Pharma code 789

an emergency room. If you feel sudden, severe pain in your abdomen, chest or back, go immediately to taking a quinolone or fluoroquinolone. In this situation, you should inform your

• if you have been diagnosed with an enlargement or “bulge” of a large blood
• if you are taking theophylline
• if you have an illness of the nervous system called myasthenia gravis (a

What you need to know before you take Ofloxacin

Do not take Ofloxacin:

• if you are allergic to 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 had a history of inflammation of the tendons (tendinitis) when you have taken fluoroquinolones or the past
• if you have epilepsy or have 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 but think you are still growing.
• if you have a rare hereditary problem of gastric 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 multicillin-resistant staphylococcus aureus (MRSA) infection.

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 (tall on ECG, electrical recording of the heart), have salt retention 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 (ischaemic infarction), are female or elderly or you are taking other medicines that result in abnormal ECG changes (have a structural heart defect or are taking other medicines).

Tell 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 tired easily).
• if you are taking corticosteroids (used to treat asthma and other chronic lung disease) as this may cause swelling and pain of your tendons.
• if you are diabetic.
• if you are taking fenofibrate or other NSADS, vitamin K antagonists
• if you are taking thalidomide
• if you have been diagnosed with an engravure or “burden” of a large blood vessel (arterial aneurysm or large vessel peripheral aneurysm).
• if you have a family history of arterial aneurysms or other risk factors or predisposing conditions (e.g. connective tissue diseases such as Marfan syndrome, or vascular Ehlers-Danlos syndrome, or vascular disorders such as Takayasu arthritis, giant cell arteritis, Behcet disease, high blood pressure, or known atherosclerosis).

Before taking this medicine

You should not take fluoroquinolones/systemic antibacterials medicines, including Ofloxacin, if you have experienced any adverse reaction in the past when taking a quinolone antibiotic. In this situation, you should inform your doctor as soon as possible.

If you feel sudden, severe pain in your abdomen, chest or back, go immediately to an emergency room.

When taking this medicine

• you may experience nausea, 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, fever, feeling dazed, feeling sick or faint, or experience dizziness on standing. If this happens, stop taking Ofloxacin and contact your doctor immediately.
• you may experience psychiatric reactions after first administration of Ofloxacin. If you suffer from depression or psychosis, your symptoms may become worse under treatment with Ofloxacin. If this happens, stop taking Ofloxacin and contact your doctor immediately.
• you may experience severe pain in your abdomen, chest or back, go immediately to an emergency room.

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 480 mg can be taken as a single dose in the morning. A dose higher than 480 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 let you know how long your treatment with Ofloxacin will last. Treatment should not exceed 2 weeks. Return to your doctor if you still feel unwell after finishing your course of tablets.
Ofloxacin is used to treat infections of:

• you may experience severe, sudden allergic reaction (an anaphylactic reaction)

When taking this medicine:

• if you have experienced a previous episode of aortic dissection (a tear in the blood vessel that supplies the heart), have salt imbalance in the blood (especially low level of potassium or sodium), or have had a gradual enlargement of the heart, have diabetes;

• if you suffer from vision disorder;

• if you have epilepsy or have you ever had a seizure or fit;

• if you are allergic to ofloxacin or any of the other ingredients of this medicine;

Before taking this medicine:

• your doctor may increase the dose to 400 mg twice a day when you need to take Ofloxacin for 7-10 days;

• you may experience dizziness, feeling sick or faint, or experience dizziness on standing. If this happens, stop taking Ofloxacin and contact your doctor immediately;

• you may experience fever, cold or flu symptoms, which may include a fever, sweating, shivering, aches or pains, weakness or tiredness and a feeling of ill health;

• if you have a history of heart disease, you may experience chest pain, feeling sick or faint;

• your doctor will tell you how long your course of tablets must be;

• if you forget to take Ofloxacin;

• if you take more Ofloxacin than you should;

• if you have any of these side effects after taking Ofloxacin, contact your doctor immediately;

• let your doctors know you are taking Ofloxacin if you are undergoing any tests for blood or urine;

• patients with kidney or liver problems;

• other medicines and Ofloxacin:

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 penicillin;

• headache, dizziness, unconsciousness and faintness;

• eye irritation, tearing, crusts, inflammation of nose;

• breathing difficulties or wheezing;

• nausea, vomiting;

• diarrhea;

• rash;

• itching;

• severe skin reaction (erythema multiforme);

• drug eruption (erythema multiforme);

• loss of appetite;

• sleepiness;

• tachycardia (fast heart rate);

• 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;

• loss of taste;

• mental disturbance (such as hallucinations);

• increase in blood sugar levels (especially in diabetics);

• nervousness;

• insomnia;

• tiredness;

• numbness or burning (paraesthesia), sensory disorders including itching;

• 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 (vasculitis);

• skin rash with extensive scaling (erythema multiforme);

• very rare cases of long lasting (up to months or years) or permanent adverse drug reactions, such as tendon inflammation, tendinitis, tendon rupture, joint pain, pain in the limbs, difficulty in walking, abnormal sensations such as pins and needles, tingling, itching, burning, numbness or pain (neuropathy), depression, fatigue, sleep disorders, memory impairment, as well as impairment of hearing, vision, and taste and smell have been associated with administration of quinolones and fluorquinolones antibiotics in some cases irrespective of pre-existing risk factors.

The 400 mg tablets are white, oval, film-coated tablets marked 'FXN 400' on one side of the breakline and '200' on the other side.

The active ingredient is Ofloxacin.

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

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

• fungal infection, resistance to penicillin;

• headache, dizziness, unconsciousness and faintness;

• eye irritation, tearing, crusts, inflammation of nose;

• breathing difficulties or wheezing;

• nausea, vomiting;

• diarrhea;

• rash;

• itching;

• severe skin reaction (erythema multiforme);

• drug eruption (erythema multiforme);

• loss of appetite;

• sleepiness;

• tachycardia (fast heart rate);

• 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;

• loss of taste;

• mental disturbance (such as hallucinations);

• increase in blood sugar levels (especially in diabetics);

• nervousness;

• insomnia;

• tiredness;

• numbness or burning (paraesthesia), sensory disorders including itching;

• 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 (vasculitis);

• skin rash with extensive scaling (erythema multiforme);

• very rare cases of long lasting (up to months or years) or permanent adverse drug reactions, such as tendon inflammation, tendinitis, tendon rupture, joint pain, pain in the limbs, difficulty in walking, abnormal sensations such as pins and needles, tingling, itching, burning, numbness or pain (neuropathy), depression, fatigue, sleep disorders, memory impairment, as well as impairment of hearing, vision, and taste and smell have been associated with administration of quinolones and fluorquinolones antibiotics in some cases irrespective of pre-existing risk factors.

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 may also report side effects direct to the NHS Yellow Card Scheme at www.nhsyellowcard.scot.nhs.uk or search for MMSA Yellow Card in the Google Play Store. By reporting side effects you can help provide more information on the safety of this medicine.

How to Use 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 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.

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 trisilicate and ferric oxide.

What Ofloxacin tablets look like and contents of the pack:

• The 200 mg tablets are white, oval, film-coated tablets marked FXN 200 on one side and FXN 400 on the other side.

• The 400 mg tablets are white, oval, film-coated tablets marked FXN 400 on one side and FXN 200 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 Authorization Holder and Manufacturer


This leaflet was last revised in March 2013.

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