1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

Summary of Product Characteristics (SmPC) in line with NAFDAC template attached

National Agency for Food & Drug Administration & Control (NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) TEMPLATE

1. NAME OF THE MEDICINAL PRODUCT

EXPEZOL

(Albendazole Tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Uncoated Tablet Contains:

Albendazole BP	200 mg
Excipients	Q.S.

Excipients with known effect:

Not applicable

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solid Dosage form (Tablets)

White coloured round, biconvex, uncoated tablets, embossed 'XPZ' on one side and other side plain.

4. Clinical particulars

4.1 Therapeutic indications

Albendazole is indicated in the treatment of single or mixed intestinal parasites. Clinical studies have shown albene ffective in the treatment of Ascaris lumbricoides (roundworm), Trichuris trichiura (whipworm), Enterobius vermicularis (pinworm/threadworm), Ancylostoma duodenale and Necator americanus (hookworm), Taenia spp. (tapeworm) and Strongyloides stercoralis.

Albendazole has been shown to be effective in the treatment of Giardia (duodenalis or intestinalis or lamblia) infections in children.

Neurocysticercosis

Albendazole is indicated for the treatment of parenchymal neurocysticercosis due to active lesions caused by larval forms of the pork tapeworm, Taenia solium.

Hydatid Disease

Albendazole is indicated for the treatment of cystic hydatid disease of the liver, lung, and peritoneum, caused by the larval form of the dog tapeworm, Echinococcus granulosus.

4.2 Posology and method of administration

400 mg Albendazole as a single dose in both adults and children over two years of age. The tablets may be chewed, swallowed or crushed and mixed with food. In heavy mixed infestation involving Strongyloides or Taeniasis, a single daily dose may be inadequate and the dose may be given for three consecutive days.

Neurocysticercosis (Taenia Solium Tapeworm)

>60 kg: 400 mg PO BID x 8-30 days

<60 kg: 15 mg/kg/day divided BID PO x 8-30 days; not to exceed 800 mg/day

Hydatid (Echinococcus Tapeworm)

>60 kg: 400 mg PO BID x 28 days, THEN 14 drug-free days x 3 cycles

<60 kg: 15 mg/kg/day divided BID PO, no more than 800 mg/day x 28 days, THEN 14 drug-free days x 3 cycles

Ancylostoma, Ascariasis, Hookworm, Trichostrongylus

400 mg PO once

Capillariasis

400 mg PO qDay x10 days

Larva Migrans, Cutaneous & Trichuriasis

400 mg PO qDay x 3 days

Larva Migrans, Visceral

400 mg PO BID x 5 days

Enterobius (Pinworm)

400 mg PO once, repeat in 2 weeks

Fluke (Clonorchis Sinensis)

10 mg/kg PO qDay x7 days

Gnathostomiasis, Microsporidiosis

400 mg BID x 21 days

Administration

Take with food

Monitor: CBC, LFTs

Method/Mode of administration: Oral

4.3 Contraindications

Albendazole is contraindicated in patients with known hypersensitivity to the benzimidazole class of compounds.

Albendazole should not be administered during pregnancy or in women thought to be pregnant. Women of childbearing age should be advised to take effective precautions, with non hormonal contraceptive measures, against conception during and within one month of completion of treatment with 'Albendazole Tablets'. Albendazole is contra-indicated in patients with a known history of hypersensitivity to 'Albendazole Tablets' (albendazole or constituents).

4.4 Special warnings and precautions for use

Use in Pregnancy: Albendazole should not be used in pregnant women except in clinical circumstances where no alternative management is appropriate.

Nursing Mothers

Albendazole is excreted in animal milk. It is not known whether it is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when albendazole is administered to a nursing woman.

Pediatric Use

Experience in children under the age of 6 years is limited. In hydatid disease, infection in infants and young children is uncommon, but no problems have been encountered in those who have been treated.

Geriatric Use

Experience in patients 65 years of age or older is limited. The number of patients treated for either hydatid disease or neurocysticercosis is limited, but no problems associated with an older population have been observed.

PRECAUTIONS

General

Patients being treated for neurocysticercosis should receive appropriate steroid and anticonvulsant therapy as required. Oral or intravenous corticosteroids should be considered to prevent cerebral hypertensive episodes during the first week of anticysticeral therapy.

Cysticercosis may, in rare cases, involve the retina. Before initiating therapy for neurocysticercosis, the patient should be examined for the presence of retinal lesions. If such lesions are visualized, the need for anticysticeral therapy should be weighed against the possibility of retinal damage caused by albendazole-induced changes to the retinal lesion.

4.5 Interaction with other medicinal products and other forms of interaction

Dexamethasone: Steady-state trough concentrations of albendazole sulfoxide were about 56% higher when 8 mg dexamethasone was coadministered with each dose of albendazole (15 mg/kg/day) in 8 neurocysticercosis patients.

Cimetidine: Albendazole sulfoxide concentrations in bile and cystic fluid were increased (about 2-fold) in hydatid cyst patients treated with cimetidine (10 mg/kg/day) (n = 7) compared with albendazole (20 mg/kg/day) alone (n = 12). Albendazole sulfoxide plasma concentrations were unchanged 4 hours after dosing.

Theophylline: The pharmacokinetics of theophylline (aminophylline 5.8 mg/kg infused over 20 minutes) was unchanged following a single oral dose of albendazole (400 mg) in 6 healthy subjects.

Praziquantel

In the fed state, praziquantel (40 mg/kg) increased mean maximum plasma concentration and area under the curve of albendazole sulfoxide by about 50% in healthy subjects (n = 10) compared with a separate group of subjects (n = 6) given albendazole alone.

4.6 Pregnancy and Lactation

Pregnancy: 'Albendazole Tablets' should not be administered during pregnancy or in women thought to be pregnant.

Lactation: 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.

4.7 Effects on ability to drive and use machines

Dizziness is reported as a common reaction. Patients should be advised that if affected they should not drive, operate machinery or take part in activities where this could put them or others at risk.

4.8 Undesirable effects

Blood and Lymphatic System Disorders: Leukopenia. There have been rare reports of granulocytopenia, pancytopenia, agranulocytosis, or thrombocytopenia. Patients with liver disease, including hepatic echinococcosis, appear to be more at risk of bone marrow suppression

Hepatobiliary Disorders: Elevations of hepatic enzymes, hepatitis, acute liver failure.

Skin and Subcutaneous Tissue Disorders: Erythema multiforme, Stevens-Johnson syndrome.

Renal and Urinary Disorders: Acute renal failure

4.9 Overdose

If poisoning or excessive overdosage is suspected it is recommended, on general principles,

that vomiting be induced or gastric lavage be performed, and such symptomatic supportive therapy be administered as appears indicated.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Albendazole is a benzimidazole carbamate with anthelmintic and antiprotozoal activity against intestinal and tissue parasites. The principal mode of action for albendazole is by its inhibitory effect on tubulin polymerization which results in the loss of cytoplasmic microtubules.

In the specified treatment indications albendazole appears to be active against the larval forms of the following organisms:
Echinococcus granulosus
Taenia solium

5.2 Pharmacokinetic properties

Absorption and Metabolism: Albendazole is poorly absorbed from the gastrointestinal tract due to its low aqueous solubility. Albendazole concentrations are negligible or undetectable in plasma as it is rapidly converted to the sulfoxide metabolite prior to reaching the systemic circulation. The systemic anthelmintic activity has been attributed to the primary metabolite, albendazole sulfoxide. Oral bioavailability appears to be enhanced when albendazole is coadministered with a fatty meal (estimated fat content 40 g) as evidenced by higher (up to 5-fold on average) plasma concentrations of albendazole sulfoxide as compared to the fasted state.

Distribution: Albendazole sulfoxide is 70% bound to plasma protein and is widely distributed throughout the body; it has been detected in urine, bile, liver, cyst wall, cyst fluid, and cerebral spinal fluid (CSF).

Metabolism and Excretion: Albendazole is rapidly converted in the liver to the primary metabolite, albendazole sulfoxide, which is further metabolized to albendazole sulfone and other primary oxidative metabolites that have been identified in human urine.

Special Populations

Patients with Impaired Renal Function

The pharmacokinetics of albendazole in patients with impaired renal function have not been studied. However, 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.

Biliary Effects

In patients with evidence of extrahepatic obstruction (n = 5), the systemic availability of albendazole sulfoxide was increased, as indicated by a 2-fold increase in maximum serum concentration and a 7-fold increase in area under the curve. The rate of absorption/conversion and elimination of albendazole sulfoxide appeared to be prolonged with mean Tmax and serum elimination half-life values of 10 hours and 31.7 hours, respectively. Plasma concentrations of parent albendazole were measurable in only 1 of 5 patients.

Pediatrics

Following single-dose administration of 200 mg to 300 mg (approximately 10 mg/kg) albendazole to 3 fasted and 2 fed pediatric patients with hydatid cyst disease (age range 6 to 13 years), albendazole sulfoxide pharmacokinetics were similar to those observed in fed adults.

Elderly Patients

Although no studies have investigated the effect of age on albendazole sulfoxide pharmacokinetics, data in 26 hydatid cyst patients (up to 79 years) suggest pharmacokinetics similar to those in young healthy subjects.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch

Purified Water

Purified Talc

Colloidal Anhydrous Silica
Magnesium Stearate
Sodium Starch Glycolate
Croscarmellose Sodium

6.2 Incompatibilities

Not applicable

This medicinal product must not be mixed with other medicinal products except those mentioned in Section 6.6.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 30°C protected from light.
Keep medicines out of reach of children

6.5 Nature and contents of container and special equipment for use, administration or implantation

Alu/PVC Blister pack of 1 x 2 tablets.

6.6 Special precautions for disposal and other handling

No special requirements

7. APPLICANT/MANUFACTURER

VAPI CARE PHARMA PVT. LTD
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Vapi - 396195. Gujarat, INDIA