

PACKAGE LEAFLET: INFORMATION FOR THE USER  
Ofloxacin 200 mg and 400 mg Film-coated Tablets  
Ofloxacin

**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 or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet:**

- 1. What Ofloxacin is and what it is used for**
- 2. What you need to know before you take Ofloxacin**
- 3. How to take Ofloxacin**
- 4. Possible side effects**
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**1. What Ofloxacin is and what it is used for**

Ofloxacin belongs to a group of antibacterial medicines known as fluoroquinolones.

Ofloxacin is an antibiotic that can be used to treat infections of:

- the bladder or the kidneys (urinary tract)
- the lungs and chest, including pneumonia and bronchitis
- the male and female genital organs. Ofloxacin can be used to treat gonorrhoea and some other genital infections.

**2. What you need to know before you take ofloxacin**

Ofloxacin is not suitable for everyone. If you are not sure about anything, ask your doctor or pharmacist before you start to take Ofloxacin.

**Do not take Ofloxacin if you:**

- are allergic (hypersensitive) to Ofloxacin or any of the other ingredients of this medicine (listed in section 6). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- have previously had an allergic reaction to a quinolone antibiotic. If you have had a reaction to any type of antibiotic in the past, check with your doctor before taking Ofloxacin
- have a history of inflammation of the tendons (tendinitis) when you have taken fluoroquinolone antibiotics in the past
- have epilepsy or have ever had a seizure or fit
- are pregnant or breast-feeding
- are under the age of 18, or if you are over 18 but think you are still growing.

**Warnings and precautions:**

Tell your doctor before you start to take this medicine if you:

- suffer from or have a history of mental illness
- have problems with your liver or kidneys. Make sure you tell your doctor about any liver or kidney problems before you start taking Ofloxacin because the dose may need to be lowered
- have an illness of the nervous system called myasthenia gravis (a disorder in which the muscles are weak and tire easily) as this medicine can make the symptoms worse
- have heart problems. Caution should be taken when using this kind of medicine, if you were born with or have family history of prolonged QT interval (seen on ECG, electrical recording of the heart), have salt imbalance 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 *Taking other medicines*)
- are prescribed corticosteroids (used to treat asthma and other chronic lung diseases) as this may increase the risk of swelling and pain of your tendons
- are diabetic
- have a condition which makes you likely to have fits (convulsions)
- have a problem with your red blood cells called "glucose-6-phosphate-dehydrogenase deficiency"

### **While you are taking Ofloxacin**

- do not expose yourself to long periods in strong sunlight whilst taking these tablets. Use a sun protection cream if you cannot avoid strong sunlight.
- do not use a sun-lamp or solarium.
- you may be more susceptible to infection with other organisms and if severe or bloody diarrhoea develops, bowel inflammation (pseudomembraneous colitis) is suspected, treatment should be discontinued.
- let your doctors know you are taking Ofloxacin if you are undergoing any medical tests, as it may interfere with the results.  
your doctor may want to monitor you with blood tests if you are taking Ofloxacin for longer period.
- you may be susceptible to inflammation of the tendon (tendonitis). This usually affects the Achilles tendon, if you develop pain in the legs stop taking the tablets and tell your doctor as soon as possible.
- you may experience numbness, tingling, pricking sensations (paresthesia), sensitivity to touch, pain or muscle weakness in your hands and legs due to damage of peripheral neurons (peripheral neuropathy). If you do, stop taking the tablets and contact your doctor.
- If your eyesight becomes impaired or if your eyes seem to be otherwise affected, consult an eye specialist immediately.

### **Other medicines and Ofloxacin:**

Tell your doctor if you are taking any of the following:

- Medicines that stop your blood clotting (anticoagulants), such as warfarin, as bleeding times may be longer
- antacids (medicines for an upset stomach), sucralfate, didanosine, aluminium, iron, magnesium or zinc preparations (see section 3, How to take Ofloxacin).
- medicines to control your blood sugar (e.g. glibenclamide), as concentrations of these medicines in the blood may be increased and cause a greater fall in the blood sugar levels.
- theophylline (used for breathing problems) or non-steroidal anti-inflammatory drugs (NSAIDs used for pain relief and inflammation) e.g. ibuprofen, diclofenac or fenbufen, as some people have fits when these are taken with Ofloxacin
- drugs that may affect your kidney function (e.g. cimetidine, furosemide, probenecid or methotrexate), as these can sometimes increase blood levels of Ofloxacin.

- you must tell your doctor if you are taking other medicines that can alter your heart rhythm: medicines that belong to the group of anti-arrhythmics (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide), tricyclic antidepressants, some antimicrobials (that belong to the group of macrolides), some antipsychotics.

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

**Pregnancy, breast-feeding and fertility:**

Do not take this medicine if you are pregnant, might become pregnant, think you may be pregnant or if you are breast-feeding. If you become pregnant while taking Ofloxacin, stop taking the tablets and contact your doctor immediately (see 'Do NOT take'). Ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines:**

Ofloxacin may make you feel sleepy, dizzy or could affect your eyesight and reaction time. If affected do not drive or operate machinery. Drinking alcohol may make these symptoms worse.

**Important information about some of the ingredients of Ofloxacin:**

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.

**3. How to take Ofloxacin**

Always take Ofloxacin exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will decide how much Ofloxacin you need to take each day and whether you can take the dose all at once or should take half in the morning and half 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. If you are taking Ofloxacin for longer periods your doctor may carry out blood tests from time to time to check on your condition.

Swallow the tablets whole with a full glass of water. Do not chew them. Ofloxacin tablets may be taken before or during meal times.

The usual dosage instructions are given below:

**Adults (including the elderly):**

The dose to be taken will depend on the type of infection to be treated. For most infections, the usual dose range is 200 mg to 800 mg of Ofloxacin daily.

Up to 400 mg may be given as a single dose, preferably in the morning.

The usual doses for different infections are shown below. However, your doctor may decide you need a different dose.

- **To treat bladder or kidney infections**

The usual dose for a simple bladder or kidney infection is 200 mg or 400 mg of Ofloxacin a day. Treatment usually lasts for 3 days. To treat complicated kidney infections, your doctor may increase the dose to 400 mg twice daily and you may need to take Ofloxacin for 7 to 10 days.

- **To treat infections of the genital organs**

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 dose is usually 400 mg each day. Treatment may last from 7-10 days.

- **To treat lung and chest infections**

The usual dose is 400 mg of Ofloxacin daily. If necessary, your doctor may increase this to 400 mg twice a day. Treatment may last from 7-10 days. For certain types of pneumonia Ofloxacin may be taken with other medicines.

**Patients with kidney or liver problems:**

If you have kidney problems (whether or not you need dialysis treatments) or have severe liver problems, your doctor may tell you to take a lower dose of Ofloxacin each day.

**Children and adolescents:**

Ofloxacin Tablets should not be given to children or growing adolescents.

**Taking Ofloxacin in combination with antacids, sulcrate, aluminium, iron, magnesium or zinc preparations:**

Take Ofloxacin at least two hours before taking any of the above medicines otherwise Ofloxacin may not work as well.

**If you forget to take Ofloxacin:**

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten tablet. Take the remaining doses at the correct time.

**If you take more Ofloxacin than you should:**

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. Overdose of Ofloxacin can cause dizziness, confusion, fits, loss of consciousness, nausea and there can be severe problems in the stomach. Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were consumed.

**If you stop taking Ofloxacin**

It is important that you complete the full course of treatment as directed by your doctor even if you feel better. If you don't do this, your symptoms may reappear.

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

#### **4. Possible side effects**

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

If the following happens, stop taking Ofloxacin 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
- fast, irregular or slower heart beat, fainting

- if you are a diabetic on treatment and feel signs of low blood sugar levels – feeling weak, sweating and/or trembling
- severe blistering, peeling of the skin, or 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 (usually the Achilles tendon), including inflammation and rupture, particularly if you are elderly or also taking corticosteroids e.g. prednisolone
- fits, agitation, nightmares, anxiety, depression, hallucinations, feeling of wanting to harm yourself and other disturbances of the mind, confusion, excessive sleepiness, ringing in the ears, unsteadiness, shaking, disturbance of sensation, numbness, pins-and-needles, blurred, double or odd colour vision problems, problems with or loss of hearing, taste or smell
- diarrhoea containing blood.

These are very serious but very rare side effects. You may need urgent medical attention or hospitalisation. These reactions can occur in some patients after the first dose of Ofloxacin, or even after treatment has stopped.

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

**Uncommon (may affect up to 1 people in 100):**

- Feeling sick or being sick, diarrhoea, stomach pain, indigestion and other stomach upsets.
- Headache, dizziness, a spinning feeling (vertigo), sleep disturbances and restlessness
- Skin rashes, itching
- Irritation of the eye
- Cough, inflammation of nose and throat
- Fungal infections,
- Increases in the number of other bacteria, which may need to be treated

**Rare (may affect up to 1 people in 1,000):**

- Loss of appetite
- Low blood pressure
- Shortness of breath, wheezing
- Fast, irregular heart beat
- Hot flushes, hives (called urticaria), sweating too much (hyperhidrosis), rash pustular
- Problems with liver function with abnormal blood test results
- Inflammation of the large intestine causing abdominal pain
- Problems with kidney function with abnormal blood test results

**Very rare (may affect up to 1 people in 10,000):**

- Jaundice (yellowing of the skin), inflammation of the liver or severe liver damage
- Anaemia (reduction in red blood cells causing unusual tiredness or weakness)
- Other blood disorders where the numbers of different types of cells in the blood may fall. Symptoms can include weakness, fever, chills, sore throat, ulcers in the mouth and throat, unusual bleeding or unexplained bruising
- Rash on exposure to strong sunlight and other severe skin reactions
- Inflammation of your tubes that carry blood around your body (vessels) due to an allergic reaction
- Discoloration, peeling or loss of nails
- Acute kidney failure
- Joint and muscle pains
- Problems moving and walking

**Not known (frequency cannot be estimated from the available data)**

- Occasional kidney failure which may be due to an allergic kidney reaction called interstitial nephritis
- It is also possible that Ofloxacin may trigger an attack of porphyria (deficiency of specific enzymes in the body which can lead to discolouration of the urine, serious skin disorders, anaemia, stomach pains and severe mental disorders) in patients who are at risk of developing this condition.
- Abnormal muscle breakdown, muscle weakness, tear, muscle rupture
- Allergic lung inflammation, severe loss of breath
- Severe liver inflammation
- 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)
- Upset stomach, excessive wind, constipation, inflammation of pancreas
- Feeling weak, elevate body temperature, pain (including pain in back, chest area and legs)
- 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)

Return to your doctor if you still feel unwell after finishing your course of tablets.

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. 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](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

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

Keep container in the outer carton to protect the tablets from light. Store in the original package. Do not use this medicine after the expiry date that which is stated on the outer packaging. The expiry date refers to the last day of that month. Do not use this medicine if you notice any defects or signs of deterioration in the tablets (such as broken tablets), please consult your pharmacist.

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 to protect the environment.

**6. 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), macrogol 3000 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, 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 'FXN 400' on one side and scored on the other side.
- The 200 mg and 400 mg tablets are available in pack sizes of 5, 10, 20 and 50 tablets. Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

The Marketing Authorisation Holder is Teva Pharma B.V., 3640 AE Mijdrecht, The Netherlands and company responsible for manufacture is TEVA UK LIMITED, Eastbourne, BN22 9AG.

OR

The Marketing Authorisation holder is Teva Pharma B.V., 3640 AE Mijdrecht, The Netherlands and the company responsible for manufacture is Pharmachemie B.V., Haarlem, The Netherlands.

OR

The Marketing Authorisation holder is Teva Pharma B.V., 3640 AE Mijdrecht, The Netherlands and the company responsible for manufacture is Teva Pharmaceutical Works Company Limited, Debrecen, Hungary.

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