Prescribing Information (Summary of Product Characteristics)

1. NAME OF THE MEDICINAL PRODUCT.

Natoa Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION.

Each 5ml contains: Mebendazole BP 100mg and excipients provided in section 6.1

3. PHARMACEUTICAL FORM.

Suspension for oral administration.
Pink, viscous, homogenous suspension, packed in 30mL amber glass/PET bottle and contained in a unit box with literature insert.

4. CLINICAL PARTICULARS.

4.1 Therapeutic Indications

Mebendazole 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 Posology and method of administration

Route of administration: Oral.
Adults and children over 2 years:
Mebendazole is given orally. The usual dose for adults and children aged 2 years 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.

4.3 Contraindications

Mebendazole is contraindicated in pregnancy and in patients who have shown hypersensitivity to the product or any excipients

4.4 Special Warnings and Precautions for Use

Not recommended in the treatment of children under 2 years.
A case-control study of a single outbreak of Stevens-Johnson syndrome /toxic epidermal necrolysis (SJS/TEN) suggested a possible association with the concomitant use of metronidazole with mebendazole. Although there are no additional data on this potential interaction, concomitant use of mebendazole and metronidazole should be avoided.
During treatment with mebendazole some worms may migrate with expulsion 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 hydatid disease should be supervised closely with monitoring of blood counts and liver function.

4.5 Interaction 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

4.8 Undesirable Effects

Throughout this section adverse reactions are reported. Adverse reactions are adverse events that were considered to be reasonably associated with the use of Mebendazole based on the comprehensive assessment of the available adverse event information. A causal relationship with mebendazole cannot be reliably established in individual cases. Further, because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

The safety of mebendazole was evaluated in 6276 subjects who participated in 39 clinical trials for the treatment of single or mixed parasitic infestations of the gastrointestinal tract. In these 39 clinical trials, no adverse drug reactions (ADRs) occurred in ≥1% of mebendazole-treated subjects.

4.9 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.

In vitro and in vivo work suggests that mebendazole blocks the uptake of glucose by adult and larval forms of helminths, in a selective and irreversible manner. Inhibition of glucose uptake appears to lead to endogenous depletion of glycogen stores within the helminth. Lack of glycogen leads to decreased formation of ATP and ultra-structural changes in the cells.

There is no evidence that mebendazole is effective in the treatment of cysticercosis.

5.2 Pharmacokinetic properties

Absorption

Following oral administration, < 10% of the dose reaches the systemic circulation, due to incomplete absorption and to extensive pre-systemic metabolism (first-pass effect). Maximum plasma concentrations are generally seen 2 to 4 hours after administration. Dosing with a high fat meal leads to a modest increase in the bioavailability of mebendazole.

Distribution

The plasma protein binding of mebendazole is 90 to 95%. The volume of distribution is 1 to 2 L/kg, indicating that mebendazole penetrates areas outside the vascular space. This is supported by data in patients on chronic mebendazole therapy (e.g., 40 mg/kg/day for 3-21 months) that show drug levels in tissue.

Metabolism

Orally administered mebendazole is extensively metabolized primarily by the liver. Plasma concentrations of its major metabolites (amino and hydroxylated amino forms of mebendazole) are substantially higher than those of mebendazole. Impaired hepatic function, impaired metabolism, or impaired biliary elimination may lead to higher plasma levels of mebendazole.

Elimination

Mebendazole, the conjugated forms of mebendazole, and its metabolites likely undergo some degree of enterohepatic recirculation and are excreted in the urine and bile. The apparent elimination half-life after an oral dose range from 3 to 6 hours in most patients.

Steady-state pharmacokinetics

During chronic dosing (e.g., 40 mg/kg/day for 3-21 months), plasma concentrations of mebendazole and its major metabolites increase, resulting in approximately 3-fold higher exposure at steady-state compared to single dosing.

5.3 Preclinical safety data

No information of relevance other than information provided in the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

- Sodium Methyl Paraben
- Sodium Propyl Paraben
- Sodium Benzoate
- Sodium Carboxymethyl Cellulose (Blanose)
- Xanthan Gum 200 Mesh
- Sugar
- Glycerin
- Polysorbate 80 (Tween 80)
- Erythrosine Soluble Colour
- Vanilla Essence Liquid
- Citric Acid
- Purified Water

6.2 Incompatibilities
None Known.

6.3 Shelf Life
36 months

6.4 Special Precautions for Storage
Store below 30ºC in a dry place.
Protect from light, do not freeze.
Keep all medicines out of reach of children.

6.5 Nature and Contents of Container
Packed in 30mL amber glass/PET bottle and contained in a unit box with literature insert.

6.6 Special precautions 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.
Company Name: Laboratory and Allied Limited.
Address: Plot No. 209/10349, Opposite Sameer Business Park, next to Libra House, Mombasa Road,
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Telephone: +254 20 8040306
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Manufacturing Site Address:
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Telephone: +254 20 8040306.
Telefax: +254 20 8040309.
E-Mail: info@laballied.com

8. MARKETING AUTHORIZATION NUMBER
Kenya: Registration No. H87123.

9. DATE OF FIRST <REGISTRATION> / RENEWAL OF THE <REGISTRATION>
Date of first authorization: 27/11/1987
Date of latest renewal: Retained Annually

10. DATE OF REVISION OF THE TEXT
October 2024.

11. DOSIMETRY (IF APPLICABLE)
Not Applicable.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)
Not Applicable.