

PATIENT INFORMATION LEAFLET
MEBENDAZOLE TABLETS USP 100 MG
(Mebendazole USP)

Read all of this leaflet carefully before you start using this medicine.

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your physician, health care provider or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your physician, health care provider or pharmacist.

WHAT IS IN THIS LEAFLET:

1. What Mebendazole Tablets USP 100 mg is and what it is used for
2. Before you use Mebendazole Tablets USP 100 mg
3. How to use Mebendazole Tablets USP 100 mg
4. Possible side effects
5. How to store Mebendazole Tablets USP 100 mg
6. Further information

1. WHAT MEBENDAZOLE TABLETS USP 100 MG IS AND WHAT IT IS USED FOR

It contains active ingredient Mebendazole. It is a benzimidazole (broad spectrum) anthelmintic used to treat parenchymal neurocysticercosis and other helminth infections. It inhibits the formation of worms microtubules and irreversibly blocks glucose uptake by the susceptible helminths, thereby depleting endogenous glycogen stored within the parasite that is required for survival and reproduction of the helminth. Mebendazole does not affect blood glucose concentration in the host. It 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. This medicine is for use in adults and children aged over 2 years.

2. BEFORE YOU USE MEBENDAZOLE TABLETS USP 100 MG

Do not use Mebendazole Tablets USP 100 mg. If you are allergic (known hypersensitivity) to Mebendazole or any of the other ingredients or any other medicines.

Take special care with Mebendazole Tablets USP 100 mg: Warnings and Precautions: Talk to your Physician or pharmacist before taking mebendazole Tablets USP 100 mg.

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. Talk to your Physician or pharmacist if the fungal infection does not improve, as alternative antifungal therapy may be needed.

Taking other medicines: Please tell your Physician, health care provider or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Preliminary evidence suggests that cimetidine inhibits mebendazole metabolism and

may result in an increase in plasma concentrations of mebendazole. Carbamazepine and hydantoin may reduce the plasma levels of concomitant mebendazole, possibly decreasing its therapeutic effect. Patients should be monitored for efficacy and may require alternative dose regimens or therapies. **Taking Mebendazole Tablets USP 100 mg with food and drink:** Patients can take your medicine with or without a meal or as directed by physician. **Pregnancy and breast-feeding:** Ask your physician, health care provider or pharmacist for advice before taking any medicine. **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. **Caution for use:** It contains lactose monohydrate: Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. **Driving and using machines:** This medicine may cause dizziness. If affected, do not drive or operate machinery.

3. HOW TO USE MEBENDAZOLE TABLETS USP 100 MG:

Method of administration: It should be administered orally. Patient should swallow Mebendazole tablets USP 100 mg. It is best to take your oral tablets dose at the same time each day. Always use dose exactly as your Physician has told you. It should be taken with or without meals or as directed by physician.

The dosage schedule of mebendazole tablets USP 100 mg is mentioned follow: 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. **If you take more Mebendazole tablets USP 100 mg than you should:** If you accidentally take too many mebendazole tablets USP 100 mg, tell your physician at once or contact your nearest hospital casualty department. Take your medicine pack with you so that people can see what you have taken. The Symptomatic therapy (GI complaints lasting upto a few hours may occur. Induce vomiting and purging activated charcoal may be given) and general supportive measures are recommended. **If you forget to take Mebendazole tablets USP 100 mg:** Do not take a double dose to make up for a forgotten dose. If you miss a dose of this medicine, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. If any further questions on the use this contact your Physician or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, mebendazole tablets USP 100 mg can cause side effects, although not everybody gets them. Check with your Physician immediately if any of the following side effects occur: 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 if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

5. HOW TO STORE MEBENDAZOLE TABLETS USP 100 MG

Keep this medicine out of the sight and reach of children. Store below 30°C. Protect from light and moisture. Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. Any

unused product or waste material should be disposed of in accordance with local requirements. These measures will help protect the environment.

6. FURTHER INFORMATION

It contains: The active substance is mebendazole USP. The other ingredient(s) is (are): Lactose (Lactose Monohydrate) 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. **Shelf Life:** 36 months. **Pack:** Mebendazole tablets USP 100 mg: Off-white to yellow coloured, round shaped, biconvex, uncoated tablet, breakline on one side and plain on other side. 6 Tablets are packed in Alu-PVC blister pack. Such 10 blisters are packed in printed carton along with packing insert. 1000 tablets are packed in Jar with packing insert.

Manufactured by:

Lincoln Pharmaceuticals Ltd

Trimul Estate, Khatraj, Tal.:- Kalol,
Dist.:- Gandhinagar, Gujarat State, India.

Phone: +91-079-41078096

Email: hiren@lincolnpharma.com

Website: www.lincolnpharma.com

For any information about this medicinal product, please contact the local representative of the supplier:

Lincoln Pharmaceuticals Ltd Trimul Estate, Khatraj, Tal.:- Kalol, Dist.:- Gandhinagar, Gujarat State, India. Phone: +91-079-41078096 Email: hiren@lincolnpharma.com Website: www.lincolnpharma.com	Abacus Pharma (A) Ltd Kigali city market, B1-R85, PO Box 4344, Kigali, Rwanda. Phone: +91-079-41078096 Telefax: +91-79-41078062 Email: abacuspharmacist@gmail.com
--	---

Date of publication or revision

16.02.2024