1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Medicinal Product

EXPEZOL

(Albendazole Oral Suspension)

1.2. Strength

200 mg/5ml

1.3. Pharmaceutical Form

Liquid Dosage form (Suspension)

2. Quality and Quantitative Composition

Qualitative Composition:

Each 5 ml contains:

Albendazole BP 200 mg

Excipients Q. S.

Sr. No.	Ingredients	Standard
1	Polysorbate-80	BP
2	Glycerin	BP
3	Sorbitol 70 %	BP

4	Propylene Glycol	BP
5	Sugar (Sucrose)	BP
6	Methyl Hydroxybenzoate (Methyl Paraben)	BP
7	Propyl Hydroxybenzoate (Propyl Paraben)	BP
8	Carmellose Sodium (Carboxymethylcellulose sodium)	BP
9	Colloidal Anhydrous Silica	BP
10	Flavour Raspberry	IH
11	Citric Acid Monohydrate	BP
12	Purified Water	BP

Quantitative Composition:

Each 5 ml contains:

Albendazole BP 200 mg

Excipients Q. S.

Sr. No.	Ingredients	Standard	mg /ml
1	Polysorbate-80	BP	2.000 mg
2	Glycerin	BP	60.000 mg
3	Sorbitol 70 %	BP	200.00 mg
4	Propylene Glycol	BP	15.00 mg
5	Sugar (Sucrose)	BP	500.00 mg
6	Methyl Hydroxybenzoate (Methyl Paraben)	BP	1.501 mg
7	Propyl Hydroxybenzoate (Propyl Paraben)	BP	0.149 mg

8	Carmellose Sodium (Carboxymethylcellulose sodium)	BP	2.000 mg
9	Colloidal Anhydrous Silica	BP	4.000 mg
10	Flavour Raspberry	IH	1.000 mg
11	Citric Acid Monohydrate	BP	1.941 mg
12	Purified Water	BP	Q.S.

3. Pharmaceutical Form

Liquid Dosage form (Suspension)

White coloured, homogenous, viscous, flavoured suspension

4. Clinical Particulars

4.1 Therapeutic indications

EXPEZOL 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,Acylostoma duodenale), whip-worm (Trichuris trichiura),thread-worm (Strongylodies,stercoralis), tape-worm(Taenia ssp and Hymenolepis nana only in the case of associated parasitism), Chlonorchiasis (Chlonorchis sinensis),Opisthorchiasis (Opisthorchis viverrini) and cutaneous larva migrans;Giardiasis (G.lamblia,G.duodenails,G.intestinalis, Lamblia intestinalis) in children .

4.2 Posology and method of administration.

1- For Round-worm, Hook-worm, Whip-worms, adult and children over 2 years of age, 10ml 4% or 20ml 2% suspension] in a single dose .

2- Children 1-2 years of age a single dose of 200mg (5ml 4% or 10ml 2% suspension can be given .

3- For Strongyloidiasis, Taeniasis, Hymenolepiasis in adults and children over 2 years of age 400mg one dose per day for 3 days.

4- For Chlonorchiasis,Opisthorchiasis-Chlonorchiasis,Opisthorch-Chlonbrchiasis,Opisthorchiasis-Chlonorchiasis iasis two dose per day for 5 days and children 2-12 years of age only 400mg, in adults and children over 2 years of age on dose per day for 5 days.

5- In order to obtain a complete cure in the case of pin-worm intestation and individuals sharing the same housing.

6- In Case of proven Hymenolepiasis, retreatment in 10-21 days in recommended.

7- If the patient is not cured after three weeks, a second course of treatment is indicated.

8- In cases of proven of proven H.nana infestation, retreatment 10-21 days is recommended.

9- No special procedures, such as fasting and purging are required.

10- The drug has not been studied in children under twelve months.

Method/Mode of administration: Oral

4.3 Contraindication

1. Should not be administered during pregnancy,or in woman thought to be pregnant.

2. EXPEZOL is contra-indicated in patients with a known history of hypersensitivity to the drug (Albendazole or constituents) .

4.4 Special Warnings and precautions

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

2- Treatment with EXPEZOL may uncover pre-existing neurocysticersosis, particularly in areas with high taenosis infection.

3- Patients may experience neurological symptoms e.g. seizures increased intracranial pressure and focal sings as a result of an inflammatory reaction caused of the parasite within the brain.

4- Symptoms may occur soon after treatment, appropriate steroid and anticonvulsant therapy should be started immediately.

5- EXPEZOL suspension contains benzoic acid which is a mild irritant to the skin, eyes and mucous membrane.

6- It may increase the risk of jaundice in newborn babies.

4.5 Interactions with other medicaments

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

1- Albendazole should not be administered during pregnancy or in women thought to be pregnant.

2- It is not known whether Albendazole or its metabolites are secreted in human breast milk.

3- Thus EXPEZOL should not be used during lactation unless the potential benefits are considered to outweight 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 and treatment

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 Pharmacodynamic 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. 0 Pharmaceutical Particulars

6.1 List of excipients

Sr. No.	Ingredients	Standard
1	Polysorbate-80	BP
2	Glycerin	BP
3	Sorbitol 70 %	BP
4	Propylene Glycol	BP
5	Sugar (Sucrose)	BP
6	Methyl Hydroxybenzoate (Methyl Paraben)	BP
7	Propyl Hydroxybenzoate (Propyl Paraben)	BP
8	Carmellose Sodium (Carboxymethylcellulose sodium)	BP
9	Colloidal Anhydrous Silica	BP
10	Flavour Raspberry	IH
11	Citric Acid Monohydrate	BP
12	Purified Water	BP

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 30°c protected from light, Keep out of reach of the children.

6.5 Nature and contents of container

1 x 10 ml Amber glass bottle.

6.6 Special precautions for disposal

No special requirements

Any unused product or waste material should be disposed of in accordance with local requirements

7. Marketing Authorization Holder

Swiss Pharma Nigeria Limited

5, Dopemu rd, Agege Lagos

8. Marketing Authorization Number

A4-4984

1.3.2 Labelling (outer & inner labels)

10 ml Amber Glass bottle is used as primary packaging material for the packing of EXPEZOL**.** One bottle in a carton along with pack insert and cartons are finally packed in shipper. Shipper Box is sealed with BOPP tape and a label is affixed on each shipper.

Both the Primary and Secondary Packaging materials are duly tested as per the following Specifications in Quality Control Laboratory & only those complying with the set In – House specifications are used.

Packaging material is routinely studied for Compatibility and Stability and the results have indicated that there is no interaction between Primary Packaging Materials (Amber Glass bottle) and the Drug Product. Further, there was no leaching or absorption phenomenon.

List of Packing Materials

S. No.	Packaging Materials
1.	Amber Glass bottles
2.	ROPP Cap

v **Labeling of Secondary packaging.**

S. No.	Packaging Materials
1.	Patient Information (Leaflet)
2.	Measuring Cup
3.	Printed Label
4.	Printed Carton
5.	Shipper