Summary of Product Characteristics

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1. NAME OF THE MEDICINAL PRODUCT

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Albendazole Tablets 400 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains:

Albendazole USP 400mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Chewable Tablets

Off-white to buff coloured, elongated, biconvex, mottled, chewable tablets score on one side.

4.0 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Albendazole is indicated for the treatment of parenchymal neurocysticercosis due to active lesions caused by larval forms of the pork tapeworm, *Taenia solium*.

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*.

Albendazole is effective in the treatment of Ascaris lumbricoides (roundworm), Trichuris trichiura (whipworm), *Enterobius* vermicularis (pinworm/threadworm), Ancylostoma duodenale and *Necator americanus* (hookworm), Taenia spp. (tapeworm) and *Strongyloides* stercoralis.

Albendazole has been shown to be effective in the treatment of Giardia (duodenalis or intestinalis or lamblia) infections in children

4.2 Posology and Method of administration

Usual Dose: 400 mg as a single dose in both adults and children over two years of age. The tablets may be chewed, swallowed or crushed and mixed with food. The usual dose in children between one and two years of age is 200 mg as a single dose.

Route of administration: oral.

4.3 Contraindications

Albendazole is contraindicated in patients with known hypersensitivity to the benzimidazole class of compounds.

4.4 Special warnings 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 28 day 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.

4.5 Interaction with other medicinal products and other forms of interact.

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 8 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 Tmax and mean plasma elimination half-life of albendazole sulfoxide were unchanged. The pharmacokinetics of praziquantel was unchanged following coadministration 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.

4.6 Pregnancy and Lactation

Pregnancy: Women should be advised to avoid pregnancy for at least 1 month following therapy. Discontinue if pregnancy occurs during treatment.

Lactation: Excretion in breast milk unknown/not recommended. Use with caution.

4.7 Effects on ability to drive and use machines

None reported

4.8 Undesirable effects

Blood and Lymphatic System Disorders: Leukopenia. There have been rare reports of granulocytopenia, pancytopenia, agranulocytosis, or thrombocytopenia. Patients with liver disease, including hepatic echinococcosis, appear to be more at risk of bone marrow suppression.

Immune System Disorders: Hypersensitivity reactions, including rash and urticaria.

Postmarketing Adverse Reactions In addition to adverse events reported from clinical trials, the following events have been identified during world-wide post-approval use of Albendazole. Because they are reported voluntarily from a population of unknown size, estimates of frequency cannot be made. These events have been chosen for inclusion due to a combination of their seriousness, frequency of reporting, or potential causal connection to Albendazole.

Blood and Lymphatic System Disorders: Aplastic anemia, bone marrow suppression, neutropenia.

Hepatobiliary Disorders

Elevations of hepatic enzymes, hepatitis, acute liver failure.

Skin and Subcutaneous Tissue Disorders

Erythema multiforme, Stevens-Johnson syndrome.

Renal and Urinary Disorders

Acute renal failure

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via EFDA yellow Card Scheme, online at https://primaryreporting.who-umc.org/ET or toll free call 8482 to Ethiopian food and drug authority (EFDA).

4.9 Overdose

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 and general supportive measures are recommended.

5.0 Pharmacological Properties

5.1 Pharmacodynamic Properties

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: Albendazole is poorly absorbed from the gastrointestinal tract due to its low aqueous solubility. Albendazole concentrations are negligible or undetectable in plasma as it is rapidly converted to the sulfoxide metabolite prior to reaching the systemic circulation. The systemic anthelmintic activity has been attributed to the primary metabolite, albendazole sulfoxide. Oral bioavailability appears to be enhanced when albendazole is coadministered with a fatty meal (estimated fat content 40 g) as evidenced by higher (up to 5-fold on average) plasma concentrations of albendazole sulfoxide as compared to the fasted state.

Maximal plasma concentrations of albendazole sulfoxide are typically achieved 2 to 5 hours after dosing and are on average 1.31 mcg/mL (range 0.46 to 1.58 mcg/mL) following oral doses of albendazole (400 mg) in 6 hydatid disease patients, when administered with a fatty meal. Plasma concentrations of albendazole sulfoxide increase in a dose-proportional manner over the

therapeutic dose range following ingestion of a fatty meal (fat content 43.1 g). The mean apparent terminal elimination half-life of albendazole sulfoxide typically ranges from 8 to 12 hours in 25 normal subjects, as well as in 14 hydatid and 8 neurocysticercosis patients.
Following 4 weeks of treatment with albendazole (200 mg three times daily), 12 patients' plasma concentrations of albendazole sulfoxide were approximately 20% lower than those observed during the first half of the treatment period, suggesting that albendazole may induce its own metabolism.

Distribution: Albendazole sulfoxide is 70% bound to plasma protein and is widely distributed throughout the body; it has been detected in urine, bile, liver, cyst wall, cyst fluid, and cerebral spinal fluid (CSF). Concentrations in plasma were 3- to 10-fold and 2- to 4-fold higher than those simultaneously determined in cyst fluid and CSF, respectively. Limited in vitro and clinical data suggest that albendazole sulfoxide may be eliminated from cysts at a slower rate than observed in plasma.

Metabolism and Excretion: Albendazole is 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. Following oral administration, albendazole has not been detected in human urine. Urinary excretion of albendazole sulfoxide is a minor elimination pathway with less than 1% of the dose recovered in the urine. Biliary elimination presumably accounts for a portion of the elimination as evidenced by biliary concentrations of albendazole sulfoxide similar to those achieved in plasma.

5.3 Preclinical Safety Data

Not applicable.

6.0 Pharmaceutical Particulars

6.1 List of Excipients

Sucrose, Povidone (K-30), Sodium Benzoate, Sodium Methyl Hydroxybenzoate, Sodium Propyl Hydroxybenzoate, Purified Talc, Magnesium Stearate, Colloidal Anhydrous Silica, Aspartame, Flavour Vanilla (Dry) and Purified water.

*Lost during processing

6.2 Incompatibilities

None stated

6.3 Shelf life

36 months from the date of manufacture.

6.4 Special precautions for storage

Store at a temperature not exceeding 30°C in a dry place. Protect from light.Keep out of reach of children.

6.5 Nature and contents of container

3 Tablets packed in Blister aluminium foil and Clear PVC film and such 50 blisters packed in a unit carton along with package insert.

6.6 Special precautions for disposal

Return any leftover medicine to your pharmacist.

7. MARKETING AUTHORISATION HOLDER

MEDICAMEN Biotech Limited

SP-1192 A&B, PHASE - IV,

Industrial Area,

Bhiwadi - 301 019

Distt. Alwar,

Rajasthan, India.

8. **NUMBER(S) IN THE NATIONAL REGISTER OF FINISHED PHARMACEUTICAL PRODUCTS**

Registration No 07729/08803/NMR/2021

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION]

Approval date 22-08-2022

10. DATE OF REVISION OF THE TEXT

July 2024