1.6.1

Prescribing Information (Summary of Product Characteristics)

1.6.1.1 Name of the medicinal Product

Mebendazole Tablets USP 100 mg

1.6.1.1.1 strength

100 mg

1.6.1.1.2 Pharmaceutical Form

Oral Tablet

1.6.1.2 Qualitative and Quantitative Composition

1.6.1.2.1 Qualitative declaration

Mebendazole USP

1.6.1.2.2 Quantitative declaration

Sr. No.	Ingredients	Specification	Overages	Standard Quantity (mg/tablet)	Reason for Inclusion
Mixing					
1.	Mebendazole (A)	USP	Nil	100.00	Anthelmintic
2.	Lactose (Lactose Monohydrate) (C)	BP	--	50.000	Diluent
3.	Maize Starch *	BP	--	69.890	Diluent
Binding					
4.	Maize Starch *	BP	--	8.600	Binder
5.	Sodium Benzoate	BP	--	1.500	Antimicrobial preservative
6.	Purified Water #	BP	--	Q.S.	Vehicle
Lubrication					
7.	Crospovidone (Polyplasdone)	USP-NF	--	9.000	Disintegrant

8.	Sodium Starch Glycolate (Type-A)	BP	--	6.000	Disintegrant
9.	Sodium Lauryl Sulphate	BP	--	3.000	Surfactant
10.	Purified Talc	BP	--	3.000	Glidant
11.	Colloidal anhydrous Silica (Aerosil)	BP	--	1.500	Glidant
12.	Magnesium Stearate	BP	--	3.000	Lubricant

Note:

* = 7% overages for loss on drying.

(A) = Quantity to be calculated on the basis of its potency.

(C) = Quantity of Lactose (Lactose Monohydrate) BP to be reduced against incremental increase in quantity of Mebendazole USP due to assay compensation.

= This will not remain in final product

1.6.1.3 Pharmaceutical Form

Oral Tablet

Off-white to yellow coloured, round shaped, biconvex, uncoated tablet, breakline on one side and plain on other side.

1.6.1.4 Clinical Particulars

1.6.1.4.1 Therapeutic Indications

Mebendazole is indicated for the treatment of Enterobius vermicularis (pinworm), Trichuris trichiura (whipworm), Ascaris lumbricoides (common roundworm), Ancylostoma duodenale (common hookworm), Necator americanus (american hookworm) in single or mixed infections.

Efficacy varies as a function of such factors as pre-existing diarrhoea and gastrointestinal transit time, degree of infection, and helminth strains..

1.6.1.4.2 Posology and Method of Administration

The same dosage schedule applies to children and adults. The tablet may be chewed, swallowed, or crushed and mixed with food.

Pinworm (enterobiasis) : 1 tablet once

Whipworm (trichuriasis), Common Roundworm (ascariasis), Hookworm : 1 tablet morning and evening for 3 consecutive days.

If the patient is not cured after three weeks of treatment, a second course of treatment is advised. No special procedures, such as fasting or purging, are required..

1.6.1.4.3 Contraindications

Mebendazole is contraindicated in persons who have shown hypersensitivity to the drug.

1.6.1.4.4 Special Warnings and Special Precautions for Use

Patients receiving high doses of Mebendazole , such as those with echinococcosis, should be supervised closely with blood counts and liver function being monitored.

Pregnancy : During pregnancy, especially during the first trimester, Mebendazole should be used only if the potential benefit justifies the potential risk to the foetus.

Nursing Mothers : It is not known whether Mebendazole is excreted in human milk, though because many drugs are excreted in human milk, caution should be exercised when Mebendazole is administered to a nursing woman.

Paediatric Use: Safety and efficacy for use in children under two years have not been established ; therefore relative benefit/risk should be considered.

There is no evidence that Mebendazole, is effective for hydatid disease. There have been rare reports of neutropenia and liver function elevations, including hepatitis, when Mebendazole is taken for prolonged periods and at dosages substantially above those recommended.

Keep all medicines out of reach of children.

1.6.1.4.5 Interaction with other medicinal products and other forms of interaction

Preliminary evidence suggests that cimetidine inhibits Mebendazole metabolism and may result in an increase in plasma concentrations of Mebendazole.

Carbamazepine and hydantoins may reduce the plasma levels of concomitant Mebendazole , possibly decreasing its therapeutic effect.

1.6.1.4.6 Fertility, Pregnancy and Lactation

Pregnancy : During pregnancy, especially during the first trimester, Mebendazole should be used only if the potential benefit justifies the potential risk to the foetus.

Nursing Mothers : It is not known whether Mebendazole is excreted in human milk, though because many drugs are excreted in human milk, caution should be exercised when Mebendazole is administered to a nursing woman.

1.6.1.4.7 Effects on ability To Drive and use Machines

None.

1.6.1.4.8 Undesirable Effects

Transient symptoms of abdominal pain and diarrhoea have occurred in cases of massive infection and expulsion of worms. Hypersensitivity reactions such as rash, urticaria and angioedema have been observed on rare occasions. Very rare cases of convulsions have been reported.

1.6.1.4.9 Overdose

GI complaints lasting upto a few hours may occur. Induce vomiting and purging Activated charcoal may be given

1.6.1.5 Pharmacological Properties

1.6.1.5.1 Pharmacodynamics Properties

Mebendazole inhibits the formation of worms microtubules and irreversibly blocks glucose uptake by the susceptible helminths, thereby depleting endogenous glycogen stored within the parasite that required for survival and reproduction of the helminth. Mebendazole does not affect blood glucose concentration in the host.

1.6.1.5.2 Pharmacokinetic Properties

Mebendazole is poorly absorbed from the gastro-intestinal tract. Peak plasma levels are reached in 2 to 4 hours. Mebendazole undergoes extensive first-pass elimination, being metabolised in the liver , eliminated in the bile as unchanged drug and metabolites and excreted in faeces. Only about 2% of a dose is excreted unchanged or as metabolites in the urine. Mebendazole is highly protein bound.

1.6.1.5.3 Preclinical Safety Data

Not Applicable.

1.6.1.6 Pharmaceutical Particulars

1.6.1.6.1 List of Excipients

Lactose (Lactose Monohydrate) (C) BP

Maize Starch BP

Sodium Benzoate BP

Purified Water BP

Crospovidone (Polyplasdone) USP-NF

Sodium Starch Glycolate (Type-A) BP

Sodium Lauryl Sulphate BP

Purified Talc BP

Colloidal anhydrous Silica (Aerosil) BP

Magnesium Stearate BP

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 below 30°C. Protect from light & moisture.

1.6.1.6.5 Nature and Contents of Container

6 tablets are packed in blister pack. Such 10 blisters are packed in a printed carton with packing insert.

1000 tablets are packed in Ribcone Jar 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.
Phone: +91-79-49135000
Telefax: +91-79-41078062
Email: info@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.
Phone: +91-79-49135000
Telefax: +91-79-41078062
Email: info@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