

Package leaflet: Information for the user

LOOBID TABLETS (Ofloxacin and Ornidazole Tablets with Lactic Acid Bacillus)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, Healthcare provider, Pharmacist
- This medicine has been prescribed for you only. 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 doctor, health care provider or pharmacist.

In this leaflet:

- a. What **LOOBID TABLETS** is and what it is used for
- b. Before you take **LOOBID TABLETS**
- c. How to take **LOOBID TABLETS**
- d. Possible side effects
- e. How to store **LOOBID TABLETS**
- f. Further Information

a. What LOOBID TABLETS is and what it is used for

Both Ofloxacin and Ornidazole are almost completely absorbed from the small intestine when administered orally, both having almost 100% bioavailability. Subsequent plasma concentrations of Ofloxacin are obtained in 1-2 hours after oral administration. Peak plasma concentrations of Ornidazole are obtained within 2 hours of administration. The plasma elimination of Ornidazole is 12 to 15 hours and less than 15% is bound to plasma proteins. It is widely distributed in body tissues and fluids. Ornidazole is metabolised in the liver and is excreted in the urine mainly as metabolites and conjugates and to a lesser extent in the faeces.

Rationality

The pharmacokinetic behaviour of the two drugs should be similar to support the use of the two agents in fixed-dose-combination.

Both the drugs in Co-trimoxazole, which is an established combination of sulphamethoxazole and trimethoprim, have their pharmacokinetic parameters like $t_{1/2}$ (about 10 hrs for both the drugs) matching with that of each other.

Similarly, the half-lives of Ofloxacin & Ornidazole fall in the same range and hence, the time course of action of the three drugs might be similar which is an important criterion for the possibility of a rational fixed-dose-combination.

How LOOBID TABLETS works

LOOBID TABLETS is indicated for Diarrhoea, Dysentery and Amoebiasis, Pelvic Inflammatory, Post Surgical Care and Typhoid Fever

b. Before you take LOOBID TABLETS

Do not take LOOBID TABLETS

- Do not take **LOOBID TABLETS** if you are allergic to any of its contents.

Take special care with LOOBID TABLETS

Clostridium difficile - associated disease:

Diarrhoea, particularly if severe and/or persistent, occurring during treatment or in the initial weeks following treatment with ofloxacin or with various other antibiotics, but especially broad spectrum antibiotics, may be symptomatic of Clostridium difficile-associated disease, the most severe form of which is pseudo-membranous colitis.

Ofloxacin may aggravate myasthenia gravis.

Ofloxacin may negativate the isolation of Mycobacterium tuberculosis, giving false negative results, in the bacteriological diagnosis of tuberculosis.

The serum concentration of ofloxacin should be monitored in patients with severe renal impairment and haemodialysis patients.

Children and adolescents

should be used with caution in children if prescribed by the doctor.

Other medicines

Concomitant administration of oral anticoagulants may increase the risk of haemorrhage due to diminished hepatic metabolism. Antacids reduce the absorption of Ofloxacin. As with other nitroimidazoles, Ornidazole may invoke a disulfiram-like reaction in some patients.

LOOBID TABLETS with food and drink

No interactions found with food.

Avoid consumption of alcohol while taking **LOOBID TABLETS** as it may cause increased dizziness.

Pregnancy and breast-feeding

Pregnancy – Should not be used in pregnancy.

Nursing Mothers – No adequate trials are available to suggest the administration of either drug during breast feeding.

Driving and using machines

Ofloxacin: None known

Ornidazole: Dizziness, tremor, rigidity, poor coordination, seizures, vertigo or temporary loss of consciousness may occur in patients receiving ornidazole. If they occur, such effects may affect tasks requiring alertness including the patient's ability to drive and operate machinery

C. How to take LOOBID TABLETS

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

1 Tablet twice daily.

Route of administration: Oral.

If you take more LOOBID TABLETS than you should

If you take more LOOBID TABLETS than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

If you forget to take LOOBID TABLETS

Do not take a double dose to make up for a forgotten dose. Take your missed dose as quickly as possible and then continue taking your medicine as normal.

If you are unsure what to do, ask your doctor or pharmacist.

If you stop taking LOOBID TABLETS

Take LOOBID TABLETS for as long as your doctor recommends it. Do not stop unless advised by your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

D. Possible side effects

Common side effects include nausea, abdominal pain, vomiting, insomnia, dizziness, vertigo, ataxia, mental confusion and hypersensitivity reactions. Leucopenia has also been occasionally reported.

E. How to store LOOBID TABLETS

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the bottle and carton

after "EXP". The expiry date refers to the last day of that month.

- Store in dry place below 30°C. Protect from light.
- Store in the original package in order to protect from moisture.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

F. Further Information

What **LOOBID TABLETS** contains

- The active substances are Ofloxacin USP and Ornidazole with Lactic Acid Bacillus
- Contains Ofloxacin USP 200mg, Ornidazole 500mg and Lactic Acid Bacillus 60 million spores as enteric Coated Granules
- The other ingredients are: Maize starch, Microcrystalline cellulose, Purified Talc, Magnesium stearate, Purified water, Cellulose acetate phthalate, Methylene chloride, Acetone, Hydroxypropyl methyl cellulose, Polyethylene Glycol (6000), Titanium Dioxide, Isopropyl alcohol, Methylene chloride, Color Idacol Quinoline Lake.

What **LOOBID TABLETS** looks like and contents of the pack

- Pale yellow colored oblong film-coated tablet, having breakline on one side.
 - Primary Container: 10 tablets packed in ALU/PVC Blister
- Secondary container: Such one blister in a printed outer carton along with Pack insert.

Marketing Authorization Holder

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