HUKZOLE

ALBENDAZOLE TABLETS

QUALITATIVE AND QUANTITATIVE COMPOSITION

EACH CHEWABLE TABLET CONTAINS:

ALBENDAZOLE B.P.400MG

PHARMACEUTICAL FORM

Tablet

CLINICAL PARTICULARS

Indications

HUKZOLE 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.

Dosage and Administration

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 or one 400 mg tablet(s) or 10 ml 4% or 20 ml 2% suspension]#	single dose
	children 1-2 years of age	200 mg (one 200 mg tablet or 5 ml 4% or 10 ml 2% suspension)	single dose
- Strongyloidiasis	adults and children over 2 years of age	400 mg (#see above)	one dose per day for 3 days

- Taeniasis - Hymenolepiasis[=]			
-.Chlonorchiasis - Opisthorchiasis	adults and children over 2 years of age	400 mg (#see above)	two doses per day for 3 days
- Giardiasis	children 2 - 12 years of age only	400 mg (#see above)	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.

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.

Special Patient Populations

Elderly

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, 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.

Contraindications

HUKZOLE should not be administered during pregnancy, or in women thought to be pregnant.

HUKZOLE is contra-indicated in patients with a known history of hypersensitivity to the drug (albendazole or constituents)

Warnings and Precautions

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

Treatment with HUKZOLE 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.

HUKZOLE 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

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

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 **HUKZOLE** should not be used during lactation unless the potential benefits are considered to outweigh the potential risks associated with treatment.

Effects on Ability to Drive and Use Machines

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, 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

Overdose

Further management should be as clinically indicated or as recommended by the national poisons centre, where available.

PHARMACOLOGICAL PROPERTIES

Pharmacokinetics

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.

PHARMACEUTICAL PARTICULARS

List of Excipients

Tablets 400 mg	LUBRICATION
Sugar	Talcum I.P
Maize Starch I.P	Magnesium Stearate I.P
Maize Starch I.P (Paste)	Aspartam
ColourSunset Yellow	Orange Flavors DC 100PH
Sod. Methyl Paraben I.P	
Sod. Propyl Paraben I.P	

* Magnesium Stearate is of vegetable origin

Or as registered locally

Shelf Life

The expiry date is indicated on the packaging.

Special Precautions for Storage

Tablets: Store below 30°C.

Nature and Contents of Container

Tablets: Alu-Alu Blister of 1 Tablets

SOLE AGENT:-

VALUELIFE PHARMACY NIGERIA LTD

NAFDAC NO:- B4-7488

Repeat: 45mm

Albendazole Tablets

Hukzole

Composition:-
Each chewable tablet contains:
Albendazole B.P. 400mg
Colour: Sunset Yellow FCF
Dosage: As prescribed by the physician
Keep all medicines out of reach of children
Store in a cool dry place below 25°C.
Caution: Contains Aspartame,
a source of Phenylalanine.
Mfg Lic. No.: KD-493
NAFDAC REG. NO.: B4-7488

Sole Agent:
Valuelife Pharmacy Co. Ltd.
No. 46, Ifite Road, High Tension Street,
Arroma, Awka, Anambara state, Nigeria.

Manufactured By :
Mancare
PHARMACEUTICALS PVT. LTD.
Plot No. 59, 60, 85, 86, V.M.I.E, Dowali Village,
Vasai (W), Dist. Thane, Maharashtra, India.

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Plot No. 59, 60, 85, 86, V.M.I.E, Dowali Village,
Vasai (W), Dist. Thane, Maharashtra, India.

Size: 156 x 57mm   Prepared On : 08Oct2016

For the use of Registered medical Practitioner or a Hospital or a Laboratory only.

Hukzole

Albendazole Tablets 400mg

COMPOSITION

Each chewable tablet contains:

Albendazole BP 400mg

INDICATIONS

Albendazole is a broad spectrum anthelmintic for the treatment of :

Enterobius vermicularis - Pinworm or thread worm
Trichuris trichiura - Whipworm
Ascaris lumbricoides - Large roundworm
Ancylostoma duodenale - Hookworm
Necator americanus - Hookworm
Strongyloides
stercoralis Taenia. spp - Tapeworm
In single or mixed infestations of any of the above.

PHARMACOLOGICAL ACTION

Albendazole is a benzamidazole carbamate with anthelmintic antiprotozoal activity against intestinal and tissue parasites. Animal studies have shown that albendazole exhibits vermicidal, ovacidaland 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. In man, after oral administration, albendazole is absorbed and completely metabalized. At a dose of 6.6mg/kg of albendazole the plasma concentration of its main metabolite, the sulfoxide, attains a maximum of 0.25 to 0.30 micrograms/ml after approximately 2 $1/2$ hours. The half-life of the sulfoxide in the plasma is 8 hours. The metabolite is essentially eliminated via the urine.

CONTRAINDICATION

Albendazole was found to be embryotoxic and teratogenic in rats and rabbits. Its use is therefore contraindicated in pregnant women and in those thatare likely to be pregnant. For women of child bearing age (15-40 years), Albendazole should be administered within 7 days of the start of normal menstruation. **Albendazole** is contraindicated in patients with a known history of hypersensitivity to albendazole or its constituents.

DOSAGE

Use as prescribed by the physician. Adults and Children over 2(two) years of age : One (1) tablet or 10ml suspention of **Albendazole** as single dose in case of pinworm, and tapeworm. Incases of Strongyloidiasis, **Albendazole** (1 tablet = 400mg) or 10 ml suspension should be given for 3 (three) consecutive days. A second course of treatment can be given after three weeks if the patient is not cured on follow-up.

SIDE EFFECTS

A few cases of gastrointestinal disturbances and headache have been reported but no definite relationship with the drug has been established.

INTERACTION

Praziquantel has been reported to increase the plasma levels of the Albendazole active metabolite. Do not use in pregnancy.

OVERDOSAGE

If poisoning or excessive overdosage is suspected it is recomended, on general principles, that vomiting be induced or gastric lavage be performed and such symptomatic supportive therapy be administered appears indicated.

CAUTION

Contains Aspartame, a source of Phenylalanine.

STORAGE CONDITION

Store in a cool dry place below 25°C.
Keep all medicines out of reach of children.

PRESENTATION

Blister of 1 tablet

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NAFDAC REG. NO.: B4-7488

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E-mail: mancerp@yahoo.co.in

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109 x 96mm Prepared On : 12Oct2016

Hukzole

Albendazole Tablets 400mg

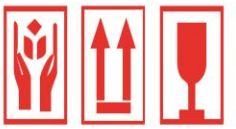
5806062953537

NAFDAC Reg.No.: B4-7488

Mancare

Valuelife

THIS SIDE UP



HANDLE WITH CARE

SHIPPING MARK:	V
CARTON NO.:	
QUANTITY:	50 x 20 x 1 Tablets
BATCH NO.:	
MFG. DATE:	
EXP. DATE:	
GROSS WT.:	
NET WT.:	