1.4.3 Patient Information Leaflet (PIL)

Enclosed

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 or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet?

1. WHAT ORNILOX IS AND WHAT IT IS USED FOR

Ofloxacin is used to treat infection by bacteria It is a type of quinolone antibiotic It is used to kill the bacteria that cause infection It works against a wide range of bacteria but some bacteria are resistant to its effects In general this drug is used to kill susceptible strains of bacteria that cause infections Benefits of being on this drug can include Treatment of infections caused by bacteria that can be killed by Ofloxacin and reduction of any pain or discomfort caused by such infections.

Ornidazole is an antiprotozoal and antibacterial agent, it is a derivative of 5-nitroimidazole. It is active against *Trichomonal vaginalis, Entamoeba histolytica, Giardia lamblia (Giardia intestinalis)* and against some anaerobic bacteria such as *Bacteroides* and *Clostridium spp.*,and anaerobic coccus. By mechanism of action Ornidazole is a DNA-tropic preparation with selective action against microorganisms, which have enzyme systems able to renew nitro group and to catalyze an interaction of proteins of ferrodoxin group and nitro compounds.

Ornidazole & Ofloxacin is indicated for empirical treatment of mixed aerobic-anaerobic infections commonly seen in clinical practice e.g. intra-abdominal infection, gynecological and pelvic infections, foot ulcers especially in diabetes, lung abscess, infections in immune-compromised patients etc.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ORNILOX

Do not take this medicine and tell your doctor if:

- You are allergic (hypersensitive) to Ofloxacin or any of the other ingredients of Ofloxacin tablets
  Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- You have ever had swelling of the tendons (called tendinitis) which can affect areas such as the wrist or the Achilles tendon
- You have epilepsy or are at risk of fits
- You have a problem with your red blood cells known as ‘glucose-6-dehydrogenase deficiency’
- You are pregnant or breast-feeding You are under 18 years of age or are still growing

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Ofloxacin & Ornidazole tablets.
Very rarely, patients treated with fluoroquinolone or quinolone antibiotics have suffered long-lasting and disabling side effects, mainly involving muscles, tendons and bones and the nervous system.
Fluoroquinolone and quinolone antibiotics should not be used

- To treat infections that might get better without treatment or are not severe (such as throat infections);
- For preventing traveller's diarrhoea or recurring lower urinary tract infections (urine infections that do not extend beyond the bladder);
- To treat patients who have previously had serious side effects with a fluoroquinolone or quinolone antibiotic;
- To treat mild or moderately severe infections unless other antibacterial medicines commonly recommended for these infections cannot be used;
- Be used with caution especially for the elderly, patients with kidney problems, patients who have had organ transplantation or those who are being treated with a systemic corticosteroid. These patients are at higher risk of tendon injury caused by fluoroquinolone and quinolone antibiotics.

3. HOW TO TAKE ORNILOX

The usual adult dose is one tablet twice a day orally administration. The doses may be increased in severe infections. The duration of treatment depends upon the type and severity of infection.
Taking this medicine

- Take this medicine by mouth
- Swallow the tablets whole with a drink of water
- Medicines containing iron (for anaemia) antacids (for indigestion or heartburn) or sucralfate (for stomach ulcers) should be avoided for two hours before or after taking this Tablets
- If you feel the effect of your medicine is too weak or strong, do not change the dose yourself, but ask your doctor

How much to take

- Your doctor will decide on how many tablets you should take
- The dose will depend on the type of infection you have

Kidney or liver problems
If you have any kidney or liver problems you may be given a lower dose.
Children and Adolescents
This medicine should not be given to children or adolescents.
Check with your doctor or pharmacist before taking your medicine if:

- You have liver or kidney problems
- You have heart disease or problems with your heartbeat
- You are taking medicines that can affect your heart (see section *Taking other medicines*)
- You were born with or have family history of prolonged QT interval (seen on ECG, electrical recording of the heart)
- You have a salt imbalance in the blood (especially low levels of potassium or magnesium in the blood)
- You have a very slow heart rhythm (called 'bradycardia')
- You have a weak heart (heart failure)
- You have a history of heart attack (myocardial infarction)
- You are female or elderly
- You are taking other medicines that result in abnormal ECG changes (see section *Taking other medicines*)
- You have or have ever had any mental health problems
- You suffer from a condition called 'myasthenia gravis' (muscle weakness)
- You have been told by your doctor that you can not tolerate some sugars.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Ofloxacin & Ornidazole tablets.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Ofloxacin & Ornidazole tablets and some other medicines can affect the way each other work.

In particular, tell your doctor if you are taking the following medicine:

- Methotrexate used for rheumatism or cancer

Other medicines that can alter your heart rhythm:

- Medicines that belong to the group of anti-arrhythmics (e.g. quinidine, hydroquindine, disopyramide, Amiodarone, sotalol, dofetilide, ibutilide)
- Tricyclic antidepressants
- Some antimicrobials (that belong to the group of macrolides)
- Some antipsychotics

Pregnancy and breast-feeding

Pregnancy C Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well controlled studies in humans but potential benefits may warrant use of the drug in pregnant women despite potential risks.

Lactation L4 There is positive evidence of risk to a breastfed infant or to breast milk production but the benefits of use in breastfeeding mothers may be acceptable despite the risk to the infant eg if the drug is needed in a life-threatening situation or for a serious disease for which safer drugs cannot be used or are ineffective.

If you take more tablets than you should

If you take more tablets than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken. The following effects may happen: feeling confused or dizzy, loss of consciousness, fits, feeling sick or blood in your stools.

If you forget to take tablets

If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose.

Do not take a double dose to make up for a forgotten tablet.

If you stop taking these tablets

Keep taking these tablets until your doctor tells you to stop. Do not stop taking these tablets just because you feel better. If you stop, your infection may get worse again. If you have any further questions on the use of this product, ask your doctor or pharmacist.

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

4. POSSIBLE SIDE EFFECTS

Ofloxacin

The overall frequency of adverse reactions from the clinical trial data base is about 7%. The commonest events involved the gastrointestinal system (about 5.0%) and the nervous system (about 2.0%).

The following provides a tabulation based on post marketing experience where occasional represents a frequency of 0.1 - 1.0%, rare <0.1%, very rare <0.01% and isolated cases <0.01%.

Digestive and liver side effects

Occasional: Nausea and vomiting, diarrhoea, abdominal pain, gastric symptoms. (Diarrhoea may sometimes be a symptom of enter colitis which may, in some cases, be haemorrhagic).

Rare: Loss of appetite, increase in liver enzymes and/or bilirubin.

Very rare: cholestatic jaundice; hepatitis or severe liver damage may develop.

A particular form of enter colitis that can occur with antibiotics is pseudomembranous colitis (in most cases due to Clostridium difficile). Even if Clostridium difficile is only suspected, administration of Ofloxacin should be discontinued immediately and appropriate treatment given. Drugs that inhibit peristalsis should not be administered in such cases.

Central nervous system

Occasional: Headache, dizziness, sleep disorders, restlessness.
Rare: Confusion, nightmares, anxiety, depression, hallucinations and psychotic reactions, drowsiness, unsteady gait and tremor (due to disorders of muscular co-ordination), neuropathy, numbness and paraesthesia or hypaesthesia, visual disturbances, disturbances of taste and smell (including, in exceptional cases, loss of function), extrapyramidal symptoms.
Very rare: Convulsions, hearing disorders (including, in exceptional cases, loss of hearing). These reactions have occurred in some patients after the first dose of Ofloxacin.
In such cases, discontinue treatment immediately.
Isolated cases: Psychotic reactions and depression with self-endangering behaviour including suicidal ideation or acts. *Cardiovascular system:*
Tachycardia and a temporary decrease in blood pressure have been reported.
Rare: circulatory collapse (due to pronounced drop in blood pressure).
Haematological side effects
Very rare: anaemia, leukopenia (including agranulocytosis), thrombocytopenia, pancytopenia.
Only in some cases are these due to bone marrow depression. In very rare cases, haemolytic anaemia may develop.
Renal side effects
Rare: Disturbances of kidney function.
Isolated cases: Acute interstitial nephritis, or an increase in serum creatinine, which may progress to acute renal failure. *Allergic and skin side effects*
Occasional: Skin rash, itching.
Very rare: Rash on exposure to strong sunlight, other severe skin reactions. Hypersensitivity reactions, immediate or delayed, usually involving the skin (e.g. erythema multiform, Stevens-Johnson syndrome, Lyell's syndrome, and Vasculitis) may occur. In exceptional circumstances, Vasculitis can lead skin lesions including necrosis and may also involve internal organs. There are rarely other signs of anaphylaxis such as tachycardia, fever, dyspnoea,shock, angioneurotic oedema, Vasculitis reactions, and eosinophilia. In these cases treatment should be discontinued immediately and where appropriate, supportive treatment given.
Isolated cases: Pneumonitis.
Other side effects
Rare: Malaise.
Very rare: Excessive rise or fall in blood-sugar levels. Weakness, joint and muscle pains (in isolated cases these may be symptoms of rhabdomyolysis).
Isolated cases: Tendon discomfort including inflammation and rupture of tendons (e.g. the Achilles tendon) particularly in patients treated concurrently with corticosteroids. In the event of signs of inflammation of a tendon, treatment with Ofloxacin must be halted immediately and appropriate treatment must be initiated for the affected tendon.
The possibility cannot be ruled out that Ofloxacin may trigger an attack of porphyria in predisposed patients.
Except in very rare instances (e.g. isolated cases of smell, taste and hearing disorders) the adverse effects observed subsided after discontinuation of Ofloxacin.
Ornidazole
Gastrointestinal effects like nausea, vomiting, anorexia and metallic or bitter taste. CNS effects like dizziness, vertigo and somnolence, rigidity, tremor, coordination problems, convulsions (rare), impairment of consciousness and signs of sensitive or mixed peripheral neuropathy have been observed. Blood dyscrasias like medullar aplasia and neutropenia may be encountered occasionally. Other adverse events such as fatigue, loose stools, and headache have also been reported.

5. HOW TO STORE ORNILOX

Keep this medicine in a safe place where children cannot see or reach it.
Do not use this tablets after the expiry date which is stated on the label. The expiry refers to the last day of that month.

Keep the blister strip in the outer carton in order to protect from moisture.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.
Store below 30°C. Keep away from the reach of children

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Ornilox contains

Active ingredients: Ornidazole and Ofloxacin

In active ingredients: Microcrystalline Cellulose, Sodium Starch Glycollate, Croscarmellose Sodium, Colloidal Anhydrous Silica, Talc, Magnesium stearate, Hypromellose, Opadry Orange II 33G53350, Lake of Quinoline Yellow.

What Ornilox looks like and contents of the pack

Orange coloured caplet shaped film-coated tablets with a "MICRO" engraved on both sides.
Alu/Alu pack of 10 tablets

Manufacturer

MICRO LABS LIMITED
92, SIPCOT,
HOSUR-635 126
INDIA

Marketing Authorization Holder

Micro Labs Limited
31, race course road
Bangalore-560001
INDIA

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