PACKAGE INSERT

SCHEDULING STATUS: S4

PROPRIETARY NAME (AND DOSAGE FORM):

WORMADOLE (Chewable tablets)

COMPOSITION:

Active ingredient:

Each **WORMADOLE** chewable tablet contains 400 mg albendazole.

Other Ingredients: Sunset Yellow colour, colloidal anhydrous silica, orange flavour, lactose monohydrate, magnesium stearate, maize starch, mannitol, saccharin sodium, sodium citrate.

Contains lactose monohydrate (sugar).

PHARMACOLOGICAL CLASSIFICATION:

A 12 Anthelmintics

PHARMACOLOGICAL ACTION:

Albendazole is a benzimidazole carbamate with anthelmintic and antiprotozoal activity against intestinal and tissue parasites.

Albendazole exhibits vermicidal, ovacidal and larvacidal activity and exerts its anthelmintic effect by inhibiting tubulin polymerization. This causes the disruption of the helminth metabolism, including energy depletion, which immobilises and then kills the susceptible helminth.

Pharmacokinetics:

After oral dose, albendazole cannot be detected in plasma, because the medicine is completely metabolized in the liver. At a dose of 6,6 mg/kg of albendazole, the plasma concentration of its main metabolite, the sulfoxide, attains a maximum of 0,25 to 0,30 microgram/ml after approximately 2,5

hours. The half life of the sulfoxide in the plasma is 8,5 hours. Albendazole sulfoxide is about 70 % bound to plasma proteins.

The metabolite is essentially eliminated via the urine.

INDICATIONS:

WORMADOLE is indicated in the treatment of single or mixed intestinal parasites.

WORMADOLE has been shown to be 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.*

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

CONTRAINDICATIONS:

WORMADOLE is known to be teratogenic and embryotoxic in animals.

WORMADOLE is contraindicated in patients with a known history of hypersensitivity to albendazole or its constituents.

The safety of **WORMADOLE** during pregnancy has not been established, and **WORMADOLE** should not be taken by pregnant women at any stage of their pregnancy or by women who are likely to become pregnant, during or shortly after the course of therapy (see **"WARNINGS AND SPECIAL PRECAUTIONS"** and **"PREGNANCY AND LACTATION")**.

WARNINGS AND SPECIAL PRECAUTIONS:

It has been noted that leucopenia has occurred when used for periods longer than recommended.

In order to avoid administering WORMADOLE during early pregnancy, women of childbearing age should initiate treatment during the first week of menstruation or after a negative pregnancy test (see **"CONTRAINDICATIONS"** and **"PREGNANCY AND LACTATION").**

INTERACTIONS:

Praziquantel has been reported to increase the plasma levels of the albendazole active metabolite.

PREGNANCY AND LACTATION:

WORMADOLE is known to be teratogenic and embryotoxic in animals.

The safety of **WORMADOLE** during pregnancy has not been established, and **WORMADOLE** should not be taken by pregnant women at any stage of their pregnancy or by women who are likely to become pregnant, during or shortly after the course of therapy (see **"CONTRAINDICATIONS"** and **"WARNINGS AND SPECIAL PRECAUTIONS")**.

In order to avoid administering **WORMADOLE** during early pregnancy, women of childbearing age should initiate treatment during the first week of menstruation or after a negative pregnancy test (see **"CONTRAINDICATIONS"** and **"WARNINGS AND SPECIAL PRECAUTIONS")**.

DOSAGE AND DIRECTIONS FOR USE:

Usual Dose: 400 mg **WORMADOLE** as a single dose in both adults and children over two years of age. The tablet may be chewed or crushed and mixed with food.

In heavy mixed infestation involving *Strongyloides* or *Taeniasis*, a single daily dose may be inadequate and the dose may be given for three consecutive days.

NOTE: If the patient is not cured after three weeks, a second course of treatment may be given. No special procedures, such as fasting or purging, are required.

Giardiasis (dose in children over 2 years of age): A single 400 mg daily dose of **WORMADOLE** for five days. The tablets may be chewed or crushed and they should be taken with food.

SIDE EFFECTS:

Nervous system disorders:	*Less frequent:* Headache, dizziness.
Gastrointestinal disorders:	*Less frequent:* Gastrointestinal discomfort, diarrhea.
Skin and subcutaneous tissue disorders:	*Less frequent:* Hypersensitivity reactions including rash, pruritus and urticaria have been reported.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

If poisoning or excessive overdosage is suspected it is recommended, on general principles, that vomiting be induced or gastric lavage be performed, and such symptomatic supportive therapy be administered as appears indicated.

IDENTIFICATION:

Cream or buff coloured, capsule shaped chewable tablets.

PRESENTATION:

Silver coloured aluminium foil strips containing 1 tablet, packed as follows:

- 1 strip packed into a unit carton (1 tablet), or
- 500 strips packed into an outer shipper (500 tablets).

STORAGE INSTRUCTIONS:

Store in a cool place (at or below 25 °C).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN..

REGISTRATION NUMBER:

A38/12/0426

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Dezzo Trading 392 (Pty) Ltd.

Cnr Birch Road and Bluegum Avenue

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DATE OF PUBLICATION OF THE PACKAGE INSERT:

15 December 2017