Professional Information - Approved

ALBENDAZOLE 400 COSPHARM

SCHEDULING STATUS

S2

1. NAME OF THE MEDICINE

ALBENDAZOLE 400 COSPHARM (Chewable tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

ALBENDAZOLE 400 COSPHARM: Each tablet contains 400 mg Albendazole.

Contains sugar:

Each ALBENDAZOLE 400 COSPHARM chewable tablet contains 150 mg Lactose monohydrate.

Contains Sweetener:

Each ALBENDAZOLE 400 COSPHARM chewable tablet contains 2 mg Saccharin sodium

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Chewable tablets.

ALBENDAZOLE 400 COSPHARM: Mottled, pale orange, rounded oblong, biconvex chewable tablets with a score line on one side and other side plain.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

ALBENDAZOLE 400 COSPHARM is indicated in the treatment of single or mixed intestinal

parasites – roundworm; whipworm; pinworm; hookworm; tapeworm, for single dose use.

4.2 Posology and method of administration

Posology

Usual Dose

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

Note

If the patient is still symptomatic after a single course of treatment, they must consult a healthcare professional for further treatment. No special procedures, such as fasting or purging, are required. Do not exceed the maximum daily dose and treatment duration recommended.

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

ALBENDAZOLE 400 COSPHARM is intended for oral use.

The ALBENDAZOLE 400 COSPHARM 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

ALBENDAZOLE 400 COSPHARM is contraindicated in patients with a known history of hypersensitivity to albendazole or any of the excipients listed in section 6.1.

ALBENDAZOLE 400 COSPHARM should not be administered during pregnancy or in women thought to be pregnant (see section 4.6).

4.4 Special warnings and precautions for use

In order to avoid taking ALBENDAZOLE 400 COSPHARM 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 Albendazole. 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 Albendazole in children under 1 years of age, therefore, use in this age group is not recommended.

Excipient lactose

Albendazole contains lactose: Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take ALBENDAZOLE 400 COSPHARM.

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 ALBENDAZOLE 400 COSPHARM; 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

ALBENDAZOLE 400 COSPHARM is known to be teratogenic and embryotoxic in animals.

ALBENDAZOLE 400 COSPHARM 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.

Breastfeeding

Adequate human data during lactation is not available. The safety of **ALBENDAZOLE 400 COSPHARM** during lactation has not been established, and **ALBENDAZOLE 400 COSPHARM** should not be taken by breastfeeding women.

Fertility

Adequate human data on fertility is not available.

4.7 Effects on ability to drive and use machines

ALBENDAZOLE 400 COSPHARM may cause dizziness.

Patients should be cautioned when driving a car or operating machinery until they know how **ALBENDAZOLE 400 COSPHARM** affects them.

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, Steven-Johnson syndrome

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Healthcare providers should also report adverse reactions to the Holder Of Certificate of Registration: Cospharm Investments (Pty) Ltd.

The contact details for our national reporting system are:

Email: rp@cospharm.org

Tel: 010 110 9348

Emergency: 0711751289

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

Croscarmellose sodium

Lactose monohydrate

Maize starch

Povidone (K 30)

Saccharin sodium

Polysorbate 80

Sodium Lauryl sulphate

Microcrystalline cellulose (pH 112)

Magnesium stearate

Sunset Yellow Lake (Sunset Yellow FCF, Aluminium Hydroxide, Water in the form of Moisture, Sodium Chloride & Sodium Sulphate)

Orange Dry powder (Emulsifier (INS 414), Maltodextrin, Natural Flavoring Substances, Nature Identical Flavoring Substances, Preservative (INS 211) & Antioxidant (INS300)

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 30 °C. Protect from light

For 1000s pack: Discard the product 28 days after initial opening.

6.5 Nature and contents of container

Albendazole 400 Cospharm is available in bulk packs of 1000s in an LDPE bag in 1800 mL HDPE jar.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Cospharm Investments (Pty) Ltd

2 Concourse Crescent

Lonehill

Sandton, Johannesburg

Gauteng, 2062

8. REGISTRATION NUMBER(S)

61/12/0846

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

27/01/2026

10. DATE OF REVISION OF THE TEXT

N/A