Ofloxacin 200 mg and 400 mg Tablets

Package leaflet: Information for the user

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

1. What Ofloxacin is and what it is used for

Ofloxacin belongs to a group of antibacterial medicines known as fluoroquinolones. Ofloxacin is used to treat infections of:

- the bladder or the kidneys
- the skin and soft tissue
- diarrhoea may develop while you are on antibiotics, including Ofloxacin, or you may experience symptoms of liver problems such as loss of appetite, 
- if you are taking fenbufen or other NSAIDS, vitamin K antagonists
- if you are diabetic
- if you have an illness of the nervous system called myasthenia gravis (a disorder in which the muscles are weak and tire easily)

Talk to your doctor before taking Ofloxacin:

- if you have had a reaction to any type of antibiotic in the past, check with your doctor before taking Ofloxacin.
- if you have a history of arrhythmia of the tendons (tendinitis) when you have taken fluoroquinolones in the past
- if you have epilepsy or you have ever had a seizure or fit
- if you suffer from glucose-6-phosphate dehydrogenase deficiency or glucose-galactose malabsorption. Ofloxacin is not suitable for people who have inherited disorders that give them problems when they take these sugars.
- if you suffer from vision disorder
- if you suffer from methicillin-resistant staphylococcus aureus (MRSA) infection
- if you are pregnant or breast-feeding
- if you suffer from glucose-6-phosphate dehydrogenase deficiency (this is an inherited disorder that affects the red blood cells). If Ofloxacin is taken the red blood cells may break down causing anaemia and jaundice.
- if you are pregnant or breast-feeding
- if you have vision disorder

Warnings and precautions

Heart problems

Cautions should be taken when using this kind of medicine, if you were born with or have family history of prolonged QT interval (long on ECG, electrical recording of the heart), have had inflamation in the blood (especially low level of potassium or magnesium in the blood), have a very slow heart rhythm (called ‘bradycardia’), have a weak heart (heart failure), have a history of heart attack (myocardial infarction), you are female or elderly or you are taking other medicines that result in abnormal ECG changes (see section 3. How to take Ofloxacin) medicines that belong to the group of anti-arrhythmics (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, defibrillate, lidilide, procainamid), tricyclic antidepressants e.g. amitriptyline, clomipramin, some antipsychotics (e.g. pimozide, perphenazine, haloperidol), some antidepressants (e.g. selective serotonin reuptake inhibitors (SSRIs)).

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Ofloxacin with food, drink and alcohol

Do not drink alcohol while taking Ofloxacin as it may make some side effects worse. Ofloxacin contains lactose:

- Patients who are intolerant to lactose should note that Ofloxacin tablets contain a small amount of lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Breastfeeding, pregnancy and fertility

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Ofloxacin may make you feel sleepy, dizzy or affect your vision, which may impair your ability to concentrate. If affected do not drive or operate machinery.

How to take Ofloxacin

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

Your doctor will decide how much Ofloxacin you need to take each day. A dose up to 400 mg can be taken as a single dose in the morning. A dose higher than 400 mg should be divided into two separate doses, and can be taken as one dose in the morning and one dose in the evening. Your doctor will tell you how long your treatment with Ofloxacin will last. Treatment should not exceed 2 months. Return to your doctor if you still feel unwell after finishing your course of tablets. The tablets should be swallowed preferably with a drink of water. Ofloxacin tablets may be taken before or with food.

The usual dose is:

- Adults (including the elderly): Your dose will depend on the type and severity of infection you have. The dosage range is 200 mg to 400 mg a day
- To treat simple bladder or kidney infections
- The usual dose is 400 mg of Ofloxacin a day. Treatment usually lasts for 3 days. To treat kidney infections, your doctor may increase the dose to 400 mg twice a day and you may need to take Ofloxacin for 7-10 days.
- To treat gonorrhoea of the genital organs
- A single dose of 400 mg of Ofloxacin in the morning is usually enough.
- To treat other infections of the genital organs for which Ofloxacin is a suitable antibiotic, the usual dose is 400 mg a day, taken for 7-10 days.
- To treat lung infections
- The usual dose is 400 mg of Ofloxacin a day. If necessary, your doctor may increase this to 400 mg twice a day. Treatment may last from 7-10 days.
- To treat skin and soft tissue infections
- The usual dose is 400 mg of Ofloxacin twice a day. Treatment may last from 7-10 days.
- In children and adolescents: Ofloxacin Tablets should not be given to children or growing adolescents.
Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If the following happens, stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:

- an allergic reaction sometimes even after taking your first dose, which may include swelling of the lips, face or neck leading to severe difficulty in breathing, skin rash or hives, fast heart rate, low blood pressure, fever, burning of the eyes, throat irritation, coughing, wheezing, shock or blood disorders
- skin disorder that comes from an allergic reaction or infection (drug eruption), visible accumulations of fluid within or beneath the skin (vesiculobullous rash), skin rashes caused by sunlight (phototoxicity reaction), inflammatory skin eruption (erythema multiforme)
- inflammation and ulceration of the mouth, eyes, gut and genitals; these may be due to Stevens-Johnson Syndrome or toxic epidermal necrolysis, which are serious illnesses
- tendon discomfort, including inflammation and rupture, particularly if you are elderly or also taking corticosteroids e.g. prednisolone
- fits, agitation, irritability, anxiety, depression, hallucinations, feeling of wanting to harm yourself and other disturbances of the mind, confusion, ringing in the ears, numbness, pins-and-needles, blurred, double or odd colour vision problems, problems with or loss of hearing, taste or smell
- diarrhoea containing blood
- inflammation of liver, which may be severe. Loss of appetite, skin and eyes becoming yellow in colour, dark-coloured urine, itching, or tender stomach (abdomen). These may be signs of liver problems which may include a fatal failure of the liver

The following side effects have been reported at the approximate frequencies shown:

Uncommon (may affect up to 1 in 100 people):
- fungal infection, resistance to pathogens
- headache, dizziness, sleep disturbances and restlessness
- eye irritation, vertigo, cough, inflammation of nose
- feeling sick or being sick, diarrhoea, stomach pain
- rash, itching

Rare (may affect up to 1 in 1000 people):
- loss of appetite
- sleeplessness
- faster heart rate (tachycardia)
- low blood pressure
- difficulty in breathing or wheezing, shortness of breath
- inflammation of bowel, which may cause bleeding
- impairment of liver function with abnormal liver blood test results
- vision trouble (blurry vision)
- menstrual disturbance (such as hot flashes), excessive sweating, putrid/stuffy nasal breathing, increased creatinine levels in the blood

Very rare (may affect up to 1 in 10,000 people):
- anaemia (decreased in red blood cells causing pallor or grey skin, unusual tiredness or weakness)
- other blood disorders when the numbers of different types of cells in the blood may fall. Symptoms can include fever, chills, sore throat, sickness in the mouth and throat, unusual bleeding or unexplained bruising
- abnormal dreams or mental illness
- impairment of voluntary movement i.e. tremors, tics. Changes in muscle tone, slowness of movement
- an allergic reaction in the eye or on the skin around the eye
- failure to circulate blood around the body
- flushing
- bluish tint on skin
- inflammation of blood vessels, often with skin rash
- muscle weakness, joint and muscle pain
- effects on kidney function, which may lead to kidney failure
- numbness or altered awareness on the other side.

Not known (frequency cannot be estimated from the available data):
- severe reduction in the number of white blood cells which makes infections more likely
- low blood sugar levels (especially in diabetics)
- abnormal fast heart rhythm, life-threatening irregular heart rhythm, alteration of the heart rhythm (called ‘prolongation of QT interval’, seen on ECG, electrical activity of the heart)
- inflammation of the lungs which causes breathlessness, cough and raised temperature (allergic pneumonitis)
- severe shortness of breath
- acute generalised exanthematous pustulosis (red swollen areas with numerous small pustules)
- pain or muscle weakness, abnormal muscle breakdown which can lead to kidney problems
- muscle tear, muscle rupture
- inflammation of the kidney which can cause swollen ankles or high blood pressure
- oesophagus may trigger an attack of pneumonia in susceptible patients.
- increases in blood sugar levels (especially in diabetics)
- nervousness
- involuntary shaking of the body or uncontrollable movement of the upper body or lower extremities
- loss of taste functions of the tongue
- temporary loss of consciousness caused by a fall in blood pressure
- fever
- painful, difficult, or disturbed digestion, which may be accompanied by symptoms such as nausea and vomiting, heartburn, bloating, and stomach discomfort, the accumulation of gas in the alimentary canal, painful defecation, inflammation of the pancreas
- inflammation of the mouth and lips
- inflammation of the joints
- loss or lack of bodily strength including pain in back, chest and extremities
- bone marrow failure may lead to pancytopenia (a medical condition in which there is a reduction in the number of red and white blood cells as well as platelets)
- inflammation of the eye (uvula)
- skin redness with extensive scaling (exfoliative dermatitis)

Reporting of side effects:
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

How to store Ofloxacin
Keep this medicine out of the sight and reach of children.

Keep the container in the outer carton supplied to protect these tablets from light. Do not transfer them to another container. Do not use Ofloxacin after the expiry date that is stated on the outer packaging. The expiry date refers to the last day of that month.

Do not throw any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Contents of the pack and other information

What Ofloxacin tablets contain:
- The active ingredient is Ofloxacin.
- The other ingredients are lactose monohydrate, pregelatinised starch, hypromellose, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate, titanium dioxide (E171), magnesium stearate and triacetin.

What Ofloxacin tablets look like and contents of the pack:
- The 200 mg tablets are white, round, film-coated tablets, scored on both sides.
- One side of the tablet is marked “FXN” on one side of the breakline and “200” on the other side.
- The 400 mg tablets are white, oval, film-coated tablets marked “300” on one side and scored on the other side.
- The 200 mg and 400 mg tablets are available in pack sizes of 5, 10, 15 and 50 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

This leaflet was last revised in June 2016
PL 00299/0133-0254