

Package leaflet: Information for the user

**OFLOXACIN 200 mg TABLETS**  
**OFLOXACIN 400 mg 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, pharmacist or nurse.
- 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please 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 Ofloxacin Tablets are and what are they used for
2. What you need to know before you take Ofloxacin Tablets
3. How to take Ofloxacin Tablets
4. Possible side effects
5. How to store Ofloxacin Tablets
6. Contents of the pack and other information

**1. What Ofloxacin Tablets are and what are they used for**

This medicine contains an active ingredient called Ofloxacin.

Ofloxacin belongs to a group of medicines called fluoroquinolones which are used for treating bacterial infections. Ofloxacin is used to treat a variety of infections in adults including elderly which include infections of:

- Urinary tract infections (bladder and kidneys infection)
- Genital tract infections in men and women (e.g. gonorrhoea, a sexually transmitted disease)
- Chest or lungs (respiratory system) such as pneumonia and bronchitis.
- Skin and soft tissue. Soft tissue is underneath the skin and includes muscle

**2. What you need to know before you take Ofloxacin Tablets**

**Do not take Ofloxacin Tablets :**

- if you are allergic (hypersensitive) to ofloxacin or any of the other ingredients listed in section 6. Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- if you have previously had an allergic reaction to another quinolone antibiotic e.g. ciprofloxacin or norfloxacin.
- if you have a history of tendonitis (inflammation and swelling of the tendons) which can affect area such as the wrist or the achilles tendon after treatment with a quinolone antibiotic e.g. ciprofloxacin, norfloxacin, or nadifloxacin.
- if you have epilepsy or are at risk of fits
- if you are pregnant or breast-feeding (see 'Pregnancy and breast feeding' section below)
- if you are under the age of 18 or are still growing
- if you have a problem with your red blood cells known as 'glucose-6-phosphate dehydrogenase deficiency' (an inherited disorder that affects the red blood cells)

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Ofloxacin Tablets.

**Warnings and Precautions:**

**Before taking this medicine**

You should not take fluoroquinolone/ quinolone antibacterial medicines, including ofloxacin, if you have experienced any serious adverse reaction in the past when taking a quinolone or fluoroquinolone. In this situation, you should inform your doctor as soon as possible. Talk to your doctor, pharmacist or nurse before taking Ofloxacin Tablets if:

- you have liver or kidney problems
- you have heart disease or problems with your heartbeat
- You have nerve problems (peripheral neuropathy)
- you are taking medicines that can affect your heart (see section *Other medicines and Ofloxacin Tablets*)
- 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 *Other medicines and Ofloxacin Tablets*)
- you have or have ever had any mental health problems
- You suffer from a condition called myasthenia gravis, which causes muscle weakness and excessive muscle fatigue
- you have received transplantation
- you have been diagnosed with an enlargement or "bulge" of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm)
- you have experienced a previous episode of aortic dissection (a tear in the aorta wall)
- if you have been diagnosed with leaking heart valves (heart valve regurgitation).
- if you have a family history of aortic aneurysm or aortic dissection or congenital heart valve disease, or other risk factors or predisposing conditions (e.g. connective tissue disorders such as Marfan syndrome, or Ehlers-Danlos syndrome, Turner syndrome, Sjögren's syndrome [an inflammatory autoimmune disease], or vascular disorders such as Takayasu arteritis, giant cell arteritis, Behçet's disease, high blood pressure, or known atherosclerosis, rheumatoid arthritis [a disease of the joints] or endocarditis [an infection of the heart]).
- if you are diabetic or suffer from low blood sugar.

There have been very rare reports of potentially life-threatening skin rashes (Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis) with the use of Ofloxacin tablets.

Symptoms of which may include: flu-like symptoms followed by a painful red or purplish rash that spreads and blisters. If you develop any of the above you must stop taking your medicine and inform your doctor straight away (see Section 4). Ofloxacin tablets are not recommended if you have a suspected MRSA infection. While being treated with Ofloxacin tablets, avoid strong sunlight and do not use sun lamps or solariums, as your skin may be more sensitive to light.

If you experience pain in your fingers or toes whilst being treated with Ofloxacin tablets, tell your doctor or nurse immediately.

**During treatment**

When taking this medicine

If your eyesight becomes impaired or if your eyes seem to be otherwise affected, consult an eye specialist immediately.

If you:

- experience a severe skin rash or allergic reaction, or develop severe diarrhoea, (which may be bloody) with stomach pain and fever, or
- notice pain, tenderness, or restricted movement of the tendons, or
- notice numbness or tingling in the hands and feet
- experience suicidal thoughts or self-endangering behaviour
- change in blood glucose levels stop taking this medicine and talk to your doctor straight away.

**Prolonged, disabling and potentially irreversible serious side effects**

Fluoroquinolone/quinolone antibacterial medicines, including Ofloxacin, have been associated with rare but serious side effects, some of them being long lasting (continuing for months or years), disabling or potentially irreversible. This includes tendon, muscle and joint pain of the upper and lower limbs, difficulty in walking, abnormal sensations such as pins and needles, tingling, tickling, numbness or burning (paraesthesia), sensory disorders including impairment of vision, taste and smell, and hearing, mental health effects which may include, but are not necessarily limited to, anxiety, panic attacks, confusion, or depression, memory impairment, severe fatigue, and severe sleep disorders. There are no medicines that have been established as being effective treatments for the symptoms of long lasting or disabling side effects associated with fluoroquinolones.

If you experience any of these side effects after taking Ofloxacin, then do not take any further doses and contact your doctor immediately. You and your doctor will decide on whether to continue treatment, considering alternative options.

You may experience psychiatric reactions when taking Ofloxacin including when taking it for the first time. If you suffer from depression or psychosis, your symptoms may become worse under treatment with Ofloxacin. In rare cases, depression or psychosis can progress to thoughts of suicide or suicide attempts. If this happens, stop taking Ofloxacin and contact your doctor immediately. You may not notice some changes in your mood and behaviour so it is very important to tell your friends and family that you are taking Ofloxacin, and that there may be rare psychiatric side effects. Others may notice changes and help you quickly identify any symptoms that you need to talk to your doctor about.

Pain and swelling in the joints and inflammation or rupture of tendons may occur rarely. Your risk is increased if you are elderly (above 60 years of age), have received an organ transplant, have kidney problems or if you are being treated with corticosteroids. Inflammation and ruptures of tendons may occur within the first 48 hours of treatment and even up to several months after stopping of ofloxacin therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking ofloxacin, contact your

doctor and rest the painful area. Avoid any unnecessary exercise as this might increase the risk of a tendon rupture.

You may rarely experience symptoms of nerve damage (neuropathy) such as pain, burning, tingling, numbness and/or weakness especially in the feet and legs or hands and arms. If this happens, stop taking this medicine and inform your doctor immediately in order to prevent the development of potentially irreversible condition.

If you feel sudden, severe pain in your abdomen, chest or back, which can be symptoms of aortic aneurysm and dissection, go immediately to an emergency room. Your risk may be increased if you are being treated with systemic corticosteroids.

If you start experiencing a rapid onset of shortness of breath, especially when you lie down flat in your bed, or you notice swelling of your ankles, feet or abdomen, or a new onset of heart palpitations (sensation of rapid or irregular heartbeat), you should inform a doctor immediately.

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

**Other medicines and Ofloxacin Tablets**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Ofloxacin and some other medicines can affect the way each other work.

**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 (e.g. clomipramine, amitriptyline).
- Some antimicrobials (that belong to the group of macrolides e.g. erythromycin, clarithromycin, azithromycin).
- Some antipsychotics used to treat mental health conditions such as schizophrenia and bipolar disorder.

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

- medicines or dietary supplements that contain iron (for anaemia) or zinc.
- sucralfate used for stomach ulcers.
- antacids used for indigestion that contain magnesium or aluminium.
- corticosteroids, used for treatment of inflammation and swelling or over-active immune system. These may increase the risk of you developing a tendon rupture.
- painkillers called non-steroidal anti-inflammatory drugs (NSAIDs) e.g. ibuprofen or diclofenac, or theophylline, used to treat asthma or chronic obstructive pulmonary disease as these could make you more prone to fits if taken with ofloxacin.
- glibenclamide, a medicine to control your blood sugar, as the amount of these medicines in the blood may increase and have a greater effect.
- drugs that may affect your kidney function e.g. cimetidine (used for stomach ulcers or indigestion), probenecid (used for gout) and methotrexate (used for rheumatism) as they can increase the level of ofloxacin in the blood.
- medicines to thin your blood, e.g. warfarin. Taking these with ofloxacin can increase the time it takes for your blood to clot.
- If you are taking didanosine (a medicine used to treat HIV infections), you should not take the chewable, buffered tablets until at least two hours after taking ofloxacin.
- water tablets (diuretics) such as furosemide.

This medicine **should not** be taken within two hours of taking iron or zinc tablets, antacids, or sucralfate, as these medicines can stop Ofloxacin from working properly.

If you are due to have urine tests for porphyrin (a pigment in the blood), or for opiates (strong painkillers), tell your doctor or nurse you are taking this medicine.

**Ofloxacin Tablets with food, drink and alcohol**

Do not drink alcohol while taking Ofloxacin Tablets. This is because it may make you feel dizzy or sleepy.

**Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. If you become pregnant while taking Ofloxacin, stop taking the tablets and contact your doctor immediately.

**Driving and using machines**

Ofloxacin can make you feel sleepy, dizzy or cause problems with your eyesight. **Do not** drive or use machines until you know how this medicine affects you. Drinking alcohol may make these symptoms worse.

**Important information regarding the ingredients in this medicine**

**Information on sodium content**

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

**3. How to take Ofloxacin 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.

**Taking this medicine**

- Take this medicine by mouth
- Swallow the tablets whole with a drink of water. Do not chew them.
- When taking Ofloxacin Tablets, avoid strong sunlight and do not use sun lamps and solarium as your skin may be more sensitive to light.
- Medicines containing iron (for anaemia), antacids (for indigestion or heartburn), or sucralfate (for stomach ulcers) or didanosine chewable or buffered tablets (for HIV) should be avoided for two hours before and after taking Ofloxacin Tablets. If you feel the effect of your medicine is too weak or strong, do not change the dose yourself, but ask your doctor.
- When taking Ofloxacin, If your eyesight becomes impaired or if your eyes seem to be otherwise affected, consult an eye specialist immediately.

**When to take your medicine**

- The length of your treatment will depend on how serious your infection is
- Treatment should not be longer than 2 months
- Doses up to 400 mg are taken as a single dose in the morning
- Higher doses should be taken in two doses, one in the morning and one in the evening

**How much to take**

**Adults (including the elderly):** The dose to be taken will depend on the location and the type of infection to be treated. For most infections the recommended dose is between 200 mg and 400 mg of Ofloxacin daily, preferably in the morning. For more severe infections your doctor may increase the dose to 400 mg of Ofloxacin twice daily (morning and evening).

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

**To treat simple urine infections:** The recommended dose is 200 mg or 400 mg of Ofloxacin daily.

**To treat complicated upper urinary tract infections:** The recommended dose is 400 mg of Ofloxacin daily. If necessary, your doctor may increase this to 400 mg twice a day.

**To treat gonorrhoea of the lower organs only:** A single dose of 400 mg of Ofloxacin in the morning is usually enough. To treat other infections of the lower genital organs for which Ofloxacin is a suitable antibiotic, the dose is usually 400 mg each day.

**To treat a chest or lung infection:** The recommended dose is 400 mg of Ofloxacin daily. If necessary, your doctor may increase this to 400 mg twice a day.

**If you have liver problems:**

Your doctor may give you a lower dose of Ofloxacin. It is recommended that the dose should not exceed 400 mg Ofloxacin daily.

**If you have kidney problems:** Your doctor may recommend that you take an initial dose as recommended above, then the dose may be reduced. It is recommended that the dose should not exceed 200 mg of Ofloxacin daily.

**Use in children and adolescents** Children or adolescents under 18 years of age should not take these tablets.

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

Keep taking Ofloxacin tablets until your doctor tells you to stop. Do not stop taking Ofloxacin 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, pharmacist or nurse.

**4. Possible side effects**

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

**Stop taking Ofloxacin tablets, tell your doctor or go to your nearest hospital casualty department straight away if you notice any of the following**

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**serious side effects - you may need urgent medical treatment:**

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

- resistance of infection causing organisms to this treatment, (you may fail to respond to treatment)

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

- cases of long lasting (up to months or years) or permanent adverse drug reactions have been associated with quinolone and fluoroquinolone antibiotics tendon inflammations, tendon rupture, joint pain, pain in the limbs, difficulty in walking, abnormal sensations such as pins and needles, tingling, tickling, burning, numbness or pain (neuropathy), fatigue, memory and concentration impairment, mental health effects (which may include sleep disorders, anxiety, panic attacks, depression and suicidal ideation), as well as impairment of hearing, vision, and taste and smell. There are no medicines that have been established as being effective treatments for the symptoms of long lasting or disabling side effects associated with fluoroquinolones.
- you have an allergic reaction. Such reactions may appear in the form of anaphylaxis (a severe form of allergic reaction) with symptoms such as:
  - severe skin rash
  - swelling of the face, lips, mouth, tongue or throat (angioedema)
  - anaphylactic shock (sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties in swallowing)
- inflammation of the bowel, which may cause severe watery diarrhoea, which may have blood in it, possibly with stomach cramps and a high temperature
- swelling of the tendons with the following symptoms: pain, tenderness, sometimes restricted movement (tendonitis). This can lead to tendon rupture, especially of the large tendon at the back of the ankle (Achilles tendon). The risk of this occurring is increased if you are also taking corticosteroids e.g. prednisolone
- numbness or tingling in the hands and feet or being very sensitive to touch, numbness or weakness of the arms and legs
- blurred, double or altered colour vision. If your eyesight becomes impaired or if your eyes seem to be otherwise affected, consult an eye specialist **immediately**.
- Delirium (acute confusional state)

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

- a condition in which the amount of oxygen carrying pigment (haemoglobin) in the blood is below normal or an illness resulting from the destruction of red blood cells with the following symptoms: feeling tired, faint, dizzy, being short of breath when exercising and having pale skin. These may be signs of anaemia or haemolytic anaemia.
- other blood disorders when the numbers of different types of cells in the blood may fall, which may cause fever, chills, sore throat, ulcers in the mouth and throat (leucopenia, agranulocytosis)
- fits (seizures)
- skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with dark ring around the edge) (erythema multiforme)
- a widespread rash with blisters and skin peeling on much of the body surface (toxic epidermal necrolysis).
- narrowing, blockage or leakage of blood vessels, in exceptional cases leading to severe skin reactions and death of areas of the skin
- severe kidney problems, which may result in your kidneys stopping working. Signs may include a rash, high temperature, general aches and pains, or blood in the urine
- hearing problems or hearing loss
- liver problems, such as inflammation of the liver (hepatitis) or blockage in the bile duct, that may cause your eyes or skin to go yellow (jaundice) or you may notice the following symptoms: nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, light coloured bowel motions, dark coloured urine.

**Frequency not known (cannot be estimated from the available data)**

- 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)
- severe depression or mental illness. Some people who are depressed think of harming or killing themselves.
- a serious reduction in all types of blood cells (pancytopenia), which may result from a failure of the bone marrow to produce these
- a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens Johnson syndrome).
- swelling of the lungs with the following symptoms: coughing, difficulty breathing, wheezing
- temporary paralysis or weakness of the muscles (rhabdomyolysis), disease of the muscles with the following symptoms: aching muscles, muscle tenderness or weakness, not caused by exercise
- an attack of porphyria (a rare blood pigment disorder) in patients with this disease
- muscle or ligament rupture
- inflammation of the pancreas (pancreatitis) - you may have severe pain in the stomach and back
- loss of consciousness (coma), due to a severe reduction in blood sugar levels
- inflammation of the eye (uveitis)
- skin redness with excessive scaling (exfoliative dermatitis)
- 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.

**Tell your doctor if any of the following side effects gets serious or lasts longer than a few days:**

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

- feeling sick (nausea) or being sick (vomiting), diarrhoea or stomach pains
- irritated or burning eyes
- headaches, dizziness, sleep disturbances including difficulty sleeping (insomnia)
- feeling dizzy, having spinning sensations
- agitation, feeling restless
- cough and inflamed sore nose or throat (nasopharyngitis)
- fungal infection
- skin rash or itching

**Rare (may affect up to 1 in 1000 people)**

- loss of appetite
- fast heart beat
- drowsiness
- loss of memory
- feeling weak or irritable, sweating and/or trembling. This could be due to lowering of blood sugar (glucose) levels especially in patients with diabetes or existing low blood sugar
- feeling confused or anxious, nightmares, seeing, feeling or hearing things that are not there, depression and mental illness
- changes in or loss of your sense of taste or smell
- shortness of breath or wheezing
- changes in levels of liver enzymes or bilirubin, which may be seen in blood tests
- excessive sweating and hot flushes
- changes in kidney function shown in blood tests
- feeling faint, light-headed or dizzy, which may be due to low blood pressure
- hives (urticaria)
- rash with pimples

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

- uncontrolled movements, unsteadiness and shaking
- unusual bleeding or bruising more easily than normal (thrombocytopenia)
- increase in some white blood cells (eosinophilia)
- ringing in the ears (tinnitus)
- joint and muscle pains
- skin rashes or eruptions, which may be caused by strong sunlight
- unusual purple discolouration under the skin, which may be due to bleeding or bruising due to leaky or damaged blood vessels

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

- a red, scaly rash with bumps under the skin and blisters (exanthemous pustulosis)
- muscular weakness, muscle tear
- an increase in blood sugar levels
- feeling of nervousness, tremor, unusual (involuntary) muscle movements,
- fainting
- digestive problems such as stomach upset (indigestion/ heartburn), constipation, or wind
- general pain, pains in your muscles and stiffness in the bones/joints (arthritis), feeling unwell (asthenia), or fever
- Persistent headache with or without blurred vision (benign intracranial hypertension)

It is possible that Ofloxacin may trigger an attack of porphyria (a rare illness which affects the metabolism) in some patients.

Cases of an enlargement and weakening of the aortic wall or a tear in the aortic wall (aneurysms and dissections), which may rupture and may be fatal, and of leaking heart valves have been reported in patients receiving fluoroquinolones. See also section 2.

**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 website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Ofloxacin Tablets**

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C. Store in the original package.
- Do not use the tablets after the expiry date stated on the carton. The expiry date refers to the last date 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. These measures will help protect the environment.

**6. Contents of the pack and other information**

**What Ofloxacin Tablets contain**

- Each tablet contains either 200mg or 400mg of the active ingredient, ofloxacin.
- The other ingredients are microcrystalline cellulose, sodium starch glycolate, hydroxypropyl cellulose, magnesium stearate, hypromellose, macrogol 400, titanium dioxide (E171).

**What Ofloxacin Tablets look like and contents of the pack**

- The 200mg tablets are white capsule shaped and scored on both sides with 'BL' and '200' debossed on one face of the tablet.
- The 400mg tablets are white capsule shaped and scored on both sides with 'BL' and '400' debossed on one face of the tablet.
- Ofloxacin 200mg Tablets are available in blister packs of 10, 20 and 100 tablets. While, Ofloxacin 400mg Tablets are available in blister packs of 5, 10 and 50 tablets.
- Not all packs may be marketed.

**Marketing Authorisation Holder and Manufacturer**

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**Ofloxacin 200mg Tablets; PL 17907/0024**

**Ofloxacin 400mg Tablets; PL 17907/0025**

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To request a copy of this leaflet in Braille, large print or audio format, please contact the marketing authorisation holder at the address (telephone or email) above.