National Agency for Food & Drug Administration & Control (NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) TEMPLATE

WORMPLAN TABLETS

ALBENDAZOLE TABLETS 400MG

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WORMPLAN TABLETS

ALBENDAZOLE TABLETS 400MG

1. **NAME OF THE MEDICINAL PRODUCT:**

   WORMPLAN (Albendazole Tablets 400mg)

2. **QUALITATIVE AND QUANTITATIVE COMPOSITION:**

   Each Chewable uncoated Tablet contains:
   Albendazole USP .....400 mg
   Approved colour used
   Excipients:……...…..q.s

3. **PHARMACEUTICAL FORM:**

   Chewable Tablet

4. **Clinical particulars :**

THERAPEUTIC INDICATION:

For the treatment of parenchymal neurocysticercosis due to active lesions caused by larval forms of the pork tapeworm, Taenia solium and for the treatment of cystic hydatid disease of the liver, lung, and peritoneum, caused by the larval form of the dog tapeworm, Echinococcus granulosus.

Albendazole 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.

This indication is based on combined clinical studies which demonstrated non-infectious cyst contents in approximately 80-90% of patients given Albendazole for 3 cycles of therapy of 28 days each. Clinical cure (disappearance of cysts) was seen in approximately 30% of these patients, and improvement (reduction in cyst diameter of $\geq$ 25%) was seen in an additional 40%.

NOTE: When medically feasible, surgery is considered the treatment of choice for hydatid disease. When administering albendazole in the pre- or post-surgical setting, optimal killing of cyst contents is achieved when 3 courses of therapy have been given.

NOTE: The efficacy of albendazole in the therapy of alveolar hydatid disease caused by Echinococcus multilocularis has not been clearly demonstrated in clinical studies.

4.2 Posology and method of administration:

Dosing of Albendazole will vary, depending upon which of the following parasitic infections is being treated. In young children, the tablets should be crushed or chewed and swallowed with a drink of water.

Patients being treated for neurocysticercosis should receive appropriate steroid and anticonvulsant therapy as required. Oral or intravenous corticosteroids should be considered to prevent cerebral hypertensive episodes during the first week of treatment.

4.3 Contraindications:

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

4.4 Special warnings and precautions for use:

Special Warning and Precautions for use:

Rare fatalities associated with the use of Albendazole have been reported due to granulocytopenia or pancytopenia. Albendazole has been shown to cause bone marrow suppression, aplastic anemia, and agranulocytosis in patients with and without underlying hepatic dysfunction. Blood counts should be monitored at the beginning of each 28day cycle of therapy, and every 2 weeks while on therapy with albendazole in all patients. Patients with liver disease, including hepatic echinococcosis, appear to be more at risk for bone marrow suppression leading to pancytopenia, aplastic anemia, agranulocytosis, and leukopenia attributable to albendazole and warrant closer monitoring of blood counts. Albendazole should be discontinued in all patients if clinically significant decreases in blood cell counts occur.

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.

Precautions :

General

Patients being treated for neurocysticercosis should receive appropriate steroid and anticonvulsant therapy as required. Oral or intravenous corticosteroids should be considered to prevent cerebral hypertensive episodes during the first week of anticysticeral therapy.

Pre-existing neurocysticercosis may also be uncovered in patients treated with albendazole for other conditions. Patients may experience neurological 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 anticonvulsant therapy should be started immediately.

Cysticercosis may, in rare cases, involve the retina. Before initiating therapy for neurocysticercosis, the patient should be examined for the presence of retinal lesions. If such lesions are visualized, the need for anticysticeral therapy should be weighed against the possibility of retinal damage caused by albendazole-induced changes to the retinal lesion.

Laboratory Tests

White Blood Cell Count

Albendazole has been shown to cause occasional (less than 1% of treated patients) reversible reductions in total white blood cell count. Rarely, more significant reductions may be encountered including granulocytopenia, agranulocytosis, or pancytopenia. Blood counts should be performed at the start of each 28-day treatment cycle and every 2 weeks during each 28-day cycle in all patients. Patients with liver disease, including hepatic echinococcosis, appear to be more at risk of bone marrow suppression and warrant closer monitoring of blood counts. Albendazole should be discontinued in all patients if clinically significant decreases in blood cell counts occur.

Liver Function

In clinical trials, treatment with albendazole has been associated with mild to moderate elevations of hepatic enzymes in approximately 16% of patients. These elevations have generally returned to normal upon discontinuation of therapy. There have also been case reports of acute liver failure of uncertain causality and hepatitis .

Liver function tests (transaminases) should be performed before the start of each treatment cycle and at least every 2 weeks during treatment. If hepatic enzymes exceed twice the upper limit of normal, consideration should be given to discontinuing albendazole therapy based on individual patient circumstances. Restarting albendazole treatment in patients whose hepatic enzymes have normalized off treatment is an individual decision that should take into account the risk/benefit of further albendazole usage. Laboratory tests should be performed frequently if albendazole treatment is restarted.

Patients with abnormal liver function test results are at increased risk for hepatotoxicity and bone marrow suppression . Therapy should be discontinued if liver enzymes are significantly increased or if clinically significant decreases in blood cell counts occur.

Theophylline

Although single doses of albendazole have been shown not to inhibit theophylline metabolism, albendazole does induce cytochrome P450 1A in human hepatoma cells. Therefore, it is recommended that plasma concentrations of theophylline be monitored during and after treatment with Albendazole.

4.5 Interaction with other medicinal products and other forms of interaction:

Interactions:

Praziquantel has been reported to increase the plasma levels of the albendazole active metabolite.

4.6 Fertility, pregnancy and lactation:

Not applicable.

4.7 Effects on ability to drive and use machines:

Not applicable.

4.8 Undesirable effects

Side-Effects And Special Precautions :

Gastrointestinal discomfort, diarrhoea, headache and dizziness have been reported. Hypersensitivity reactions including rash. pruritus and urticaria have been reported less frequently.

5 Pharmacological properties:

5.1 Pharmacodynamic properties:

Pharmacological Classification:

A12 Anthelmintics.

Mechanism Of Action:

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.

5.2 Pharmacokinetic properties:

Absorption

Poorly absorbed from the gastrointestinal tract due to its low aqueous solubility. Oral bioavailability appears to be enhanced when co-administered with a fatty meal (estimated fat content 40 g).

Volume of distribution

Not Available

Protein binding

70% bound to plasma protein

Metabolism

Hepatic. Rapidly converted in the liver to the primary metabolite, albendazole sulfoxide, which is further metabolized to albendazole sulfone and other primary oxidative metabolites that have been identified in human urine.

5.3 Preclinical safety data:

No additional data of relevance.

6 Pharmaceutical particulars

6.1 List of excipients:

1. Maize Starch BP
2. Sucrose BP
3. Gelatine BP
4. Saccharine sodium BP
5. Col. Sunset yellow (supra) IHS
6. Colloidal silicon dioxide BP
7. Purified Talc BP
8. Methyl Paraben BP
9. Propyl Paraben BP
10. Sodium Benzoate BP
11. Flavour orange dc100 IHS
12. Magnesium stearate BP

6.2 Incompatibilities: Not applicable.

6.3 Shelf life: 36 Months

6.4 Nature and contents of container: 20 X 1 X 1

20 Blister Packed in carton. Each Blister contain one Tablet.

6.5 Special precautions for disposal and other handling: Keep in a cool, dark and dry place.

7. Applicant/manufacturer:

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