1.6.1

Prescribing Information (Summary of Product Characteristics)

1.6.1.1 Name of the medicinal Product

Albendazole Tablets

1.6.1.1.1 strength

400 mg/tablet

1.6.1.1.2 Pharmaceutical Form

Oral tablet

1.6.1.2 Qualitative and Quantitative Composition

1.6.1.2.1 Qualitative declaration

Albendazole USP

1.6.1.2.2 Quantitative declaration

Sr. No	Ingredients Chemical Name	Specification	Quantity (mg/tablet)	Reason for Inclusion
01	Albendazole (A)	USP	400.000	Broad Spectrum Anthelmintic
02	Mannitol	BP	70.000	Diluent
03	Lactose (Lactose Monohydrate) (C)	BP	120.000	Diluent
04	Aspartame	BP	3.500	Sweetener
05	Colour Sunset Yellow Supra	IHS	0.700	Colouring agent
06	Sodium Lauryl Sulfate	BP	7.000	Surfactant
07	Maize Starch	BP	18.700	Binding Agent
08	Maize Starch	BP	14.300	Binding Agent
09	Purified water	BP	Q.S.	Vehicle
10	Sodium Starch Glycolate (Type A)	BP	14.000	Disintegrating Agent
11	Microcrystalline Cellulose (pH 102)	BP	21.000	Diluent
12	Ess. Orange powder	IHS	3.500	Flavouring Agent
13	Magnesium Stearate	BP	4.900	Lubricant
14	Colloidal Anhydrous Silica (Aerosil)	BP	5.600	Glidant

Note:

(A) = Quantity of active Ingredient is to be calculated on the basis of its 100% assay & on anhydrous basis.

(C) = Quantity of Lactose to be reduced against incremental Increase in quantity of Albendazole USP

1.6.1.3 Pharmaceutical Form

Chewable Tablet

Orange coloured, capsule shaped, uncoated chewable tablets, breakline on one side and plain on other side.

1.6.1.4 Clinical Particulars

1.6.1.4.1 Therapeutic Indications

Albendazole is indicated in for single or mixed intestinal infections caused by Enterobius vermicularis (Pinworm, Threadworm), Trichuris trichiura (Whipworm), Ascaris lumbricoides (Roundworm), Ancylostoma duodenale & Necator americanus (Hookworm), Taenia solium & Taenia saginata (Tapeworm), Strongyloides stercoralis. Also, in giardiasis in children over 2 years of age. Treatment of parenchymal neurocysticercosis caused by cystic hydatid disease of liver, lung & peritoneum caused by Echinococcus granulosus.

1.6.1.4.2 Posology and Method of Administration

Children (1-2 years): 200 mg as a single dose (half of Albendazole 400mg chewable tablet or 5ml suspension)

Adults and children over two years: Enterobius vermiculsris, Trichiura, Ascaris lumbricoides, Ancyclostoma dueodenal and necator americanus : 400 mg (1 tablet or 10ml Suspension) as single dose. Similar dose for giardiasis. Strongyloidiasis or taeniasis, 400mg (one tablet or 10ml suspension) as a single dose should be given for three consecutive days.

Giardiasis:400mg(1 tablet or 10 ml Suspension)once daily for five days

Neurocysticercosis: <60 kg: 15 mg/kg/day in 2 divided doses (maximum: 800 mg/day),400 mg (1 tablet or 10ml suspension) twice daily with meals for 8-30 days.

≥60 kg: 400 mg (1 tablet or 10ml suspension) twice daily with meals for 8- 30 days.

Hydatid disease: <60 kg: 15 mg/kg/day in 2 divided doses (maximum: 800 mg/day), 400 mg (1 tablet or 10ml suspension) twice daily with meals for 28 days, followed by a 14-day albendazole-free interval. Repeat for a total of 3 dosage cycles.

≥60 kg: 400 mg (1 tablet or 10ml suspension) twice daily with meals for 28 days,followed by 14- day albendazole-free interval. Repeat for a total of 3 dosage cycles.

Geriatric: Refer to adult dosing

1.6.1.4.3 Contraindications

Albendazole should not be administered during pregnancy or in women thought to be pregnant. Contraindicated in persons known to be hypersensitive to Albendazole or any component.

1.6.1.4.4 Special Warnings and Special Precautions for Use

Leucopenia with albendazole when used for periods longer than recommended. Albendazole should be discontinued in all patients if clinically significant decreases in blood cell counts occur. Use with caution in patients with hepatic or renal disease. Administer corticosteroids with albendazole to minimize inflammatory reactions & prevent cerebral hypertension. Pregnancy & Lactation: Not to be used during pregnancy. Caution should be exercised when administered to nursing woman due to excretion in human milk.

1.6.1.4.5 Interaction with other medicinal products and other forms of interaction

H antagonist increases plasma concentration of Albendazole.

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

1.6.1.4.6 Fertility, Pregnancy and Lactation

Pregnancy & Lactation: Not to be used during pregnancy. Caution should be exercised when administered to nursing woman due to excretion in human milk.

1.6.1.4.7 Effects on ability To Drive and use Machines

Not Applicable

1.6.1.4.8 Undesirable Effects

Epigastric pain, diarrhoea, headache, nausea, vomiting, dizziness, constipation, purities and dry mouth.

1.6.1.4.9 Overdose

Symptomatic therapy with gastric lavage, activated charcoal & general supportive measures.

1.6.1.5 Pharmacological Properties

1.6.1.5.1 Pharmacodynamics Properties

Albendazole causes degenerative alterations in intestinal cells of worm by inhibiting polymerisation or assembly of tubules into microtubules. Degenerative changes in endoplasmic reticulum, mitochondria of germinal layer & subsequent lysosomes release result in decreased ATP production producing diminished energy production causing parasite to immobilize & eventually dies.

1.6.1.5.2 Pharmacokinetic Properties

Albendazole is poorly absorbed orally in GI which significantly enhanced with fatty meal. Albendazole rapidly undergoes extensive first-pass metabolism in liver & not detected in plasma with 70% bound to plasma protein. Albendazole sulphoxide is primary metabolite. Cmax is 2–5 hours & T1/2 is 8½ hours. Albendazole principally eliminated in bile, with only small proportion appearing in urine.

1.6.1.5.3 Preclinical Safety Data

Not Applicable.

1.6.1.6 Pharmaceutical Particulars

1.6.1.6.1 List of Excipients

Mannitol

Lactose (Lactose Monohydrate)

Aspartame

Colour Sunset Yellow Supra

Sodium Lauryl Sulfate

Maize Starch

Sodium Starch Glycolate (Type A)

Microcrystalline Cellulose (pH 102)

Ess. Orange powder

Magnesium Stearate

Colloidal Anhydrous Silica (Aerosil)

1.6.1.6.2 Incompatibilities

Not applicable.

1.6.1.6.3 Shelf Life

36 months

1.6.1.6.4 Special Precautions for Storage

Store under normal conditions (15-30°C). Protect from light & moisture.

1.6.1.6.5 Nature and Contents of Container

1 Tablets are in Blister Pack. Such 1 Blisters are packed in Printed Carton with Packing Insert.

1.6.1.6.6 Special precaution for disposal and other handling

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

1.6.1.7 Marketing Authorization Holder And Manufacturing Site Addresses

1.6.1.7.1 Name and Address of Marketing Authorization Holder

Lincoln Pharmaceuticals Limited

Trimul Estate, Khatraj, Taluka: Kalol,

District: Gandhinagar Gujarat, India.

Telephone no.: +91-79-41078096

Fax: +91-79-41078062

Email: hiren@lincolnpharma.com

Website: www.lincolnpharma.com

1.6.1.7.2 Name and Address of manufacturing site(s)

Lincoln Pharmaceuticals Limited

Trimul Estate, Khatraj, Taluka: Kalol,
District: Gandhinagar Gujarat, India.
Telephone no.: +91-79-41078096
Fax: +91-79-41078062
Email: hiren@lincolnpharma.com
Website: www.lincolnpharma.com

1.6.1.8 Marketing Authorization Number

To be included after obtaining first registration.

1.6.1.9 Date of First <Registration> / Renewal of The <Registration>

It will be applicable after registration of this product.

1.6.1.10 **Date of Revision of the Text**

1.6.1.11 Dosimetry (If Applicable)

Not Applicable

1.6.1.12 Instructions for preparation of radiopharmaceuticals (if Applicable)

Not Applicable