SUMMARY OF PRODUCT CHARACTERISTICS

2.16.1 Product Information for Health Professionals (For All Products subject to Medical Prescription)

2.16.1.1. Name of the medicinal product:

1.1 (Invented) name of the medicinal product:
TACIZOL SUSPENSION

1.2 Strength:

Each 5 mlContains:

Albendazole USP…….100 mg

Flavoured Base……. Q.S

1.3 Pharmaceutical form

Liquid Oral Suspension (Suspension)

2.16.1.2. Qualitative and quantitative composition:

Sr. No.	Ingredients	Grade	Qty. Required 5 ml (mg)	% Overages	Qty. Require/ 1000 liter (kg)
1	Albendazole	USP	100.000	5 %	21.000
2	Sodium methyl paraben	BP	10.000	-	2.000
3	Sodium propyl paraben	BP	2.500	-	0.500
4	Sodium benzoate	BP	5.000	-	1.000
5	Sucrose	BP	2000.000	-	400.000
6	Sorbitol 70%	BP	500.000	-	100.000
7	Glycerin	BP	250.000	-	50.000
8	Propylene glycol	BP	125.000	-	25.000
9	Poly sorbate-80	BP	1.250	-	0.250
10	Citric acid monohydrate	BP	12.500	-	2.500
11	Sodium citrate	BP	5.000	-	1.000
12	Xanthan gum	BP	15.000	-	3.000
13	Sodium CMC	USP	10.000	-	2.000
14	Colloidal silicon dioxide (aerosil)	BP	12.500	-	2.500
15	Colour erythrosine supra	IHS	0.500	-	0.100
16	Flavour peppermint	IHS	5.000	-	1.000
17	Flavour Rose white Liquid	IHS	5.000	-	1.000
18	Sodium sachharin	IP	2.500	-	0.500
Filled Volume / Bottle			**20 ml/30ml Bottle**		
	Final volume_____ liter				

2.16.1.3. Pharmaceutical form: Liquid Oral Suspension (Suspension)

2.16.1.4. Clinical particulars

4.1 Therapeutic indications:

TACIZOL SUSPENSION is an anthelmintic drug indicated for:

Treatment of parenchymal neurocysticercosis due to active lesions caused by larval forms of the pork tapeworm, Taenia solium.

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

Age 12 to 24 months: 200 mg as a single dose (5 ml suspension).

Adults & children (over two years): 400 mg (10 ml suspension) as a single dose in cases of Enterobius vermicularis, Trichuris trichiura, Ascaris lumbricoides, Ancylostoma duodenale and Necator americanus.

In cases of strongyloidiasis or taeniasis, 400 mg (10 ml suspension) as a single dose should be given for three consecutive days.

Giardiasis: 400 mg (10 ml suspension) once daily for five days.

(Albendazole) in hydatid disease (Echinococcosis) : In the treatment of echinococcosis, Albendazole is given by mouth with meals in a dose of 400 mg twice daily for 28 days for patients weighing over 60 kg.

A dose of 15 mg/kg body weight daily in two divided doses (to a maximum total daily dose of 800 mg) is used for patients weighing less than 60 kg. For cystic echinococcosis the 28- days course may be repeated after 14 days without treatment to a total of three treatment cycles.

For alveolar echinococcosis, cycles of 28 days of treatment followed by 14 days without treatment may need to continue for months or years. When three courses of therapy have been given in the pre or post surgical setting, optimal killing of cyst contents is achieved.

4.3 Contraindications

Should not be administered during pregnancy or in women thought to be pregnant as it has been shown to be teratogenic and embryotoxic in some animals.

Contraindicated in persons who are known to be hypersensitive to albendazole, other benzimidazole derivatives, or any component of product.

4.4 precautions for use:

Gastrointestinal discomfort, diarrhoea, headache and dizziness have been reported. Hypersensitivity reactions including rash. pruritus and urticaria have been reported less frequently.

Interactions:

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

4.5 Interaction with other medicinal products and other forms of interaction

Cimetidine, praziquantel and dexamethasone have been reported to increase the plasma levels of the albendazole active metabolite responsible for the systemic efficicacy of the product.

Ritonavir, phenytoin, carbamazepine and phenobarbital may have the potential to reduce plasma concentrations of the active metabolite of albendazole; albendazole sulfoxide. The clinical relevance of this is unknown, but may result in decreased efficacy, especially in the treatment of systemic helminth infections. Patients should be monitored for efficacy and may require alternative dose regimens or therapies

4.6 Pregnancy and lactation:

Albendazole should not be administered during pregnancy or in women thought to be pregnant.It is not known whether albendazole or its metabolites are secreted in human breast milk. Thus TACIZOL 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

NA

4.8 Undesirable effects:

Hypersensitivity reactions including rash, pruritis and urticaria (rare).

Headache and dizziness (uncommon).

Upper gastrointestinal symptoms (e.g. epigastric or abdominal pain, nausea, vomiting) and diarrhoea

(uncommon).

Elevations of hepatic enzymes (rare).

Erythema multiforme, Stevens-Johnson syndrome (very rare).

4.9 Overdose:

In case of overdosage, symptomatic therapy and general supportive measures are recommended.

5. Pharmacological properties

Pharmacology:

Albendazole tablet is a broad-spectrum anthelmintic, which is highly effective against a wide range of intestinal helminths. Albendazole tablet is also effective against tissue helminth infections, such as cutaneous larva migrans.
Albendazole therapy has also been used in the high dose, long term treatment of tissue helminth infections including hydatid cysts and cysticercosis.
The antihelminthic action of albendazole is thought to be mainly intra-intestinal. However, at higher albendazole doses, sufficient is absorbed and metabolised to the active sulphoxide metabolite, to have a therapeutic effect against tissue parasites.
Albendazole exhibits larvicidal, ovicidal and vermicidal activity, and is thought to act via inhibition of tubulin polymerization. This causes a cascade of metabolic disruption, including energy.
Pharmacokinetics
In man, the full extent of albendazole absorption following oral administration has not been established. However, it is known that albendazole is poorly absorbed with most of an oral dose remaining in the gastrointestinal tract. The poor absorption is believed to be due to the low aqueous solubility of albendazole. Absorption is significantly enhanced (approximately 5 fold) if albendazole is administered with a fatty meal.
Albendazole rapidly undergoes extensive first-pass metabolism in the liver, and is generally not detected in plasma. Albendazole sulphoxide is the primary metabolite, which is thought to be the active moiety in effectiveness against systemic tissue infections. The plasma half-life of albendazole sulphoxide is 8½ hours. Albendazole sulphoxide and its metabolites appear to be principally eliminated in bile, with only a small proportion appearing in the urine. depletion, which immobilizes and then kills the susceptible helminth.

6. Pharmaceutical particulars

2.16.1.6. Pharmaceutical particulars

6.1 List of excipients

The excipients used in the formulation are:

Sodium methyl paraben

Sodium propyl paraben

Sodium benzoate

Sucrose

Sorbitol 70%

Glycerin

Propylene glycol

Poly sorbate-80

Citric acid monohydrate

Sodium citrate

Xanthan gum

Sodium CMC

Colloidal silicon dioxide (aerosil)

Colour erythrosine supra

Flavour peppermint

Flavour Rose white Liquid

Sodium saccharin

6.2 Incompatibilities :

N.A.

6.3 Shelf life: 24 months

6.4 Special precautions for storage:

Keep in a cool and dry place, away from light.

6.5 Nature and contents of container

20 ml in white plastic bottle (30ml capacity) with plug and cap in one carton with a package insert.

6.6 Special precautions for disposal

No special requirements.

7. Registrant

Product Marketing Authorization

GB Pharma Limited
65 Chatsworth Road, London NW2 4BG,
United Kingdom

Name and Complete Address(es) of the Manufacturer(s) of the FPP

Name: Imperia Life Sciences Pvt. Ltd.
Address: At- Survey no.: 750/1, Village: Indrad - 382721, Taluka: Kadi, District: Mehsana, State: Gujarat INDIA

8 Date of revision of the text

N.A.

9. DOSIMETRY (IF APPLICABLE)

N.A.

10. 1NSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)

N.A.