ZENTEL

HALEON

TABLET 200mg

Albendazole 200mg

Each tablet contains 200mg Albendazole, Lactose, Maize Starch, Microcrystalline Cellulose, Sodium Starch Glycolate, Povidone, Hydroxypropyl Methylcellulose, Magnesium Stearate, Sodium Lauryl Sulphate, Saccharin Sodium, Propylene Glycol, Carnauba Wax, Purified Water.

Product Description
White or off-white film-coated tablet, with white or off-white cores.

Indication
Treatment of roundworm infection (ascariasis), whipworm infection (trichuriasis), hookworm disease (ancylostomiasis and necatoriasis), pinworm infection (enterobiasis), threadworm infection (strongyloidiasis), and tapeworm infection (hymenolepsiasis and taeniasis).

Dosage & Route of Administration
For oral administration only.

No special procedures, such as fasting or purging, are required.

If the patient is still symptomatic after a single course of treatment, they must consult a Healthcare Professional for further treatment.

The maximum duration of treatment will vary according to the indication. Please refer below for information on maximum doses for each indication. Do not exceed the maximum daily doses and treatment durations recommended.
Not to be used in children aged under 1-year.
Some people, particularly young children, may experience difficulties swallowing the tablets whole and should be encouraged to chew the tablets with a little water, alternatively tablets may be crushed. The suspension can also be administered as an alternative.

Dosage
For roundworm, whipworm, hookworm and pinworm
Adults and children above 24 months: 2 tablets (400mg) as a single dose.
Children 12-24 months: Take half the adult dose.
For threadworm and tapeworm
Adults and children above 24 months: 2 tablets (400mg) once a day for 3 consecutive days.

Populations
Elderly
Experience in patients 65 years of age or older is limited. Reports indicate that no dosage adjustment is required; however, elderly patients with evidence of hepatic dysfunction must seek advice from a Healthcare Professional before taking this medicine (see Hepatic Impairment and Pharmacokinetics).

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 who have been diagnosed with renal impairment must seek advice from Healthcare Professional before taking this medicine (see Pharmacokinetics).

Hepatic Impairment
Since albendazole is rapidly metabolized by the liver to the primary pharmacologically active metabolite, albendazole sulfoxide, hepatic impairment would be expected to have significant effects on the pharmacokinetics of albendazole sulfoxide. Patients who have been diagnosed with hepatic impairment must seek advice from a Healthcare Professional before taking this medicine (see Pharmacokinetics).

Contraindications
Albendazole must not be used during pregnancy. Albendazole is contraindicated in patients with a known history of hypersensitivity to albendazole or other constituents of the dose forms.

Warnings & Precautions
In order to avoid administering albendazole during early pregnancy, women of childbearing age should initiate treatment within the first 10 days of starting their menstrual period or immediately after a negative pregnancy test.

Treatment with albendazole may uncover preexisting neurocysticercosis, particularly in areas with high rates of tapeworm (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. Patients experiencing such symptoms, after taking this medicine, must seek advice from a Healthcare Professional as soon as possible.

Albendazole treatment has been associated with mild to moderate elevations of hepatic enzymes. Hepatic enzymes generally normalize on discontinuation of treatment. Patients diagnosed with hepatic impairment must seek advice from a Healthcare Professional before taking this medicine (see Dosage and Administration: Hepatic Impairment and Adverse Reactions).

Patients diagnosed with renal impairment must seek advice from a Healthcare Professional before taking this medicine (see Dosage and Administration: Renal Impairment and Adverse Reactions).
Keep out of the sight and reach of children / *Jauhkan daripada pandangan dan capaian kanak-kanak.*

This product SHOULD NOT BE ADMINISTERED DURING CONFIRMED OR SUSPECTED PREGNANCY.

Interactions
Clinically relevant interactions are not anticipated at the dose and duration of treatment for non-prescription use.

Pregnancy & Lactation
Pregnancy
Albendazole must not be used during pregnancy (see Contraindications).

Lactation
Adequate human and animal data on use during lactation are not available. Thus albendazole should not be used during breast feeding unless the potential benefits are considered to outweigh the potential risks associated with treatment. Patients who are breast feeding must seek advice from a Healthcare Professional prior to taking this medicine.

Effects on Ability to Drive and Use Machinery
Adverse effects on the ability to drive or operate machinery have not been observed.

Adverse Reactions
The following convention is used for classification of adverse reaction frequencies:

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
Please contact a Healthcare Professional if you notice any of these symptoms.

Symptoms and Treatment of Overdose
Please consult a Healthcare Professional for advice in the event of overdose.

Pharmacodynamics
Mechanism of Action
Albendazole is a benzimidazole carbamate with antiprotozoal and antihelmintic effects against intestinal and tissue parasites. Albendazole exhibits larvicidal, ovicidal and vermicidal activity, and is thought to exert its antihelmintic effect by inhibiting tubulin polymerization. This causes the disruption of the helminth metabolism, including energy depletion, which immobilizes and kills the susceptible helminth.

Pharmacokinetics
Absorption
In man, albendazole is poorly absorbed (less than 5%) following oral administration.

Distribution
Following oral administration of a single dose of 400 mg albendazole, the pharmacologically active metabolite, albendazole sulphoxide, has been reported to achieve plasma concentrations of 0.698µg/mL when taken with breakfast.

Metabolism
Albendazole rapidly undergoes extensive first-pass metabolism in the liver, and is generally not detected in plasma.

Elimination
The plasma half-life of albendazole sulphoxide is 8 ½ h.

Special Patient Populations
Elderly
No specific studies have investigated the effect of age on albendazole sulfoxide pharmacokinetics.

Renal Impairment
The pharmacokinetics of albendazole in patients with impaired renal function has not been studied.

Hepatic Impairment
The pharmacokinetics of albendazole in patients with impaired hepatic function has not been studied.

Pack Size
4s, 10s

Storage Condition
Store below 30°C.

Shelf life
36 months

Manufactured by:
Tianjin TSKF Pharmaceutical Co., Ltd., Tianjin, China.

Product Registration Holder:
Haleon Malaysia Sdn. Bhd.
[Registration No: 195901000115 (3467-X)]
Lot 89, Jalan Enggang, Ampang/ Hulu Kelang Industrial Estate, 68000 Ampang, Selangor, Malaysia.

Imported by: Brunei -
Kingston Beverage & Creamery Sdn Bhd,
Plot 73, Lot 3, 4, 5 & 6,
Beribi Industrial Complex, Jalan Gadong, Gadong BE 1118, Negara Brunei Darussalam.

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