712 7 182050

ZENTEL™

albendazole

Presentations

Off-white, circular TILTAB™ tablet with a pentagonal projection on both sides, containing 200 mg albendazole.
A pleasant tasting, fruit-flavoured suspension, each 5 ml of which contains 100 mg albendazole.

Indications

ZENTEL is a benzimidazole carbamate with antihelmintic and antiprotozoal activity against the following intestinal and tissue parasites: Round-worm *(Ascaris lumbricoides)*, pin-worm *(Enterobius vermicularis)*, hook-worm *(Necator americanus, Ancylostoma duodenale)*, whip-worm *(Trichuris trichiura)*, thread-worm *(Strongyloides stercoralis)* and tape-worm *(Taenia spp and Hymenolepis nana only in the case of associated parasitism)*.

Dosage

Indications	Age	Dose	Period
- Round-worm - Pin-worm* - Hook-worms - Whip-worm	adults and children over 2 years of age	400 mg [two 200 mg tablets or 20 ml 2% suspension]#	single dose
	children 1-2 years of age	200 mg (one 200 mg tablet or 10 ml 2% suspension)	single dose
- Strongyloidiasis - Taeniasis - Hymenolepiasis**	adults and children over 2 years of age	400 mg (#see above)	one dose per day for 3 days

* In order to obtain a complete cure in the case of pin-worm infestation, prescribe strict measures of hygiene, also treat the relatives and individuals sharing the same housing.
** In cases of proven Hymenolepiasis, retreatment in 10-21 days is recommended.

Method of administration

If the patient is not cured after three weeks, a second course of treatment is indicated.
No special procedures, such as fasting or purging, are required.
The tablets can be chewed or taken with water.

Contra-indication

ZENTEL should not be administered during pregnancy, or in women thought to be pregnant.
ZENTEL is contra-indicated in patients with a known history of hypersensitivity to the drug (albendazole or constituents).

Special Warnings and Special Precautions for Use

Warnings

ZENTEL 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.

Precautions

Pregnancy and lactation:
In order to avoid administering **ZENTEL** during early pregnancy, women of childbearing age should initiate treatment during the first week of menstruation or after a negative pregnancy test.
It is not known whether albendazole or its metabolites are secreted in human breast milk. Thus **ZENTEL** should not be used during lactation unless the potential benefits are considered to outweigh the potential risks associated with treatment.

Drug interactions

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

Undesirable effects

As with other benzimidazoles, upper gastrointestinal symptoms (e.g. epigastric or abdominal pain, nausea, vomiting) and diarrhoea may occur rarely. Headache and dizziness have also been reported rarely. Such effects have also been observed with the underlying disease.
Hypersensitivity reactions including rash, pruritis and urticaria have been reported very rarely.
Adverse effects on the ability to drive or operate machinery have not been observed.

Overdose

In case of overdosage, symptomatic therapy (gastric lavage) and general supportive measures should be undertaken.

Further information

ZENTEL exhibits larvicidal, ovicidal and vermicidal activity, and exerts its antihelmintic effect by inhibiting tubulin polymerisation. This disrupts helminth metabolism, causing energy depletion, which immobilises and then kills the susceptible helminth.

Shelf life

Use before the expiry date clearly indicated on the packaging.

Special Precautions for storage

Tablets : Do not store above 30°C.
Suspension : Do not store above 30°C and protect from direct sunlight.

Instructions for Use and Handling

Suspension : Shake well before use.

Package Quantities

Tablets in single dose, 2-tablet blister packs.
Suspension in single dose 20 ml bottle.
Various larger sizes are also available.

Not all presentations are available in every country

Glaxo Wellcome Production*
Mayenne, France
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