1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

ALDAZ (Albendazole Tablets 400 mg)

1.1 Strength : 400 mg

1.2 Pharmaceutical Form : Chewable Uncoated Tablet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable uncoated tablet contains:
Albendazole BP…….400 mg
For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Chewable Uncoated Tablets
Light orange colour, caplet shaped chewable uncoated tablets having break line on one side and plain on other side.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Albendazole 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), tape-worm (Taenia spp and Hymenolepis nana only in the case of associated parasitism), Chlonorchiasis (*Chlonorchis sinensis*), Opisthorchiasis (*Opisthorchis viverrini*) and cutaneous larva migrans; Giardiasis (*G.lamblia, G.duodenalis, G.intestinalis, Lamblia intestinalis*) in children.

Low-dose Albendazole tablets for short-term treatment is indicated for the treatment of single or mixed intestinal infestations caused by the following helminths/protozoa:
Ascaris lumbricoides (Ascaridiasee) *Trichuris trichiura* (Tricuriase) *Enterobius vermicularis* (Oxifuiase) *Ancylostoma duodenale* and *Necator americanus* (Hookworm) *Hymenolepis nana* and *Taenia spp* (Taeniasis) *Strongyliodes steralaris* (Strongyloid phase) *Opistorchis viverini* and *Clonorchis sinensis Giardia lamblia* (Giardiasis in children)

Low-dose Albendazole tablets for short-term treatment is also indicated for the treatment of cutaneous larva migrans

Albendazole tablets in high-dose, long-term treatment is indicated for the treatment of the following systemic helminths infestations:
Hydatid disease:
Albendazole tablets has been shown to be most effective in treating cysts located in the liver, wrists and peritoneal space. Experience with bone, heart and central nervous system

cysts is limited.

Cystic hydatid disease (caused by *Echinococcus granulosus*) Albendazole tablets can be used in patients with cystic hydatid disease: When surgical intervention is not feasible Before the surgical intervention In the postoperative period if the preoperative treatment was too short, if a stroke occurred, or when viable cysts were found during surgery After percutaneous drainage of cysts for diagnosis or therapy

Alveolar hydatid disease (caused by *Echinococcus multilocularis*) Albendazole tablets can be used in patients with alveolar hydatid disease, In cases of inoperable disease, particularly in cases of local and distant metastases After palliative surgery After radical surgery or liver transplantation

Neurocysticercosis (larval infestation by *Taenia solium*) Albendazole tablets can be used in patients with Cyst OR multiple cysts OR granulomatous lesions of the parenchyma of the brain Arachnoidal or intraventricular cysts racemose cysts

Capillariasis (infested by *Capillaria philippinensis*)
Gnathostoma:miasis (caused by *Gnathostoma spinigerum* and related species)
Trichinosis (caused by *Trichinella spiralis* and *T.pseudosspiralis*)
Toxocarose (caused by *Toxocara canis* and other related species)

4.2 Posology and Method of Administration

Some people, particularly young children, may find it difficult to swallow the tablets whole, so they should be encouraged to chew the tablets with a little water or, alternatively, the tablets can be crushed. The existing alternative pharmaceutical form, such as Albendazole 20 mg/ml oral suspension, can also be used.
Dosage :

Indications	Age	Dose	Period
-Round worm - Pin Worm* - Hook Worm - Whip Worm	Adults and children over 2 years of age	400mg [two 200mg or one 400mg tablets(s)]	Single dose
	Children 1-2 years of age	200mg (one 200mg tablet)	Single dose
- Stronglyoidiasis - Taeniasis Hymenolepiasis#	Adults and children over 2 year of age	400mg	One dose per day for 3 days
-.Chlonorchiasis - Opisthorchiasis	adults and children over 2 years of age	400 mg	two doses per day for 3 days
- Giardiasis	children 2 - 12 years of age only	400 mg	one dose per day for 5 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.

Special Patient Populations

Elderly Populations

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 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 with evidence of renal impairment should be carefully monitored.

Hepatic impairment

Since albendazole is rapidly metabolized by the liver to the primary pharmacologically active metabolite, albendazole sulfoxide, and 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.

Doses are dependent on the parasite involved, the patient's weight, and the severity of the infestation:

Parasite	Weight of the patient (Kg)	Dose and Duration of treatment
Hydatidosis OR Cystic echinococcosis (*Echinococcus granulosus*)	> 60	800 mg divided into two equal doses (1 tablet twice a day) for 28 days. It may be necessary to repeat after 14 days without treatment, making a total of 3 cycles
	< 60	15 mg/Kg/day divided into two equal doses (maximum dose 800mg/day). It may be necessary to repeat after 14 days without treatment, making a total of 3 cycles
Operable cysts OR multiples	Albendazole Tablets 400mg can be administered for up to three cycles of 28 days, for the treatment of cysts in the liver, lungs and cysts located in the peritoneal cavity. Longer treatment may be required for cysts located in the bones and brain.	
Preoperative	When possible before surgery, two cycles of 28 days should be administered. When the surgical intervention and If	

	necessary before both cycles are completed, Albendazole Tablets 400mg should be administered for as long as possible.	
Postoperative period	If emergency surgery is necessary and the preoperative treatment has been carried out for a short period of time, Albendazole Tablets 400mg should be administered postoperatively, in 2 cycles of 28 days with intervals of 14 days without treatment.	
After 6s percutaneous drainage of cysts	Additionally, when viable cysts are found after presurgical treatment or when effusion occurs, a full two cycles of treatment should be administered. Treat as mentioned above for the postoperative period.	
Hidatidose alveo1ar (*Echinococcus multilocularis*)	> 60	800 mg divided into two equal doses (1 tablet twice a day), in 28-day cycles, with a 14-day break between cycles. The treatment can be prolonged for months or years. Continuous treatment with the same dose used for periods of up to 20 months.
	< 60	15mg/Kg/day divided into two equal doses (maximum dose 800 mg/day), in cycles of 28 days, with a 14-day break between cycles. The treatment can be prolonged for months or years. Continuous treatment with the same dose used for periods of up to 20 months.
Neurocysticercosis± (Tape only)	> 60	800 mg divided into two equal doses (1 tablet twice a day), for 7 to 30 days, depending on the answer. A second course of treatment may be administered with an interval of 2 weeks between treatments.
	< 60	15mg/Kg/day divided into 2 equal doses (maximum dose 800mg/day), for 7 to 30 days, depending on of the answer. A second course of treatment may be administered with an interval of 2 weeks between treatments.
Cysts Parenchymal It Is Granulomas	> 60	800 mg divided into two equal doses (1 tablet 2 times a day). No treatment per 28 days is usually needed for non-cysts parenqu1ma1s.

	< 60	15mg/Kg/day divided into 2 equal doses (maximum dose 800mg/day), 0 treatment for 28 days and usually necessary for non pareruiuimais cysts.
Cysts Arachnoidal It Is Ventricular	> 60	800 mg divided into two equal doses (1 tablet 2 times a day). 0 treatment per 28 days is usually needed for non-cysts parenqmma 1s.
	< 60	15mg/Kg/day divided into 2 equal doses (maximum dose 800mg/day), 0 treatment for 28 days and usually necessary for non-parental cysts.
Cysts Racemoses	> 60	800 mg divided into two equal doses (1 pill 2 times a day). Usually the treatment is carried out continuously for 28 days, however the duration should be determined by the clinical and radiological response.
	< 60	15mg/Kg/day divided into 2 equal doses (maximum dose 800mg/day). Usually the treatment and done continuously for 28 days, however the duration should be determined by the clinical and radiological response.

*Alveolar hydatid disease: Treatment for cystic echinococcosis is usually carried out in cycles of 28 days and can last for months or years. Current studies suggest that survival times are substantially improved after treatment prolonged. In a limited number of patients continuous treatment has been shown to lead to apparent cure.

±Patients with neurocysticercosis being treated with albendazole should receive adequate treatment with anticonvulsants and steroids. The hypothesis of preventive medication with corticosteroids should be considered in order to prevent the occurrence of intracranial hypertension in the first week of treatment.

Other Systemic Infestations		
Parasite	Age of Patient	Dose and duration of treatment
Capillariasis (*Capillaria philippnesis*)	Children and adults	400 mg (1 tablet) per day for 10 days. #Usually one cycle of treatment is enough, however further cycles may need to be administered if the clinical and parasitological data remain positive.

Gnatostomiasis (*Gnastostoma spinigerum*)	Children and adults	400 mg (1 Tablet) per day for 10 to 20 days
Trichinosis (*Trichinella spiralis* from *T. pseudospiralis*)	Children and adults	400 mg (1 Tablet) per day for 5 to 10 days
Toxocariasis (*Toxocara canis e species* related)	Children and adults	400 mg (1 Tablet) per day for 5 to 10 days

Paediatric Population

Limited data of the albendazole concentrations in plasma are available in children and adolescents 1 to 16 years of age. These data do not indicate substantially higher systemic exposure to albendazole in subjects 3 to 16 years of age compared to adults.

In subjects 1 to <3 years of age, systemic exposure is higher than in adults due to higher mg/kg dose relative to adults.

4.3 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. 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 the tablets may be crushed.

4.4 Contraindications

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

4.5 Special Warnings and Precautions for Use

In order to avoid administering **Albendazole Tablets** 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 Tablets 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 Tablets 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.
Use in systemic helminthic infestations: Long-term treatment and high dosage.

Treatment with albendazole has been associated with a mild to moderate elevation of liver enzymes in approximately 16% of patients. These normalize with discontinuation of treatment. Liver function tests should be performed prior to the start of each treatment cycle and at least every two weeks during treatment. If a significant increase in enzymes to twice the upper limit of the normal state range occurs, albendazole should be discontinued. The treatment with albendazole can be resumed when the liver enzymes return to normal limits, however laboratory tests must be carried out frequently in the repetition of the therapy.

Albendazole has occasionally been shown to cause bone marrow suppression and therefore blood tests should be performed at the start of treatment and every other week during the 28 day cycles. Patients with liver disease, including Echinococcus liver infection, are more susceptible to mild bone marrow suppression, leading to pancytopenia, aplastic anemia, agranulocytosis and leukopenia, implying a rigorous follow-up of blood counts. Treatment with albendazole could be continued if the decrease is small and does not show progression.

In order to avoid administration of albendazole during early pregnancy, women of childbearing age should: only start treatment after negative pregnancy tests. These tests must be repeated at least once before starting the next cycle.

They will be advised to use effective contraception during and one month after the end of treatment with albendazo1.

Patients taking albendazole to treat neurocysticercosis may show symptoms associated with an inflammatory reaction triggered by the death of the installed parasite
In the brain. This symptomatology includes seizures, increased intracranial pressure and focal signs. In these cases, patients should be treated with appropriate steroids or anticonvulsants. Oral corticosteroids, as well as intravenous ones, are indicated for the prevention of episodes of intracranial hypertension during the first week of treatment.

Pre-existing neurocysticercosis may be detected in patients taking albendazole elsewhere, particularly in areas where Taenia infection is high. Patients may present neurological symptoms such as seizures, increased intracranial pressure and focal signs, resulting from the inflammatory reaction triggered by the death of the parasite installed in the brain. These symptoms may appear soon after treatment, so the patient should immediately start appropriate therapy with steroids or anticonvulsants.
This medicine contains anhydrous lactose. Patients with rare hereditary problems of fructose intolerance, galactose intolerance, galactosemia OR glucose galactose should not take this medicine.

This medicine contains sodium. This information should be taken into account in patients

with controlled sodium intake.

4.6 Paediatric Population

Limited data of the albendazole concentrations in plasma are available in children and adolescents 1 to 16 years of age. These data do not indicate substantially higher systemic exposure to albendazole in subjects 3 to 16 years of age compared to adults.

In subjects 1 to <3 years of age, systemic exposure is higher than in adults due to higher mg/kg dose relative to adults.

4.7 Interaction with other Medicinal Products and other Forms of Interaction

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

4.8 Additional Information on Special Populations

Elderly Populations

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 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 with evidence of renal impairment should be carefully monitored.

Hepatic impairment

Since albendazole is rapidly metabolized by the liver to the primary pharmacologically active metabolite, albendazole sulfoxide, and 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.

Doses are dependent on the parasite involved, the patient's weight, and the severity of the infestation:

Parasite	Weight of the patient (Kg)	Dose and Duration of treatment
Hydatidosis OR Cystic echinococcosis (*Echinococcus granulosus*)	> 60	800 mg divided into two equal doses (1 tablet twice a day) for 28 days. It may be necessary to repeat after 14 days without treatment, making a total of 3 cycles
	< 60	15 mg/Kg/day divided into two equal doses (maximum dose 800mg/day). It may be necessary to repeat after 14

		days without treatment, making a total of 3 cycles
Operable cysts OR multiples	Albendazole Tablets 400mg can be administered for up to three cycles of 28 days, for the treatment of cysts in the liver, lungs and cysts located in the peritoneal cavity. Longer treatment may be required for cysts located in the bones and brain.	
Preoperative	When possible before surgery, two cycles of 28 days should be administered. When the surgical intervention and If necessary before both cycles are completed, Albendazole Tablets 400mg should be administered for as long as possible.	
Postoperative period	If emergency surgery is necessary and the preoperative treatment has been carried out for a short period of time, Albendazole Tablets 400mg should be administered postoperatively, in 2 cycles of 28 days with intervals of 14 days without treatment.	
After 6s percutaneous drainage of cysts	Additionally, when viable cysts are found after presurgical treatment or when effusion occurs, a full two cycles of treatment should be administered. Treat as mentioned above for the postoperative period.	
Hidatidose alveo1ar (*Echinococcus multilocularis*)	> 60	800 mg divided into two equal doses (1 tablet twice a day), in 28-day cycles, with a 14-day break between cycles. The treatment can be prolonged for months or years. Continuous treatment with the same dose used for periods of up to 20 months.
	< 60	15mg/Kg/day divided into two equal doses (maximum dose 800 mg/day), in cycles of 28 days, with a 14-day break between cycles. The treatment can be prolonged for months or years. Continuous treatment with the same dose used for periods of up to 20 months.
Neurocysticercosis± (Tape only)	> 60	800 mg divided into two equal doses (1 tablet twice a day), for 7 to 30 days, depending on the answer. A second course of treatment may be administered with an interval of 2 weeks between treatments.
	< 60	15mg/Kg/day divided into 2 equal doses (maximum dose 800mg/day), for 7 to 30 days, depending on of the answer. A second course of treatment may be administered with an interval of 2 weeks between treatments.
Cysts Parenchymal It Is Granulomas	> 60	800 mg divided into two equal doses (1 tablet 2 times a day). No treatment per 28 days is usually needed for non-cysts parenqu1ma1s.

	< 60	15mg/Kg/day divided into 2 equal doses (maximum dose 800mg/day), 0 treatment for 28 days and usually necessary for non pareruiuimais cysts.
Cysts Arachnoidal It Is Ventricular	> 60	800 mg divided into two equal doses (1 tablet 2 times a day). 0 treatment per 28 days is usually needed for non-cysts parenqmma 1s.
	< 60	15mg/Kg/day divided into 2 equal doses (maximum dose 800mg/day), 0 treatment for 28 days and usually necessary for non-parental cysts.
Cysts Racemoses	> 60	800 mg divided into two equal doses (1 pill 2 times a day). Usually the treatment is carried out continuously for 28 days, however the duration should be determined by the clinical and radiological response.
	< 60	15mg/Kg/day divided into 2 equal doses (maximum dose 800mg/day). Usually the treatment and done continuously for 28 days, however the duration should be determined by the clinical and radiological response.

*Alveolar hydatid disease: Treatment for cystic echinococcosis is usually carried out in cycles of 28 days and can last for months or years. Current studies suggest that survival times are substantially improved after treatment prolonged. In a limited number of patients continuous treatment has been shown to lead to apparent cure.

±Patients with neurocysticercosis being treated with albendazole should receive adequate treatment with anticonvulsants and steroids. The hypothesis of preventive medication with corticosteroids should be considered in order to prevent the occurrence of intracranial hypertension in the first week of treatment.

Other systemic infestations		
Parasite	Age of Patient	Dose and duration of treatment
Capillariasis (*Capillaria philippnesis*)	Children and adults	400 mg (1 tablet) per day for 10 days. #Usually one cycle of treatment is enough, however further cycles may need to be administered if the clinical and parasitological data remain positive.
Gnatostomiasis (*Gnastostoma spinigerum*)	Children and adults	400 mg (1 Tablet) per day for 10 to 20 days
Trichinosis (*Trichinella*	Children and	400 mg (1 Tablet) per day for 5 to

spiralis from *T. pseudospiralis*)	adults	10 days
Toxocariasis (*Toxocara canis e species* related)	Children and adults	400 mg (1 Tablet) per day for 5 to 10 days

4.9 Paediatric population

Limited data of the albendazole concentrations in plasma are available in children and adolescents 1 to 16 years of age. These data do not indicate substantially higher systemic exposure to albendazole in subjects 3 to 16 years of age compared to adults.
In subjects 1 to <3 years of age, systemic exposure is higher than in adults due to higher mg/kg dose relative to adults.

4.10 Fertility, Pregnancy and Lactation

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

It is not known whether albendazole or its metabolites are secreted in human breast milk. Thus Albendazole Tablets should not be used during lactation unless the potential benefits are considered to outweigh the potential risks associated with treatment.

4.11 Effects on ability to drive and use machines

Adverse effects on the ability to drive or operate machinery has not been observed

4.12 Undesirable Effects

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, pruritis 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

4.13 Overdose

Limited information is available on acute overdose of albendazole. Symptoms of an acute albendazole overdose may include the undesirable effects listed in section 4.8 and section 4.4. In addition, undesirable effects associated with long-term and high-dose use of albendazole are also to be expected (eg when used in the treatment of systemic helminth infestations). Such undesirable effects may include disorders of the blood and lymphatic system (leukopenia, pacytopenia, aplastic anemia, agranulocytosis or bone marrow suppression), hepatitis or alopecia.

Treatment:
In cases of overdose, symptomatic therapy (gastric lavage) and general supportive measures should be applied.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics Properties

Cluster pharmacotherapeutic: 1.4.1 Medicines anti-infectives. Antiparasitics. Anti-helminthic, code ATC: P02CA03

Mechanism of Action:
Albendazole is one carbamate in benzimidazole with effects antiprotozoal and anthelmintic against parasites _ intestinal It is of the fabrics. O albendazole displays activity larvicidal, ovicidal, vermicide and is considered exercise your It is made anthelmintic inhibiting the polymerization from the tubulin. It is, cause the interruption of metabolism of the helminths, including depletion energetic what immobilize It is Woods you helminths susceptible inhibiting tubulin polymerization. This causes disruption of helminth metabolism, including energy depletion that immobilizes and kills susceptible helminths.
Intestinal and cutaneous Larva migrans infections, including: Nematodes:
Ascaris lumbricoides (roundworms)

Trichuris trichiura (trichocephalus) *Enterobius vermicularis* (pinworm) *Ancylostoma duodenale* (hookworm) *Necator americanus* (hookworm)
Strongyloides stercoralis Larva migrans cutaneous

Cestodes: *Hymenolepis nana Taenia solium* (Taenia)
Taenia saginata (Taenia) Trematodes:

Opisthorchis viverini and *Clonorchis sinensis* Protozoa:
Giardia lamblia (also called Giardia intestinalis or Giardia duodenalis)

2 - Systemic helminthic infections:
Albendazole is effective in the treatment of tissue parasites, cystic echinococcosis and alveolar echinococcosis caused by infestations of *Echinococcus granulosus* and *Echinococcus multilocularis*, respectively. Albendazole is also effective in the treatment of neurocysticercosis caused by larval infestation by *T.solium*, capillariasis caused by *Capillaria philippinensis*, and gnathostomiasis caused by infestation by *Gnathostoma spinigerum.*

Albendazole has been shown (in clinical trials) to eradicate cysts or significantly reduce cyst size in up to 80% of patients with E. granulosus cysts who were treated.

When cysts were investigated for their viability after treatment with albendazole, 90% turned out to be non-viable in laboratory or animal studies, compared to, without treatment, the percentage of non-viable cysts was only 10%.

In the treatment of cysts due to *E.multilocularis*, a minority of patients were considered cured and the majority had an improvement or stabilization of the disease due to Albendazole therapy.

5.2 Pharmacokinetic Properties

Absorption and Biotransformation
In man, after oral administration, albendazole is poorly absorbed (<5%). Albendazole undergoes rapid and extensive first-pass metabolism in the liver, and is generally not detected in plasma. The main metabolite is the sulfoxide of albendazole which is believed to be the active part in the effectiveness against systemic infections. The half-life of albendazole sulfoxide is 8.5 hours.

It has been reported that after oral administration of a single dose of 400 mg of albendazole, the metabolite with pharmacological activity, albendazole sulfoxide reaches a plasmatic concentration of 1.6 to 6.0 µmoVliter as taken by breakfast90.

The systemic pharmacological effect of albendazole is increased if the dose is administered with a meal rich in lipids, increasing its absorption about 5 times.

Elimination
Albendazole sulfoxide and its metabolites appear to be eliminated primarily in the bile, and only a small proportion is excreted in the urine. Cyst clearance after high and prolonged dosing has been shown to occur over several weeks.

Special Patient Populations

- **Elderly**

Although no studies have investigated the effect of age on albendazole sulfoxide

pharmacokinetics, data in twenty-six hydatid cyst patients (up to 79 years) suggest pharmacokinetics similar to those in young healthy subjects. The number of elderly patients treated for either hydatid disease or neurocysticercosis is limited, but no problems associated with an older population have been observed.

- **Renal Impairment**
  The pharmacokinetics of albendazole in patients with impaired renal function have not been studied.
- **Hepatic Impairment**
  The pharmacokinetics of albendazole in patients with impaired hepatic function have not been studied.

5.3 Preclinical Safety Data

Albendazole has been shown to be teratogenic and embryotoxic in rats and rabbits. Albendazole tested negative for evidence of mutagenicity or genotoxicity in a panel of in vitro (including activated and inactivated Ames) and in vivo tests. In prolonged toxicity studies conducted in mice and rats at daily doses up to 30 times the recommended human doses, no treatment-related tumours were detected.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

- Maize Starch
- Microcrystalline Cellulose
- Saccharin Sodium
- Povidone
- Sodium Lauryl Sulfate
- Croscarmellose Sodium
- Sodium Starch Glycolate (Type A)
- Colloidal Anhydrous Silica
- Magnesium Stearate
- Orange Flavour
- Tutti-Frutti Flavour
- Colour Sunset Yellow

6.2 Incompatibilities

Not applicable

6.3 Shelf-life

3 years

6.4 Special Precautions for Storage

Store at temperature not exceeding 30°C, protect from moisture.

6.5 Nature and Content of Container

50 × 1 × 1 Tablets in Alu-PVC Blister pack

6.6 Special Precautions for Disposal

There are no special requirements for deletion.
Any unused medicine or waste must be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Zim Laboratories Limited.
Sadoday Gyan (Ground Floor),
Opp. NADT, Nelson Square,
Nagpur – 440013,
India

8. MARKETING AUTHORISATION NUMBERS

FDA-HMP-MA-0761

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30/12/2023

10. DATE OF REVISION OF THE TEXT

05/01/2024