ZENTEL™

albendazole

Suspension

Qualitative and Quantitative Composition

Each 5ml contains 100mg albendazole. (See List of Excipients)

Therapeutic indications

- pinworm (*Enterobius vermicularis*);
- roundworm (*Ascaris lumbricoides*);
- hookworm (*Ankylostoma duodenale, Necator americanus*);
- whipworm (*Trichuris trichiura*);
- threadworm (*Strongyloides stercoralis*);
- tapeworm (*Taenia saginata, Taenia solium*); treatment with albendazole must be envisaged only in cases of associated parasitoses sensitive to albendazole;
- giardiosis (*Giardia intestinalis* or *duodenalis*) in children;
- trichinellosis (*Trichinella spiralis*).

Posology and method of administration

Posology:

Indications	Daily dose	Duration of treatment
Pinworm	*Children from 1 to 2 years:* 200 mg, i.e. 10 ml (half of 20 ml bottle) of oral suspension at 2%. *Adults and children over 2 years:* 400 mg, i.e. one 20 ml bottle of oral suspension at 2%. Strict hygiene measures must be imposed and the family circle must also be treated.	Single dose to be repeated 7 days later.
Roundworm Hookworm Whipworm	*Children from 1 to 2 years:* 200 mg, i.e. 10 ml (half of 20 ml bottle) of oral suspension at 2%. *Adults and children over 2 years:* 400 mg, i.e. one 20 ml bottle of oral suspension at 2%.	Single dose ***
Threadworm Tapeworm (associated with other parasitoses)	*Adults and children over 2 years:* 400 mg, i.e. one 20 ml bottle of oral suspension at 2%.	One daily dose for 3 consecutive days. ***
Giardiosis	*Children:* 400 mg, i.e. one 20 ml bottle of oral suspension at 2%.	One daily dose for 5 consecutive days.
Trichinellosis	*Children:* 15 mg/kg/day split into 2 doses per day. *Adults:* 800 mg, i.e. two 20 ml bottles of oral suspension at 2% twice a day.	One morning dose and one evening dose for 10 to 15 days depending on the severity of symptoms and how quickly treatment is started.

*** particularly in the case of threadworm, whipworm and tapeworm, if the parasitological examination of the stools performed 3 weeks after treatment is positive, a second course of treatment must be given.

Method of administration:

Oral. No purging or fasting prior to treatment is necessary.

Contraindications

- Albendazole should not be administered during pregnancy or in women thought to be pregnant.
- Albendazole is contraindicated in patients with a known history of hypersensitivity to albendazole or other constituents of the dose forms.

Warnings and Precautions

In order to avoid administering albendazole during early pregnancy, women of childbearing age should initiate treatment during the first week of menstruation or after a negative pregnancy test.

Treatment with albendazole may uncover pre-existing neurocysticercosis, particularly in areas with high taenosis 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.

Albendazole suspension contains benzoic acid which is a mild irritant to the skin, eyes and mucous membrane. It may increase the risk of jaundice in newborn babies.

Interactions

Cimetidine, praziquantel and dexamethasone have been reported to increase the plasma levels of the albendazole metabolite responsible for the systemic efficacy of the product.

Ritonavir, phenytoin, carbamazepine and phenobarbital may have the potential to reduce plasma concentrations of the active metabolite of albendazole; 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.

Pregnancy and Lactation

Pregnancy

Albendazole should not be administered during pregnancy or in women thought to be pregnant (see Contraindications).

Lactation
Adequate human and animal data on use during lactation are not available.
Ability to perform tasks that require judgement, motor or cognitive skills
Adverse effects on the ability to drive or operate machinery have not been observed.
Adverse Reactions
Data from large clinical studies were used to determine the frequency of very common to rare undesirable reactions. The frequencies assigned to all other undesirable reactions (i.e. those occurring at < 1/1000) were mainly determined using post-marketing data and refer to a reporting rate rather than a true frequency.
The following convention has been used for the classification of frequency:
Very common: ≥ 1/10, Common: ≥ 1/100 and <1/10, Uncommon: ≥ 1/1000 and < 1/100, Rare: ≥ 1/10,000 and < 1/1000 & Very rare: < 1/10,000
Immune system disorders
Rare: Hypersensitivity reactions including rash, pruritus and urticaria
Nervous system disorders
Uncommon: Headache and dizziness
Gastrointestinal disorders
Uncommon: Upper gastrointestinal symptoms (e.g. epigastric or abdominal pain, nausea, vomiting) and diarrhoea.
Hepatobiliary disorders
Rare: Elevations of hepatic enzymes
Skin and subcutaneous tissue disorders
Very rare: Erythema multiforme, Stevens-Johnson syndrome
Overdosage
Further management should be as clinically indicated or as recommended by the national poisons centre, where available.
List of Excipients:
Aluminium magnesium silicate, Carboxymethylcellulose sodium, Glycerin, Polysorbate 80, Sorbitan monolaureate, Potassium sorbate, Benzoic acid, Sorbic acid, Silicone antifoam 1510, Saccharin sodium, Orange flavour, Vanilla flavour, Passion fruit flavour and Purified water
Shelf Life:
The expiry date is indicated on the packaging.
Special Precautions for Storage:
Store below 30°C and protect from direct sunlight
Manufactured by: Farmaclair, Hérouville-Saint-Clair, France.
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THIS IS A MEDICAMENT
Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children.

Council of Arab Health Ministers, Union of Arab Pharmacists.