Approved Professional Information for Medicines for Human Use: WORMADOLE

SCHEDULING STATUS

S2

1. NAME OF THE MEDICINE

WORMADOLE 400 mg (chewable tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each WORMADOLE chewable tablet contains 400 mg albendazole.

Contains sugar:

Each WORMADOLE 400 mg chewable tablet contains 250 mg lactose monohydrate.

Each WORMADOLE 400 mg chewable tablet contains 150 mg mannitol.

Contains sweetener:

Each WORMADOLE 400 mg chewable tablet contains 7 mg saccharin sodium.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Chewable tablets

Cream or buff coloured, capsule shaped chewable tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

WORMADOLE is indicated in the treatment of intestinal parasites, as a single oral dose.

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*.

4.2 Posology and method of administration

Posology

Usual Dose

400 mg WORMADOLE as a single oral dose in both adults and children over two years of age.

Special populations

Elderly population

Experience in patients 65 years of age or older is limited.

Reports indicate that no dosage adjustment is required; however, albendazole should be used with caution in elderly patients with evidence of hepatic dysfunction (see Hepatic Impairment below).

Renal impairment

Since renal elimination of albendazole and its primary metabolite, albendazole sulfoxide, is negligible, it is unlikely that clearance of these compounds would be altered in these patients. No dosage adjustment is required; however, patients with evidence of renal impairment should be carefully monitored.

Hepatic impairment

Since albendazole is rapidly metabolised by the liver to the pharmacologically active metabolite, albendazole sulfoxide, hepatic impairment would be expected to have significant effects on the pharmacokinetics of albendazole sulfoxide. Patients with abnormal liver function test results (transaminases) prior to commencing albendazole therapy should be carefully monitored.

Paediatric population

Albendazole has not been adequately studied in children under one year of age.

Method of administration

WORMADOLE is intended for oral use.

The WORMADOLE tablet may be chewed or crushed and mixed with food.

Some people, particularly young children, may experience difficulties swallowing the tablet whole and should be encouraged to chew the tablet with a little water; alternatively, the tablet may be crushed and mixed with food.

4.3 Contraindications

- Hypersensitivity to albendazole or to any of the excipients listed in section 6.1.
- Pregnancy and lactation (see section 4.4 and 4.6)

4.4 Special warnings and precautions for use

In order to avoid taking WORMADOLE during early pregnancy, women of childbearing age should initiate treatment during the first week of menstruation or after a negative pregnancy test (see section 4.3 and 4.6).

Sub-clinical neurocysticercosis may manifest after a single dose of WORMADOLE. Treatment with albendazole may uncover pre-existing neurocysticercosis, particularly in areas with high taeniasis infection. Patients may experience neurological symptoms e.g. seizures, increased intracranial pressure and focal signs as a result of an inflammatory reaction caused by death of the parasite within the brain. Symptoms may occur soon after treatment, appropriate steroid and anticonvulsant therapy should be started immediately.

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

Paediatric population

There is limited experience with WORMADOLE in children under 1 years of age, therefore use in this age group is not recommended (see section 4.2).

Excipient lactose

WORMADOLE contains lactose: Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take WORMADOLE.

4.5 Interaction with other medicines and other forms of interaction

Praziquantel

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

Ritonavir, phenytoin, carbamazepine and phenobarbital

Ritonavir, phenytoin, carbamazepine and phenobarbital may reduce plasma concentrations of the active metabolite of WORMADOLE; 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.

Paediatric population

Safety and efficacy in children under 1 year of age has not been established.

4.6 Fertility, pregnancy and lactation

Pregnancy

WORMADOLE is known to be teratogenic and embryotoxic in animals.

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 section 4.3 and 4.4).

Breastfeeding

Adequate human data during lactation is not available.

The safety of WORMADOLE during lactation has not been established, and WORMADOLE should not be taken by breastfeeding women (see 4.3).

Fertility

Adequate human data on fertility is not available.

4.7 Effects on ability to drive and use machines

WORMADOLE may cause dizziness.

Patients should be cautioned when driving a car or operating machinery until they know how WORMADOLE affects them.

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4.8 Undesirable effects

a) Tabulated list of adverse reactions

The table below shows all adverse drug reactions (ADRs) observed during clinical trials and post-market spontaneous reports with albendazole

System Organ Class	**Frequency**		
	Frequent	**Less Frequent**	**Not known**
Immune system disorders		Hypersensitivity reactions	
Nervous system disorders		Headache, dizziness	
Gastrointestinal disorders		Upper gastrointestinal symptoms (e.g. epigastric or abdominal pain, nausea, vomiting) and diarrhoea	
Hepatobiliary disorders		Elevations of hepatic enzymes	
Skin and subcutaneous tissue disorders		Rash, pruritus and urticaria.	Erythema multiforme, Stevens-Johnson syndrome

Reporting of suspected adverse reactions

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Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of WORMADOLE. Healthcare professionals are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

Suspected side effects can also be reported directly to the Holder of the HCR via medsafety@austell.co.za

4.9 Overdose

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

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and Class: A 12 Anthelmintics

Pharmacotherapeutic group: antiparasitic products, insecticides and repellents.

ATC Code: P02CA03

Mechanism of 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.

5.2 Pharmacokinetic properties

Absorption

After oral dose, albendazole cannot be detected in plasma, because the medicine is completely metabolized in the liver.

Distribution

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.

Albendazole sulfoxide is about 70 % bound to plasma proteins.

Elimination

The half-life of the sulfoxide in the plasma is 8,5 hours.

The metabolite is essentially eliminated via the urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sunset yellow colour

Colloidal anhydrous silica

Orange flavour

Lactose monohydrate

Magnesium stearate

Maize starch

Mannitol

Saccharin sodium

Sodium citrate

6.2 Incompatibilities

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6.3 Shelf life

24 months

6.4 Special precautions for storage

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

6.5 Nature and contents of container

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).

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements

7. Holder of Certificate of Registration

Shanur Healthcare (Pty) Ltd

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3A Eton Road

Parktown

Johannesburg

2193

8. REGISTRATION NUMBER

WORMADOLE 400 mg (chewable tablets): A38/12/0426

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

7 July 2006

10. DATE OF REVISION OF THE TEXT

22 January 2024