SUMMARY OF PRODUCT CHARACTERISTICS.

1. Name of the medicinal product.

Natoa Tablets.

2. Qualitative and Quantitative Composition.

Each chewable tablet contains: **Mebendazole BP 100mg.**

3. Pharmaceutical form.

Chewable tablet.

Pink, circular, FFBE tablets scored on one side and plain on reverse. Packed in blisters 6's, 100's contained in a unit box and 1000's in HDPE container with literature insert.

4. Clinical Particulars.

4.1 Therapeutic indication

Mebendazole being poorly absorbed from the gastro-intestinal tract, is used principally in the treatment of intestinal nematode infections mainly Ascaris (roundworm infection), enterobiasis (threadworm infection), hookworm infection (ancylostomiasis and necatoriasis) and trichuriasis (whipworm infection). It's used in mixed infections. Mebendazole is also used in the treatment of capillariasis. Mebendazole is also active against the adult and larva forms of some cestodes worms and has been tried in high doses in treatment of hydatid disease though albendazole is preferred.

4.2 Contraindication.

Mebendazole is contraindicated in pregnancy and babies aged below 2 years.

4.3 Dosage and Administration

Mebendazole is given orally. The usual dose for adults and children aged 2 year or over with enterobiasis is 100mg as a Single dose, repeated, if necessary, after 2 to 3 weeks; for ascariasis, hookworm infections and trichuriasis the dosage is 100mg twice daily for 3 days.

4.4 Precautions.

During treatment with mebendazole some worms may migrate with ex pulsion through the mouth and nose in patients heavily infected with Ascaris. This might cause choking and coughing in these patients especially children. Patients receiving high doses of mebendazole such as those with hydatic disease should be supervised closely with monitoring of blood and liver function.

4.5 Interactions with other medicinal products and other forms of interaction

Concomitant treatment with cimetidine may inhibit the metabolism of mebendazole in the liver, resulting in increased plasma concentrations of the drug. Concomitant use of mebendazole and metronidazole should be avoided.

4.6 Pregnancy and lactation.

Pregnancy

Since Mebendazole is contra-indicated in pregnancy, patients who think they are, or may be, pregnant should not take this preparation.

Lactation

As it is not known whether mebendazole is excreted in human milk, it is not advisable to breast feed following administration.

4.7 Effects on ability to drive and use machines

Mebendazole has no influence on the ability to drive and use machines.

4.6 Side effects.

Mebendazole is poorly absorbed from the gastro-intestinal tract, hence at the usual therapeutic doses Side effects are restricted to gastro-intestinal disturbances such as abdominal pain and diarrhoea. However, allergic reactions, raised liver enzyme level, leucopenia and alopecia have been reported with high doses tried in the treatment of hydatid disease.

4.3 Overdose

In patients treated at dosages substantially higher than recommended or for prolonged periods of time, the following adverse reactions have been reported rarely: alopecia, reversible liver function disturbances, hepatitis, Agranulocytosis, neutropenia and glomerulonephritis. With the exception of Agranulocytosis and glomerulonephritis, these also have been reported in patients who were treated with mebendazole at standard dosages.

Signs and symptoms

In the event of accidental over dosage, abdominal cramps, nausea, vomiting and diarrhoea may occur.

Treatment

There is no specific antidote. Activated charcoal may be given if considered appropriate.

5. Pharmacological properties

5.1 Pharmacodynamics properties

Pharmacotherapeutic group: **benzimidazole derivatives,**

ATC code: **P02CA01.**

Mebendazole is a benzimidazole carbamate derivative, with an anthelmintic activity against most nematodes (Ancylostoma duodenale. Ascaris lumbricoides, Enterobius vermicularis, Necator americanus, Strongyloides stercoralis, trichuris trichiura) and some cestodes (*Echinoccus spp and Taenia spp*.) Activity against some larval stages and ova has been demonstrated. Mebendazole's antheminitic activity is considered to be dependent on the inhibition or destruction of cytoplasmic microtubules in the worm's intestinal or absorptive cells; inhibition of glucose uptake and depletion of glycogen stores follow as do other inhibitory effects leading to death of the worm within several days.

5.2Pharmacokinetic properties

Mebendazole is poorly absorbed from the gastrointestinal tract and undergoes extensive first-pass elimination, being metabolized in the liver, eliminated in the bile as unchanged drug and metabolites, and excreted in the faeces. Only about 2% of a dose is excreted unchanged or as metabolites in the urine. Mebendazole is highly protein bound.

5.3 Preclinical safety data

No information submitted.

6. Pharmaceutical particulars

6.1 List of Excipients

- Dextrose Anhydrous
- Lactose Monohydrate
- Sodium starch glycolate
- Erythrosine soluble colour
- Povidone K-30
- Potassium sorbate
- Sodium benzoate
- White corn starch (for paste)
- Purified water
- Aspartame
- Crospovidone
- Vanilla flavour
- Aerosil
- Magnesium stearate

6.2 Incompatibilities

None known

6.3 Shelf life:

36 months

6.4 Special precautions for storage

Store below 30^0 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 blister packs of 6', 100's in a unit box and 1000's in HDPE container with literature insert.

6.6 Special precautions for disposal and other handling

None stated.

7. Marketing authorization holder/Registrant.

Laboratory & Allied Limited

Plot No. 209/10349, Opposite Sameer Business Park, Next to Libra House, Mombasa Road.
P.O Box 42875 GPO 00100, Nairobi –Kenya.

Manufacturer.

Laboratory & Allied Limited.

Plot No. 209/10349, Opposite Sameer Business Park, Next to Libra House, Mombasa Road.
P.O.BOX 42875 GPO 00100, Nairobi –Kenya.
Email: info@laballied.com.

8. Marketing authorization number(s)
H85/289
9. Date of first authorization/renewal of the authorization
Date of first authorization: **31/7/1985**
Retained: **Annually.**
10. Date of revision of the text
May 2023.