

SUMMARY OF PRODUCT CHARACTERISTICS.

1. Name of the medicinal product.

Altoa Tablets

2. Qualitative and quantitative composition.

Each chewable tablet contains: Albendazole USP 400mg.

Each chewable tablet contains: Lactose Monohydrate BP 114.75mg.

3. Pharmaceutical form.

Chewable Tablets.

Pale orange, circular FFBE tablets scored on one side plain on reverse.

4. Clinical Particulars.

4.1 Therapeutic Indications.

Ancylostomiasis (Hookworm infection), Ascariasis (Roundworm infection), Cysticercosis, Enterobiasis (threadworm infection), Hydatid disease, Opisthorchiasis, strongyloidiasis (pinworm infection) Taenia (Tapeworm infection) and Trichuriasis (Whipworm infection) Altoa will alleviate the discomfort of cutaneous larva migrans.

4.2 Posology and method of administration.

Route of administration: Oral.

Altoa preparations are usually given to adults and children aged 2 years and above orally as follows:

- For Ascariasis, Ancylostomiasis or Trichuriasis, 400mg is given as a single dose.
- Capillariasis; 400mg daily in divided doses for 10 to 20 days.
- strongyloidiasis; 400mg daily for 3 consecutive days and may be repeated, if necessary, after 3 weeks.
- Taeniasis; when mixed with other worms' infections as for strongyloidiasis.
- Cutaneous larva migrans; 400mg twice daily for 3 to 5 days.
- Opisthorchiasis; 400mg daily for 3 to 7 days.
- Neurocysticercosis; 15 to 30mg/kg of body weight daily for 1 month.
- Hydatid disease; 10 to 15mg/kg of body weight daily or 400mg twice daily for 28days treatment-circles for 1 to 12 treatment circles. Two weeks rest period should intercede treatment-circles.
- For enterobiasis; the recommended treatment is; children 2 years; 100mg first and again repeated after 7 days.
- Children of 1-2 years of age may be given 200mg of albendazole orally for strongyloidiasis.

4.3 Contraindications.

Altoa is contra-indicated in patients with a known history of hypersensitivity to albendazole.

4.4 Special warnings and precautions for use.

Patients on high dose treatment regimens should be closely monitored for development of serious adverse reactions by conducting blood counts and liver function tests. Albendazole has been shown as having teratogenic and embryotoxic effects in rats and rabbits; its use is contraindicated in pregnant women or those likely to be pregnant. For women of child bearing age (15-40years) should be administered within 7 days of the start of normal menstruation.

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

Praziquantel increase the plasma levels of the active metabolite of albendazole.

Ritonavir, phenytoin, carbamazepine and phenobarbital may reduce plasma concentrations of the active metabolite of albendazole; albendazole sulfoxide. The clinical relevance of this is unknown, but may result in decreased efficacy, especially in the treatment of systemic helminth infections. Patients should be monitored for efficacy and may require alternative dose regimens or therapies.

Pregnancy and Lactation.

Altoa should not be administered during pregnancy or in women thought to be pregnant (refer to CONTRA-INDICATIONS).

Albendazole is known to be teratogenic and embryotoxic in animals. Adequate human data during lactation are not available

4.6 Effects on ability to drive and use machines.

Since dizziness has been reported following treatment with albendazole, caution is recommended in patients performing skilled tasks.

4.7 Undesirable effects.

Altoa is largely free of adverse reactions at the usual low doses. With-high dose regimens the following one or several adverse drug reactions occur in 18 to 23% of cases; Raised serum transaminase, leucopenia, depressed bone marrow activity, allergic reactions mostly urticaria and itching, loss of hair, abdominal pains and or other gastro-intestinal symptoms, severe headache,

fever fatigue, thrombocytopenia hepatocellular type abnormality and cholestatic jaundice.

4.8 Overdose and treatment.

Known Symptoms of Overdosage and Particulars of its treatment: Further management should be as clinically indicated or as recommended by the national poisons center, Where available.

5. Pharmacological properties.

5.1 Pharmacodynamic properties.

ATC Code: P02CA03

The active ingredient in Altoa is albendazole.

Albendazole is a benzimidazole that is also similar in its antihelmintic activity and structure to mebendazole it is effective against most common nematodes and some cestodes. Other less common parasitic worms that are also sensitive to albendazole are; Capillaria philippinensis, Echnococcus granulosus cysts, Echinococcus multilocularis cysts and Opisthorchis viverrini.

5.2 Pharmacokinetic properties.

Albendazole is poorly absorbed from the gastrointestinal tract and any small amount that happens to be absorbed undergoes rapid and extensive first-pass metabolism. It is largely due to this fact that the free albendazole is not readily detectable in the blood. The principal metabolite, albendazole sulphoxide also have antihelmintic activity. About 70% of this metabolite present in the plasma is bound to the proteins and has a plasma half-life of about eight and half hours. The sulphoxide derivative is excreted largely in urine. Other metabolites also excreted in urine are albendazole sulphone and its 2-amino derivative; and 2-amino albendazole sulphoxide.

5.3 Preclinical safety data.

There is no pre-clinical data of relevance to a prescriber, which is additional to that already included in other sections of the SPC.

6. Pharmaceutical Particulars.

6.1 List of Excipients.

- White Maize Starch.
- Lactose Monohydrate.
- Sodium Starch Glycolate.
- Sodium Lauryl Sulphate.
- Sodium saccharin.
- Povidone (K-30).
- Potassium sorbate.
- Sodium Benzoate.
- Sunset yellow colour (Soluble).
- Purified Water.
- Aspartame Powder.
- Vanilla Flavour powder
- Strawberry flavour Powder.
- Purified Talc.
- Magnesium stearate.

6.2 Incompatibilities.

None.

6.3 Shelf Life.

36 months

6.4 Special precautions for storage.

Store in a dry place, below 30°C in a dry place. Protect from light.
Keep all medicines out of reach of children.

6.5 Nature and contents of container

Packed in a blister pack of 1x1's contained in a unit box and 100's in a HDPE container with literature insert.

6.6 Special precaution for disposal and other handling.

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

7 Marketing Authorization Holder and Manufacturing Site Addresses.

Marketing Authorization Holder:

Company Name: LABORATORY & ALLIED LTD

Address: Plot No. 209/10349, Opposite Sameer Business Park, Next to Libra House, Mombasa road, P.O. Box 42875 GPO 00100, Nairobi,

Country : Kenya

Telephone : +254 20 8040306

Telefax : +254 20 8040309

E-Mail : info@laballied.com.

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E-Mail : info@laballied.com

8 Marketing Authorization Number:

Kenya: H2013/CTD733/061

9 Date of first Registration/ Renewal of the Registration:

Date of registration: 22/02/2013

Retained: Annually.

10 Date of revision of the text:

April 2024.