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SYNCOM FORMULATIONS INDIA LIMITED
256-257, Sector-1, Pithampur, Dist.-Dhar, (M.P) 454775
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Bringing a smile on every face..

Product Name : ALBENDAZOLE TAB:LETS 400 mg
Brand Name : NCI ALBENDAZOLE TABLETS

1.3.1 Summary of product characteristics (SmPC)

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1.3.1 **SUMMARY OF PRODUCT CHARACTERISTICS**

1 Name of the Medicinal Product

Albendazole Tablets

2.Composition

Each chewable tablet contains:

Albendazole USP 400mg

Colour: Sunset Yellow Supra

Approved Flavour

Sr.No.	Ingredient	Specification	Function	Mg/tablets	Unit
1.	Albendazole	USP	Active	400.00	mg
2.	Starch (Maize)	BP	Diluents	222.33	mg
3.	Calcium Hydrogen Phosphate (DCP)	BP	Diluents	70.00	mg
4.	Sucrose (Sugar)	BP	Sweetener	150.00	mg
5.	Gelatin	BP	Binder	15.00	mg
6.	Sunset Yellow Supra	IH	Colour	1.00	mg
7.	Starch (Maize) for Paste	BP	Binder	10.00	mg
8.	Purified talc	BP	Glidant	13.00	mg
9.	Magnesium Stearate	BP	Lubricant	10.00	mg
10.	Starch (Maize)	BP	Binder	11.67	mg
11.	Orange DM No. 01 (Flavour)	IH	Flavour	5.00	mg
12.	Colloidal Anhydrous Silica (Aerosil - 200)	BP	Lubricant	2.00	mg

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3. PHARMACEUTICAL FORM

Oral Dosage Form

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Albendazole is a benzimidazole and anthelmintic agent most commonly used in the treatment of echinococcosis (also known as Hydatid cysts) and neurocysticercosis . It causes degenerative alterations to the tegument and intestine of worms; this leads to impaired uptake of glucose and causes a depletion of glycogen stores . Albendazole ultimately causes a decrease in the production of ATP which causes immobilization and death of the worm. (albendazole) is a broad-spectrum anthelmintic, which is highly effective against a wide range of intestinal helminths. Albendazole is also effective against tissue helminthes infections, such as cutaneous larva migrans. Albendazole therapy has also been used in the high dose, long term treatment of tissue helminthes infections including hydatid cysts and cysticercosis. The antihelminthic action of albendazole is thought to be mainly intraintestinal. However, at higher albendazole doses, sufficient is absorbed and metabolised to the active sulphoxide metabolite, to have a therapeutic effect against tissue parasites. Albendazole exhibits larvicidal, ovicidal and vermicidal activity, and is thought to act via inhibition of tubulin polymerization. This causes a cascade of metabolic disruption, including energy depletion, which immobilizes and then kills the susceptible helminthes.

4.2 Posology and method of administration

Adults and Children (over two years):

• Enterobius vermicularis, Ascaris lumbricoides, Ancylostoma duodenal, Necator americanus and Trichuris trichiura: 400mg (two albendazole 200mg tablets) as a single dose, taken on an empty stomach.

• Suspected or confirmed Strongyloides stercoralis infestation: albendazole 400mg once daily, taken on an empty stomach for three consecutive days. Patients should then be appropriately followed for at least 2 weeks to confirm cure.

• Cutaneous larva migrans: 400mg once daily, taken with food for one to three days has been reported to be effective.

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• Suspected or confirmed Taenia spp. or Hymenolepis nana infestation, when other susceptible helminths species are present: Albendazole 400mg once daily, taken on an empty stomach for three consecutive days. If the patient is not cured after three weeks, a second course of ALBENDAZOLE treatment is indicated. In cases of proven H. nana infestation, retreatment in 10- 21 days is recommended.

• Mixed worm infestations including Opisthorchis viverrini and Clonorchis sinensis: 400mg wice a day, taken with food for three days is effective. Patients should be re-examined 1 month after treatment to confirm fluke eradication.

Method of Administration oral use Oral use.

4.3 Contraindications:

Albendazole should not be administered during pregnancy or in women thought to be pregnant. albendazole has been shown to be teratogenic and embryotoxic in rats and rabbits. Women of childbearing age should be advised to take effective precautions against conception during and within one month of completion of treatment with albendazole . Albendazole is contraindicated in persons who are known to be hypersensitive to albendazole, other benzimidazole derivatives, or any component of the tablets.

4.4 Special warning and Precautions for use:

Use in Systemic Helminthes Infections (longer duration of treatment at higher doses) Mild to moderate elevations of liver enzymes have been reported with albendazole. In prolonged higher dose albendazole therapy for hydatid disease there have been rare reports of severe hepatic abnormalities associated with jaundice and histological hepatocelluler damage, which may be irreversible. Enzyme abnormalities usually normalise on discontinuation of treatment. Patients with abnormal liver function test results (transaminases) prior to commencing albendazole therapy should be carefully evaluated and therapy should be discontinued if liver enzymes are significantly increased (greater than twice the upper limit of normal) or full blood count decreased by a clinically significant level.

Albendazole treatment may be restarted when liver enzymes have returned to normal limits, but

patients should be carefully monitored for a recurrence. Case reports of hepatitis have also been received Liver function tests should be obtained before the start of each treatment cycle and at least every two weeks during treatment.

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Albendazole has been shown to cause bone marrow suppression and therefore blood counts should be performed at the start and every two weeks during each 28 day cycle. Patients with liver disease, including hepatic echinococcosis, appear to be more susceptible to bone marrow suppression leading to pancytopenia, aplastic anaemia, agranulocytosis and leukopenia and therefore warrant closer monitoring of blood counts. Albendazole should be discontinued if clinically significant decreases in blood cell counts occur. Symptoms associated with an inflammatory reaction following death of the parasite may occur in patients receiving albendazole treatment for neurocysticercosis (e.g. seizures, raised intracranial pressure, focal signs). These should be treated with appropriate steroid and anticonvulsant therapy. Oral or intravenous corticosteroids are recommended to prevent cerebral hypertensive episodes during the first week of treatment. Pre-existing neurocysticercosis may also be uncovered in patients treated with albendazole for other conditions, particularly in areas with high taenosis infection. Patients may experience neurological 4 symptoms e.g. seizures, increased intracranial pressure and focal signs as a result of an inflammatory reaction caused by death of the parasite within the brain. Symptoms may occur soon after treatment, appropriate steroid and nticonvulsant therapy should be started immediately. There is a risk that treatment of Taenia solium infections may be complicated by cysticercosis, and appropriate measures should be taken to minimize this possibility. Confirmation of eradication of many intestinal and tissue parasites is necessary after treatment. Use in Impaired Renal or Hepatic Function ,The use of albendazole in patients with impaired renal or hepatic function has not been studied. However, caution should be used in patients with pre-existing liver disease, since albendazole is metabolised by the liver and has been associated with idiosyncratic hepatotoxicity. Use In Children There is limited experience with albendazole in children under 2 years of age, therefore use in this age group is not recommended. Carcinogenicity and Mutagenicity. No evidence of carcinogenic activity was observed in mice given albendazole in the diet at doses up to 400mg/kg/day for 25 months. In rats, dietary administration of doses of 3.5, 7 and 20mg/kg/day did not affect the total incidence of adrenocortical tumours (adenoma plus carcinoma), however, in females there was an increased incidence of adrenocortical carcinomas. Mutagenicity tests with bacterial cells and an assay of chromosomal damage in vivo have shown no clear evidence that albendazole has genotoxic activity. A cell transformation assay showed a slight dose-related increase in the transformation rate of cultured mouse cells in the presence of metabolic activation.

4.5 Interactions with other medicinal products and other forms of interaction

Cimetidine, praziquantel and dexamethasone have been reported to increase the plasma levels of the albendazole active metabolite. Ritonavir, phenytoin, carbamazepine and Phenobarbital may have the potential to reduce plasma concentrations of the active metabolite of albendazole; albendazole sulphoxide. The clinical relevance of this is unknown, but may result in decreased efficacy, especially in the treatment of systemic helminthes infections. Patients should be monitored for efficacy and may require alternative dose regimens or therapies.

4.6 Pregnancy and 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 machine:

Due to its neurological effects, ciprofloxacin may affect reaction time. Thus, the ability to drive or to operate machinery may be impaired.

4.8 Undesirable effects:

Adverse reactions are adverse events that were considered to be reasonably associated with the use of Albendazole based on the comprehensive assessment of the available adverse event information. A causal relationship with Albendazole cannot be reliably established in individual cases. Further, because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

The safety of Albendazole was evaluated in 6276 subjects who participated in 39 clinical trials for the treatment of single or mixed parasitic infestations of the gastrointestinal tract. In these 39 clinical trials, no adverse drug reactions (ADRs) occurred in 1% of Albendazole-treated subjects.

4.9 Overdose:

Further management should be as clinically indicated or contact the Poisons Information Centre (telephone 131126) for advice on overdose management.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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In vitro and in vivo work suggests that albendazole blocks the uptake of glucose by adult and larval forms of helminths, in a selective and irreversible manner. Inhibition of glucose uptake ppears to lead to endogenous depletion of glycogen stores within the helminth. Lack of glycogen leads to decreased formation of ATP and ultrastructural changes in the cells

5.2 Pharmacokinetic properties

In man, the full extent of albendazole absorption following oral administration has not been established. However, it is known that albendazole is poorly absorbed with most of an oral dose remaining in the gastrointestinal tract. The poor absorption is believed to be due to the low aqueous solubility of albendazole. Absorption is significantly enhanced (approximately 5 fold) if albendazole is administered with a fatty meal. Albendazole rapidly undergoes extensive first- ass metabolism in the liver, and is generally not detected in plasma. Albendazole sulphoxide is the primary metabolite, which is thought to be the active moiety in effectiveness against systemic tissue infections. The plasma half life of albendazole sulphoxide is 8½ hours. Albendazole sulphoxide and its metabolites appear to be principally eliminated in bile, with only a small proportion appearing in the urine.

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 Incompatibilities

None known

6.2 Shelf life

48 Months

6.3 Special precautions for storage

None stated.

6.4 Nature and contents of container

Aluminium PVC Blister of 1, tablets packed in carton with leaflet.

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6.5 Special precaution for disposal and other handling

No special requirements.

7. Marketing Authorisation Holder

NCI Pharmchem Ind. Ltd.

8.Marketing Authorisation Number(s)

Yet to receive

9. Date of first Authorisation/Renewal of the Authorisation

Not applicable

10. Date of revision of the text

Not applicable