of subjects (n=6) given albendazole alone. Mean T max and mean plasma elimination half-life of albendazole sulfoxide were unchanged. The pharmacokinetics of praziquantel were unchanged following co administration with albendazole (400 mg).
- Cimetidine Albendazole sulfoxide concentrations in bile and cystic fluid were increased (about 2-fold) in hydatid cyst patients treated with cimetidine (10 mg/kg/day) (n=7) compared with albendazole (20 mg/kg/day) alone (n=12). Albendazole sulfoxide plasma concentrations were unchanged 4 hours after dosing.
- Theophylline The pharmacokinetics of theophylline (aminophylline 5.8 mg/kg infused over 20 minutes) were unchanged following a single oral dose of albendazole (400 mg) in 6 healthy subjects.

OVER DOSAGE:

Significant toxicity and mortality were shown in male and female mice at doses exceeding 5,000 mg/kg; in rats, at estimated doses between 1,300 and 2,400 mg/kg; in hamsters, at doses exceeding 10,000 mg/kg; and in rabbits, at estimated doses between 500 and 1,250 mg/kg. In the animals, symptoms were demonstrated in a dose-response relationship and included diarrhea, vomiting, tachycardia, and respiratory distress.
One overdosage has been reported with albendazole in a patient who took at least 16 grams over 12 hours. No untoward effects were reported. In case of overdosage, symptomatic therapy (e.g., gastric lavage and activated charcoal) and general supportive measures are recommended.

PRESENTATION:

Blister of 1 Tablet in a carton along with the pack insert
100 Tablets in a bottle.

STORAGE:

Store below 30ºC.
Protect from Moisture & direct Sunlight.
Keep out of reach of children.

SHELF LIFE: 3 years from date of manufacture.

Manufactured by –

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