

PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Oflox 400 Tablets*

ofloxacin 400 mg film-coated tablets

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, health care provider 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, health care provider or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Oflox 400 Tablets is and what it is used for
2. What you need to know before you take Oflox 400 Tablets
3. How to take Oflox 400 Tablets
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1. WHAT OFLOX 400 TABLETS IS AND WHAT IT IS USED FOR

Oflox 400 Tablets contains ofloxacin as the active ingredient. This belongs to a group of antibiotics called fluoroquinolones. Ofloxacin works by killing bacteria that cause infections, including the bacteria that cause tuberculosis (TB).

Oflox 400 Tablets is used to treat TB caused by *Mycobacterium tuberculosis*. It is always given together with other medicines for TB.

To help clear up your TB completely, you must keep taking this medicine for the full time of treatment, even if you begin to feel better. This is very important. It is also important that you do not miss any doses.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE OFLOX 400 TABLETS

Do not take Oflox 400 Tablets:

- if you are allergic to ofloxacin, any other quinolone antibiotic such as moxifloxacin, ciprofloxacin or levofloxacin, or any of the other ingredients of Oflox 400 Tablets (listed in Section 6 below). Signs of an allergic reaction include: rash, swelling or breathing problems, swelling of your lips, face, throat or tongue
- if you have ever had epilepsy
- if you have ever had a problem with your tendons such as tendinitis that was related to treatment with a 'quinolone antibiotic'.
- if you are breast-feeding

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or health care provider before taking Oflox 400 Tablets.

* Trade names are not prequalified by WHO. This is under local drug regulatory authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

Warnings and precautions

Talk to your doctor, health care provider or pharmacist before taking Oflox 400 Tablets:

- If you are 65 years or older
- If you are using corticosteroids, sometimes called steroids (see “Other medicines and Oflox 400 Tablets” below)
- If you have ever had a fit (seizure)
- If you have had damage to your brain due to a stroke or other brain injury
- If you have kidney problems
- If you have something known as ‘glucose – 6 – phosphate dehydrogenase deficiency’. If so, you are more likely to have serious problems with your blood when taking this medicine
- If you have ever had mental health problems
- If you have ever had heart problems
- If you are diabetic
- If you have ever had liver problems
- If you are taking any medicine that decreases your blood potassium levels
- If you suffer from myasthenia gravis (abnormal muscle fatigue leading to weakness and in serious cases paralysis), taking Oflox 400 Tablets may worsen the symptoms of your disease.
- If you or any member of your family have glucose-6-phosphate dehydrogenase deficiency (a rare hereditary disease), tell your doctor, who will advise whether Oflox 400 Tablets is suitable for you

When taking Oflox 400 Tablets

- The risk of heart problems may increase with higher doses, therefore, you should keep to the prescribed dose.
- There is a small risk that you may experience a severe, sudden allergic reaction (an anaphylactic reaction/shock) even with the first dose. Symptoms include tightness in the chest, feeling dizzy, feeling sick or faint, or dizziness when standing up. If so, stop taking Oflox 400 Tablets and seek medical help immediately.
- Oflox 400 Tablets may cause a rapid and severe inflammation of the liver which could lead to life-threatening liver failure (including fatal cases, see section 4, ‘Possible side effects’). If you suddenly feel unwell and/or are being sick and also have yellowing of the whites of the eyes (jaundice), dark urine, itching of the skin, a tendency to bleed or confusion (symptoms of a reduced liver function or a rapid and severe inflammation of the liver), please contact your doctor before taking any more tablets.
- If you develop a skin reaction or blistering / peeling of the skin and/or mucosal reactions (see section 4, ‘Possible side effects’) contact your doctor immediately before you continue treatment.
- Quinolone antibiotics, including Oflox 400 Tablets, may cause convulsions. If this happens, stop taking Oflox 400 Tablets and contact your doctor immediately.
- You may experience symptoms of neuropathy such as pain, burning, tingling, numbness and/or weakness. If this happens, inform your doctor immediately prior to continuing treatment with Oflox 400 Tablets.
- You may experience mental health problems even when taking quinolone antibiotics, including Oflox 400 Tablets, for the first time. In very rare cases depression or mental health problems have led to suicidal thoughts and self-endangering behaviour such as suicide attempts (see section 4, ‘Possible side effects’). If you develop such reactions, stop taking Oflox 400 Tablets and inform your doctor immediately.
- You may develop diarrhoea whilst or after taking antibiotics including Oflox 400 Tablets. If this becomes severe or persistent or you notice that your stool contains blood or mucus you should stop taking Oflox 400 Tablets immediately and consult your doctor. You should not take medicines that stop or slow down bowel movement.

- Oflox 400 Tablets may occasionally cause pain and inflammation of your tendons, particularly if you are elderly or if you are also taking corticosteroids. At the first sign of any pain or inflammation you should stop taking Oflox 400 Tablets, rest the affected limb and consult your doctor immediately. Avoid any unnecessary exercise, as this might increase the risk of a tendon rupture. Inflammation and ruptures of tendons may occur even up to several months after discontinuing therapy with Oflox 400 Tablets.
- Quinolone antibiotics may make your skin become more sensitive to sunlight or UV light. You should avoid prolonged exposure to sunlight or strong sunlight and should not use a sunbed or any other UV lamp while taking Oflox 400 Tablets.
- If you have diabetes and are using medicines to control your blood sugar, you should monitor your blood sugar levels carefully, as Oflox 400 Tablets in such cases may lower blood sugar levels.

Other medicines and Oflox 400 Tablets

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Oflox 400 Tablets can affect the way some other medicines work. Also some medicines can affect the way Oflox 400 Tablets work.

In particular, tell your doctor if you are taking any of the following medicines. This is because it can increase the risk of you getting side effects, when taken with Oflox 400 Tablets:

- Corticosteroids, sometimes called steroids – used for inflammation. You may be more likely to have inflammation and/or breakage of your tendons.
- Warfarin - used to thin the blood. You may be more likely to have a bleed. Your doctor may need to take regular blood tests to check how well your blood can clot.
- Theophylline - used for breathing problems. You may be more likely to have a fit (seizure) if you take theophylline with Oflox 400 Tablets.
- Non-steroidal anti-inflammatory drugs (NSAIDs) - used for relief of pain and inflammation such as aspirin, ibuprofen, fenbufen, ketoprofen and indomethacin. You may be more likely to have a fit (seizure) if taken with Oflox 400 Tablets.
- Medicines known to affect the way your heart beats. This include medicines used for abnormal heart rhythm (antiarrhythmics such as quinidine and amiodarone), for depression (tricyclic antidepressants such as amitriptyline and imipramine) and for bacterial infections ('macrolide' antibiotics such as erythromycin, azithromycin and clarithromycin), for pain or for treatment of drug addiction (methadone).
- Probenecid - used for gout, cimetidine - used for stomach ulcers and heartburn, and methotrexate – used for rheumatism or cancer. Special care should be taken when taking either of these medicines with Oflox 400 Tablets. If you have kidney problems, your doctor may want to give you a lower dose.

Do not take Oflox 400 Tablets at the same time as the following medicines. This is because it can affect the way Oflox 400 Tablets work:

- Iron tablets (for anaemia), magnesium or aluminium-containing antacids (for heartburn) or sulcralfate (for stomach ulcers). Do not take these medicines at the same time as Oflox 400 Tablets. Take your dose at least 2 hours before or after Oflox 400 Tablets.

Pregnancy and breastfeeding

If you become pregnant, or are planning to become pregnant, you must contact your doctor or health care provider to discuss the potential benefits and risks of your tuberculosis therapy to you and your child.

Since the safety of taking Oflox 400 Tablets during pregnancy has not been investigated in humans, you should avoid becoming pregnant during treatment you or your partner need to use a reliable form of barrier contraception (for example, a condom), or oral (pill) or other hormonal contraceptives (for example, implants, injection).

Since ofloxacin may pass over into the mother's milk and might hurt the development of your child's skeleton, you must not breast-feed while taking Oflox 400 Tablets.

Driving and using machines

You may get side effects after taking this medicine, including feeling dizzy, sleepy, a spinning feeling (vertigo) or changes to your eyesight. Some of these side effects can affect you being able to concentrate and your reaction speed. If this happens, do not drive or carry out any work that requires a high level of attention.

Oflox 400 Tablets contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor or health care provider before taking this medicinal product.

3. HOW TO TAKE OFLOX 400 TABLETS

Always take Oflox 400 Tablets exactly as your doctor or health care provider told you. You should check with your doctor, health care provider or pharmacist if you are not sure.

The usual dose for adults is one tablet (400 mg ofloxacin) taken twice daily. For children, or if you have impaired kidney function, your doctor may decide on a lower dose. You can take Oflox 400 Tablets with or without food. Oflox 400 Tablets are for oral use. Swallow the tablet whole and with plenty of liquid. Try to take the tablet at approximately the same time each day.

If you take more Oflox 400 Tablets than you should

If you accidentally take more tablets than you should, tell a doctor or get other medical advice straight away. Take the medicine pack with you. This is so the doctor knows what you have taken.

If you forget to take Oflox 400 Tablets

If you forgot to take a dose, take it as soon as you remember unless your next dose is due within 4 hours. Do not double-up the next dose to make up for the missed dose.

If you stop taking Oflox 400 Tablets

Do not stop taking Oflox 400 Tablets just because you feel better. It is important that you complete the course of tablets that your doctor has prescribed for you. If you stop taking the tablets too soon, the infection may return, your condition may get worse and the bacteria may become resistant to the medicine.

If you have any further questions on the use of this medicine, ask your health care provider.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Oflox 400 Tablets can cause side effects, although not everybody gets them. When treating tuberculosis, it is not always possible to differentiate between unwanted effects caused by Oflox 400 Tablets, and those caused by any other medicines you may be taking at the same time, or by the disease itself. For this reason, it is important that you inform your doctor or health care provider of any change in your health.

Uncommon side effects (between 1 and 10 in every 1000 people are likely to get these):

- Itching and skin rash
- Feeling sick (nausea), diarrhoea, loss of appetite, being sick (vomiting) or pain in your stomach area
- Headache, feeling dizzy, a spinning feeling (vertigo)
- Increases in the number of other bacteria or fungi that are normally found on the body, which may need to be treated
- Feeling stressed (anxiety) or feeling restless (agitation)
- Irritation of the eyes
- Cough, sore throat
- Difficulties sleeping

Rare side effects (between 1 and 10 in every 10,000 people are likely to get these):

- Watery diarrhoea, which may have blood in it, possibly with stomach cramps and a high temperature. These could be signs of a severe bowel problem
- Pain and inflammation in your tendons. The Achilles tendon is affected most often and in some cases, the tendon could break
- Tingly feeling in your hands and feet (paraesthesia) or trembling
- Unusual fast beating of your heart or low blood pressure
- Joint pain or muscle pain
- Difficulty breathing or wheezing (bronchospasm)
- Shortness of breath (dyspnoea)
- Severe itching or hives (called urticaria)
- Sweating too much (hyperhidrosis)
- Hot flushes
- Allergic reactions. The signs may include: rash, swallowing or breathing problems, swelling of your lips, face, throat, or tongue
- Depression, mental problems, feeling confused, feeling sleepy
- Problems with your hearing or eyesight or changes in the way things taste and smell
- Visual disturbance
- Increase in the level of some liver enzymes in your blood
- Blood tests may show abnormal results due to kidney problems

Very rare side effects (between 1 and 10 in every 100,000 people are likely to get these):

- Burning, tingling, pain or numbness. These may be signs of something called 'neuropathy'
- Fits (convulsions)
- Problems moving and walking
- Tinnitus, loss of hearing
- Increased sensitivity of your skin to sun and ultraviolet light
- Loss of circulation (anaphylactic like shock)
- Inflammation of the liver
- Kidney failure which may be due to an allergic kidney reaction called interstitial nephritis
- Lowering in red blood cells (anaemia).
- Bruising and bleeding easily due to a lowering in the number of blood platelets
- Fever, sore throat and a general feeling of being unwell that does not go away. This may be due to a lowering in the number of white blood cells
- Severe skin rashes which may include blistering or peeling of the skin around your lips, eyes, mouth, nose and genitals
- Inflammation of your blood vessels due to an allergic reaction
- Seeing or hearing things that are not there (hallucinations), change in your opinion and thoughts (psychotic reactions) with a risk of having suicidal thoughts or actions
- Jaundice (skin and eyes becoming yellow in color) due to inhibition of bile flow

Other possible side effects, occurring at an unknown frequency, include

- Liver inflammation with symptoms such as loss of appetite, skin and eyes becoming yellow in colour, dark-coloured urine, itching, or tender stomach (abdomen).
- Exaggerated immune response (hypersensitivity)
- Breakdown of muscles (rhabdomyolysis)
- Muscle weakness. This is important in people with myasthenia gravis (a rare disease of the nervous system)
- Fever and allergic lung reactions
- Attacks of porphyria in people who already have porphyria (a very rare metabolic disease)
- Lowering of your blood sugar levels (hypoglycaemia). This is most relevant for people that are treated with medicines for diabetes
- Life-threatening irregular heart rhythm

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or health care provider.

5. HOW TO STORE OFLOX 400 TABLETS

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

Do not store above 30°C.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day 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 Oflox 400 Tablets contains

The active ingredient is ofloxacin. Each tablet contains 400 mg of ofloxacin.

The other ingredients are:

Core tablet: Corn starch, hydroxypropyl cellulose, lactose anhydrous, magnesium stearate and sodium starch glycolate.

Film coat (Opadry yellow O4F52565): Hypromellose, iron oxide yellow, polyethylene glycol and titanium dioxide.

What Oflox 400 Tablets looks like and contents of the pack

Oflox 400 Tablets are pale, yellowish-white coloured, capsule shaped, biconvex, film-coated tablets with central break-line on one side and plain on other side, provided in PVC-Al blister packs containing 100 (10 x 10) tablets per pack or in HDPE bottles containing 100, 500 or 1000 tablets with a desiccant (silica gel bag) and a filler (rayon coil).

The tablet can be divided into equal halves.

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For any information about this medicinal product, please contact the supplier.

This leaflet was last approved in July 2012

Detailed information on this medicine is available on the World Health Organization (WHO) web site:
<http://www.who.int/prequal/> .