1. NAME OF THE MEDICINAL PRODUCT

Drutazole (Albendazole 400mg) Chewable Tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Mannitol, Lactose monohydrate, Microcrystalline cellulose (Avicel 101), Polyinyl Pyrolidone K-30 (Paste), Red iron oxide (Paste), Aspartan, Vanilla flavour, Sodium starch glycolate, Aerosil, Magnesium stearate.

3. PHARMACEUTICAL FORM

Solid-(Tablet, Chewable)

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Albendazole is indicated in the treatment of single and mixed intestinal nematode infections including ascariasis, enterobiasis, hookworm, strongyloidiasis and trichuriasis.

It may be used in the treatment of capillariasis, gnathostomiasis and trichostrongyliasis

Albendazole may be effective in the treatment of the tissue nematode infections cutaneous larva migrants, toxocariasis and trichinosis.

In combination with other antihelmintics, in the management of the filarial nematode infection, lymphatic filariasis.

It is used in relatively high doses in the treatment of the cestode infection cysticercosis and echinococcosis (hydatid disease).

4.2 Posology and method of administration

Posology

Ascaris, hookworm infections, enterobiasis and trichostrongyliasis;
Adults and Children over 2 years: 400mg (one chewable tablet) as a single dose. Children 12 months-2 years: 200mg as a single dose.

Trichuriasis;
Adult and Children over 2 years 400mg (one chewable tablet) as a single dose (for moderate infections or 400mg daily for 3 days (severe infections). Children 12 months-2 years; 200mg as a single dose (for moderate infections) or 200mg initially then 100mg twice daily for 3 days (severe infections).

Strongyloidiasis;
Adult and children over 2 years 400mg once or twice daily for 3 days.

Capillariasis:
Adult and children over 2 years 400mg daily for 10 days.

Method of administration: Oral Administration

4.3 Contraindications

Hypersensitivity to albendazole or any component of the formulation.

4.4 Special warnings and precautions for use

4.5 Interaction with other medicinal products and other forms of interaction

- Albendazole serum levels are increased when taken with dexamethasone, and praziquantel.
- Cimetidine may increase Albendazole metabolism.
- Albendazole serum levels may be increased if taken with a fatty meal (increases the oral bioavailability by 4-5 times).

4.6 Pregnancy and lactation

Albendazole has been shown to be teratogenic in laboratory animals and should not be used during pregnancy; if at all possible.
For women of childbearing age (15-40 years), Drutazole should be administered within 7days of the start of normal menstruation.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

Adverse reactions: The following adverse events were observed during clinical studies. It should however be noted that causality has not necessarily been established for these events. Common (≥1%) Abdominal pain was the most frequently reported symptom (1%) during short term dosing, however this frequency was not significantly different from that in placebo-treated patients. Uncommon (>0.1% and < 0.1%) Rarely reported events included bone pain, proteinuria, and low red cell count. Leucopenia and transiently raised hepatic enzymes were reported in studies with laboratory monitoring, however, no definite relationship to the drug was shown. Hypersensitivity reactions including rash, pruritis and urticaria have been reported very rarely. During prolonged higher-dose albendazole therapy of hydatid disease, there have also been reports of severe hepatic abnormalities, including jaundice and hepatocellular damage which may be irreversible.

4.9 Overdose

Significant toxicity and mortality were shown in animal studies 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. In case of overdosage, symptomatic therapy and general supportive measures are recommended.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anthelminthic, ATC code: P02CA03

Mechanism of action:
Albendazole causes degenerative alterations in the tegument and intestinal cells of the worm by diminishing its energy production, ultimately leading to immobilization and death of the parasite. It works by binding to the colchicine-sensitive site of tubulin, thus inhibiting its polymerization or assembly into microtubules. As cytoplasmic microtubules are critical in promoting glucose uptake in

larval and adult stages of the susceptible parasites, the glycogen stores of the parasites are depleted. 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.

5.2 Pharmacokinetic properties

Absorption of albendazole from the gastrointestinal tract is poor but may be enhanced by a fatty meal. Albendazole rapidly undergoes extensive first-pass metabolism. It principal metabolite albendazole sulfoxide has antihelmintic activity and a plasma half-life of about 8.5 hours. Albendazole sulfoxide is widely distributed throughout the body including into the bile and the cerebrospinal fluid. It is about 70% bound to plasma protein. Albendazole sulfoxide is eliminated in the bile. Only a small amount appears to be excreted in the urine.

5.3 Preclinical safety data

Genotoxicity: Albendazole was concluded that albendazole was non-genotoxic in multiple assay systems.
Carcinogenesis: Albendazole was non-carcinogenic in mice.

Reproductive toxicity: The most significant toxicological effect was teratogenicity, limb defects in the rat being the most sensitive indicator of developmental toxicity. A composite NOEL of 5 mg/kg bw/day was derived from the results of a series of Segment II studies in Long-Evans rats. An ADI of 0-0.05 mg/kg bw was established based on this NOEL and a safety factor of 100. A safety factor of 100 was chosen for this compound after taking into consideration poor absorption in humans, rapid metabolism, the lack of teratogenic potential of most metabolites, the use of the drug in humans, and the identity of residues in food.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Mannitol
- Lactose monohydrate
- Microcrystalline cellulose (Avicel 101)
- Polyvinyl Pyrolidone K-30 (Paste)
- Red iron oxide (Paste)
- Aspartame
- Vanilla flavour
- Sodium starch glycolate
- Aerosil
- Magnesium stearate.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

48 months

6.4 Special precautions for storage

Store below 30ºC in tight container protected from light and moisture.

6.5 Nature and contents of container

Drutazole® is presented as 400mg Albendazole chewable tablet in a blister of 1's per pack and 100's per pack.

6.6 Special precautions for disposal <and other handling>

Any unused product or waste material should be disposed of in accordance with local requirements.

7. APPLICANT/MANUFACTURER

Drugfield Pharmaceuticals Limited
Lynson Chemical Avenue
Km38, Lagos-Abeokuta
Expressway Sango-Otta,
Ogun State, Nigeria
Tel: +2348033513989
Email:Info@drugfieldpharma.com

8. DATE OF FIRST AUTHORISATION

28/02/2019

10. DATE OF REVISION OF THE TEXT

05/2023