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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.

- 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 symptoms are the same as yours.
- If you get any of the side effects talk to your doctor or pharmacist. 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
5. How to store Ofloxacin
6. Contents of the pack and other information

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 lungs, including pneumonia
- the skin and soft tissue
- the male and female genital organs when the infections involve the cervix (neck of the womb) in women and the genital organs in men. Ofloxacin can be used to treat both gonorrhoea and some other genital infections

2 What you need to know before you take Ofloxacin

Do not take Ofloxacin:

- if you are allergic to ofloxacin or any of the other ingredients of this medicine
- if you 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.
- if you have a history of inflammation of the tendons (tendonitis) when you have taken fluoroquinolone antibiotics in the past
- if you have epilepsy or have you ever had a seizure or fit
- 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 are under the age of 18, or are over 18 years old but think you are still growing
- if you have a rare hereditary problem of galactose intolerance, Lapp lactase 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 methicillin-resistant staphylococcus aureus (MRSA) infection
- if you suffer from vision disorder

Warnings and precautions

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*).

Talk to your doctor before taking Ofloxacin:

- if you suffer from or have a history of mental illness
- if you 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.
- if you have an illness of the nervous system called myasthenia gravis (a disorder in which the muscles are weak and tire easily)
- if you are elderly or have been prescribed corticosteroids (used to treat asthma and other chronic lung diseases) as this may cause swelling and pain of your tendons
- if you are diabetic
- if you are taking fenbufen or other NSAIDs, vitamin K antagonists
- if you are taking theophylline
- if you have been diagnosed with an enlargement or "bulge" of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm)
- if 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, Behcet's disease, high blood pressure, or known atherosclerosis rheumatoid arthritis [a disease of the joints] or endocarditis [an infection of the heart]).

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.

- 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.

When taking this medicine

- you may experience severe, sudden allergic reaction (an anaphylactic reaction/shock). Even with the first dose, there is a chance that you may experience a severe allergic reaction with the following symptoms: tightness in the chest, feeling dizzy, feeling sick or faint, or experience dizziness on standing. If this happens, stop taking Ofloxacin and contact your doctor immediately
- **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

- you may experience symptoms of liver problems such as loss of appetite, yellowing of the skin or whites of the eyes, dark urine, itching or tender of stomach, Ofloxacin should be stopped immediately

- diarrhoea may develop while you are on antibiotics, including Ofloxacin, or even several weeks after you have stopped using them. If it becomes severe or persistent or you notice that your stool contains blood or mucus tell your doctor immediately. Ofloxacin treatment will have to be stopped immediately, as this can be life-threatening

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 Ofloxacin and inform your doctor immediately in order to prevent the development of potentially irreversible condition.

- tell your doctor if you or a member of your family is known to have a deficiency in glucose-6-phosphate dehydrogenase (G6PD), since you may experience a risk of anemia with ciprofloxacin

- 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

- 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 than 2 weeks

- you may experience skin reaction problems such as Stevens-Johnson syndrome a rare, serious disorder of your skin and mucous membrane or toxic necrolysis skin's outermost layer, to detach from the layers of skin below.

Quinolone antibiotics may cause an increase of your blood sugar levels above normal levels (hyperglycaemia), or lowering of your blood sugar levels below normal levels, potentially leading to loss of consciousness (hypoglycaemic coma) in severe cases (see section 4). This is important for people who have diabetes. If you suffer from diabetes, your blood sugar should be carefully monitored.

Other medicines and Ofloxacin:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines

- anticoagulants (tablets that stop your blood clotting, e.g. warfarin), as bleeding times may be longer
- antacids, 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 they may have a greater effect
- theophylline or non-steroidal anti-inflammatory drugs (NSAIDs), 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 they 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, procainamide, amiodarone, sotalol, dofetilide, ibutilide, disopyramide), tricyclic antidepressants (e.g. amitriptyline, clomipramine, some antimicrobials (that belong to the group of macrolides e.g. erythromycin or azithromycin), some antipsychotics (e.g. olanzapine, quetiapine).

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 any 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.

Ofloxacin contains Sodium:

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

Pregnancy, breast-feeding 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 could affect your eyesight, which may impair your ability to concentrate. If affected do not drive or operate machinery.

3 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.

Pharma Code

Pharma Code

Pharma Code

Pharma Code

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 800 mg a day.

- **To treat simple bladder or kidney infections**
The usual dose is 200 mg or 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 dose is usually 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.

Use in children and adolescents:

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

Patients with kidney or liver problems:

Your doctor may tell you to take a lower dose of Ofloxacin than the usual dose.

Taking Ofloxacin in combination with antacids, sucralfate, didanosine, 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 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. An overdose is likely to cause dizziness, confusion, fits, loss of consciousness, increases in QT interval, the alleged perception of an object when no object is present, involuntary shaking of the body or limbs, nausea and severe stomach problems. Please take this leaflet, any remaining tablets with you to the hospital or doctor so that they know which tablets were consumed.

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 dose.

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 medicine, 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 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 (photosensitivity 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, nightmares, anxiety, depression, hallucinations, feeling of wanting to harm yourself and other disturbances of the mind, confusion, 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.
- 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
- rashes, itching

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

- Cases of long lasting (up to months or years) or permanent adverse drug reactions have been associated with quinolone and fluoroquinolone antibiotics. These may include tendon inflammation, tendon rupture, joint pain, pain in the limbs, difficulty in walking, abnormal sensations such as pins and needles, tingling, pricking, burning, numbness or pain (neuropathy), fatigue, sleep disorders, memory impairment, mental health effects which may include, but are not necessarily limited to, anxiety, panic attacks, confusion, or depression, 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
- loss of appetite
- sleepiness
- faster heart rate (tachycardia)
- low blood pressure
- difficult in breathing or wheezing, shortness of breath
- inflammation of bowel, which may cause bleeding
- impairment of liver function with abnormal liver blood test results
- hives (nettle rash)
- menstrual disturbance (such as hot flushes), excessive sweating, pustular rash

- increased creatinine levels in the blood
- delirium (acute confusional state).

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

- anaemia (reduction in red blood cells causing pale or yellow 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, ulcers 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
- bruise like rash
- inflammation of blood vessels, often with skin rash
- muscle weakness, joint and muscle pain
- effects on kidney function, which may lead to kidney failure
- unbalanced walk

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

- severe reduction in the number of white blood cells which makes infections more likely
- loss of consciousness due to severe decrease in blood sugar levels (hypoglycaemic coma). See section 2).
- 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 area 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
- ofloxacin may trigger an attack of porphyria in susceptible patients.
- increase 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 and stiffness 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 (uveitis)
- skin redness with extensive scaling (exfoliative dermatitis)

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 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 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

Keep this medicine out of the sight and reach of children.

Keep the blister in the outer carton supplied to protect these tablets from light.

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 away any medicine via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. 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. 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 '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

Marketing Authorisation Holder:

Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom.

Company Responsible for Manufacture:

TEVA Pharmaceutical Works Private Limited Company, Pallagi street 13, Debrecen, H-4042, Hungary.

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