

Evaflox 200/400

Ofloxacin Tablets USP 200 mg and 400 mg

Consumer Medication Information Leaflet (RiMUP)

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1. What is Evaflox used for

Evaflox tablets contain a medicine called ofloxacin. This belongs to a group of medicines called antibiotics. It works by killing bacteria that cause infections.

Evaflox tablets are used for infections of the:

- Kidneys or bladder (urinary tract)
- Chest or lungs
- Male or female sex organs (genital tract). This includes gonorrhoea which is a sexually transmitted infection that can affect both men and women
- Skin and soft tissue. Soft tissue is underneath the skin and includes muscle

2. How Evaflox works

Evaflox works by killing bacteria that cause infections

3. Before you use Evaflox

-When you must not use it

- You are allergic (hypersensitive) to ofloxacin or any of the other ingredients of Evaflox tablets (listed in Section 8 below) Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- You have ever had swelling of the tendons (called tendinitis) which can affect areas such as the wrist or the achilles tendon
- You have epilepsy or are at risk of fits
- You have a problem with your red blood cells known as 'glucose-6-dehydrogenase deficiency'
- You are pregnant or breast-feeding (see 'Pregnancy and breast-feeding' section below)
- You are under 18 years of age or are still growing

- 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 Evaflox tablets.

-Before you start to use it

Check with your doctor or pharmacist before taking your medicine if:

- You have liver or kidney problems
- You have heart disease or problems with your heartbeat
- You are taking medicines that can affect your heart (see section Taking other medicines)
- 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 taking other medicines that result in abnormal ECG changes (see section Taking other medicines)
- You have or have ever had any mental health problems
- You suffer from a condition called 'myasthenia gravis' (muscle weakness)
- You have been told by your doctor that you can not tolerate some sugars. If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Evaflox tablets.
- Tell your healthcare providers if you have been diagnosed with an enlargement or "bulge" of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm).
- Tell your healthcare providers if you have experienced a previous episode of aortic dissection (a tear in the aorta wall).
- Tell your healthcare providers if you have a family history of aortic aneurysm or aortic dissection or other risk factors or predisposing conditions (e.g. connective tissue disorders such as Marfan syndrome, or vascular Ehlers-Danlos syndrome, or

vascular disorders such as Takayasu arteritis, giant cell arteritis, Behcet's disease, high blood pressure, or known atherosclerosis).

- You should not take fluoroquinolone antibacterial medicines, including Evaflox, if you have experienced any serious adverse reaction in the past when taking a fluoroquinolone (see section Things to be careful of and Side effects). In this situation, you should inform your healthcare providers as soon as possible.

-Taking other medications

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 Evaflox tablets and some other medicines can affect the way each other work.

In particular, tell your doctor if you are taking the following medicine:

- Methotrexate used for rheumatism or cancer
- Other medicines that can alter your heart rhythm:
- Medicines that belong to the group of anti-arrhythmics (e.g. quinidine, hydroquinidine, disopyramide, amioderone, sotalol, dofetilide, ibutilide)
 - Tricyclic antidepressants
 - Some antimicrobials (that belong to the group of macrolides)
 - Some antipsychotics

4. How to use Evaflox

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

-How much to use

- Your doctor will decide on how many Evaflox tablets you should take
- The dose will depend on the type of infection you have

The usual dose for adults, including the elderly, is between 200 mg and 800 mg each day. The dose depends on the location and type of infection:

- Kidney or bladder infections (urinary tract): 200 to 800 mg each day

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- Chest or lung: 400 to 800 mg each day
- Male or female sex organ infections (genital tract): 400 mg each day
- Gonorrhoea a single dose of 400 mg
- Skin and soft tissue infections: 400 to 800 mg each day

Kidney or liver problems

If you have any kidney or liver problems you may be given a lower dose.

Children and Adolescents: This medicine should not be given to children or adolescents

-When to use it

The length of your treatment will depend on how serious your infection is

- The medicine is usually taken for 5 to 10 days and 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 long to use it

Keep taking Evaflox tablets until your doctor tells you to stop. Do not stop taking Evaflox 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 or pharmacist.

-If you forget to use it

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 use too much (overdose)

If you take more Evaflox 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.

5. While you are using it

-Things you must do

If you take more Evaflox 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.

You may experience mental health problems even when taking/ using fluoroquinolone antibiotics, including Evaflox for the first time. In very rare cases depression or mental health problems have led to suicidal thoughts and self-injurious behaviour such as suicide attempts. If you develop such reactions, stop taking/ using Evaflox and inform your doctor immediately.

-Things you must not do

Keep taking Evaflox tablets until your doctor tells you to stop. Do not stop taking Evaflox 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 or pharmacist.

-Things to be careful of

You may feel sleepy or dizzy or have problems with your eyesight while taking this medicine. If this happens, do not drive or use any tools or machines.

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

Prolonged, disabling and potentially irreversible serious side effects

Fluoroquinolone antibacterial medicines, including Evaflox, have been associated with very rare but serious side effects, some of them being long lasting (continuing months or years), disabling or potentially irreversible.

Stop taking your fluoroquinolone antibiotic and contact your healthcare providers immediately if you have the following signs of a side effect:

- Tendon pain or swelling, often beginning in the ankle or calf. If this happens, rest the painful area until you can see your healthcare providers.
- Pain in your joints or swelling in your shoulder, arms, or legs.
- Abnormal pain or sensations (such as persistent pins and needles, tingling, tickling, numbness, or burning), weakness in your body, especially in the legs or arms, or difficulty walking.
- Severe tiredness, depressed mood, anxiety, problems with your memory, or severe problems sleeping.
- Changes in your vision, taste, smell, or hearing.

Tell your healthcare providers if you have had one of the above effects during or shortly after taking a fluoroquinolone – this means you should avoid them in the future. You and your healthcare providers will decide on continuing the treatment considering also an antibiotic from another class.

Tendinitis and tendon rupture

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 Evaflox therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking Evaflox, contact your healthcare providers and rest the painful area. Avoid any unnecessary exercise as this might increase the risk of a tendon rupture.

Peripheral neuropathy

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 Evaflox and inform your healthcare providers immediately in order to prevent the development of potentially irreversible condition.

6. Side effects

Like all medicines, Evaflox tablets can cause side effects, although not everybody gets them.

Stop taking Evaflox tablets and see a doctor or go to a hospital straight away if:

- You have an allergic reaction. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue. Stop taking Evaflox tablets and see a doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

Very Rare (affects less than 1 in 10,000 people)

- An uneven or fast heartbeat, you may also feel faint
- Watery diarrhoea, which may have blood in it, possibly with stomach cramps and a high temperature
- Fits
- Hearing problems or hearing loss
- Liver problems that may cause your eyes or skin to go yellow (jaundice)
- Severe skin rashes which may include blistering or peeling of the skin around the lips, eyes, mouth, nose and genitals
- Skin rashes caused by strong sunlight
- Feeling faint, light-headed or dizzy, due to low blood pressure
- Muscle weakness, joint and muscle pains
- Feeling weak or irritable, sweating and/or trembling. This could be due to lowering of blood sugar levels
- Feeling thirsty and passing water more often than usual. This could be due to a raise in blood sugar levels
- Swelling or discomfort in your tendons, such as in the achilles tendon
- Severe inflammation of the kidneys, which may result in your kidneys stopping working. Signs may include a rash, high temperature and general aches and pains
- Psychotic behaviour

Rare (affects less than 1 in 1000 people)

- Numbness or tingling in the hands and feet or being very sensitive to touch
- Psychotic reactions with a risk of having suicidal thoughts or actions, hallucination, depression

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

- Psychotic reactions with a risk of having suicidal thoughts or actions
- 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)

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

Uncommon (affects less than 1 in 100 people)

- Feeling or being sick, diarrhoea or stomach pains
- Headaches, sleeping problems, feeling dizzy or restless
- Skin rash or itching

Rare (affects less than 1 in 1000 people)

- Loss of appetite
- Feeling confused or anxious, nightmares, seeing things that are not there, depression and mental illness, feeling drowsy, trembling, problems walking due to poor muscle control
- Changes in eyesight
- Changes in or loss of your sense of taste or smell
- Changes in levels of liver enzymes shown in blood tests
- A general feeling of being unwell

Very Rare (affects less than 1 in 10,000 people)

- Feeling tired, faint, dizzy and having pale skin. These could be signs of anaemia
- You may bruise more easily than usual.

This could be because of a blood problem called 'thrombocytopenia'

- Cough or shortness of breath, caused by lung inflammation

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

Fluoroquinolones have been reported to cause serious side effects involving tendons, muscles, joints, and the nerves – in a small proportion of patients, these side effects caused long-lasting or permanent disability

(see section Before you start to use it and Things to be careful of).

Talk to your doctor or pharmacist if any of the side effects gets serious or lasts longer than a few days, or if you notice any side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

7. Storage and Disposal of Evaflox

-Storage
Store at temperature not exceeding 30°C. Protected from light and moisture. Keep medicines out of the reach of children.

Do not use Evaflox tablets after the expiry date which is stated on the label. The expiry refers to the last day of that month.

-Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

8. Product Description

-What it looks like :

Evaflox 200: Light pink, round, biconvex, film coated tablets.
Evaflox 400 : Light pink, oblong, biconvex, film coated tablets.

-Ingredients

• Active ingredient(s) :

Ofloxacin USP

• Inactive ingredient(s)

- Lactose Monohydrate Ph.Eur/ BP
- Maize Starch Ph.Eur/ BP
- Croscarmellose sodium USP-NF
- Talc Ph.Eur/ BP
- Colloidal Silicon Dioxide Ph.Eur/ BP
- Magnesium Stearate Ph.Eur/ BP
- Hydroxypropyl methyl cellulose 15 cps Ph.Eur/ BP
- Macrogol 400 Ph.Eur/ BP
- Isopropyl Alcohol Ph.Eur/ BP
- Dichloromethane Ph.Eur/ BP
- Opadry 04B540002 Pink O. Sp.
- Purified water

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-MAL number :

Evaflox 200 : MAL 20040755AZ

Evaflox 400 : MAL 20040756AZ

9 Manufacturer

Unichem Laboratories Limited
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Product Registration Holder

Healol Pharmaceuticals Sdn Bhd.
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