

Flonoxin 400mg Tablet

Moxifloxacin (400mg)

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What Flonoxin is used for

Flonoxin is used in patients aged 18 years and above to treat infections caused by certain bacteria which include:

- Infections of the sinuses
- Sudden worsening of long-term inflammation of the airways
- Infection of the lower respiratory tract (pneumonia) acquired outside hospital
- Mild to moderate infections of the female upper genital tract (pelvic inflammatory disease), including infections of the fallopian tubes and uterus mucous membrane. Flonoxin is not sufficient on its own for treating this kind of infection hence another antibiotic in addition to Flonoxin should be prescribed by your doctor for treatment of these infections.
- Infection of the skin, soft tissue and infection occurring within the abdomen.

How Moxifloxacin works

Flonoxin works by killing bacteria that cause infections.

Before you use Flonoxin

- When you must not take it

Do not take this medicine

- If you have an allergy to Flonoxin, other quinolone antibiotics or any of the other ingredients listed at the end of this leaflet
- If you are pregnant or breast-feeding
- If you are under 18 years of age
- If you previously had problems with your tendons related to treatment with quinolone antibiotics
- If you are born with or have

- Any condition with abnormal heart rhythm (as in ECG)
- Salt imbalance in the blood (especially low levels of potassium in the blood)
- A very slow heart rhythm (bradycardia)
- A weak heart (heart failure)
- A history of abnormal heart rhythms or if you are taking other medicines that result in abnormal ECG changes.

- If you have severe liver disease or increased liver enzymes (transaminases) higher than 5 times the upper normal limit

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

- Before you start to use it

Check with your doctor or pharmacist before taking Flonoxin if you are experiencing or have experienced any of the following conditions:

- Abnormal heart rhythm
- Allergic reactions to quinolone antibiotics
- Severe liver disorders
- Seizure or a condition which makes you likely to have convulsions
- Any mental health problems
- Antibiotic-associated diarrhoea
- Myasthenia gravis (abnormal muscle fatigue and weakness)
- Tendon inflammation & rupture
- Glucose-6-phosphate dehydrogenase deficiency (G6PD)
- A complicated infection of the female upper genital tract (pelvic inflammatory disease)

You should not take fluoroquinolone antibacterial medicines, including Flonoxin, 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

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).

- Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop. For Flonoxin, be aware of the following:

- If you are taking other medicines that affect your heart rhythm
- If you are taking other medicines that can lower your blood potassium levels or slow your heart rate
- Any medicine containing magnesium or aluminium (such as antacids for indigestion), iron, zinc or sucralose as these drugs can interfere with the action of Flonoxin. Take Flonoxin 4 hours before or 2 hours after taking those medicines.
- Charcoal as it reduces the action of Flonoxin. These two medicines should not be taken together.
- If you are currently taking blood thinning medicine such as warfarin, your doctor may need to monitor your blood clotting time.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to use Flonoxin

Follow all directions given to you by your doctor and pharmacist carefully. These directions may differ from the information contained in this leaflet. If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

- How much to use

Adult: One 400mg tablet once daily

- When to use it

Take as directed by your doctor or pharmacist. Take it at the same time each day.

How long to use it

Continue taking Flonoxin for as long as your doctor recommends.

It is important that you complete the course of treatment even if your symptoms start to improve. If you stop taking Flonoxin before the full prescribed length of time or if you skip doses, your infection may not be completely treated and the bacteria may become resistant to antibiotics.

- If you forget to use it

Take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting an unwanted side effect.

- If you use too much (overdose)

Immediately telephone your doctor for advice or go to Accident and Emergency (Casualty) at your nearest hospital if you think that you or anyone else may have taken too much Flonoxin.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

You may experience mental health problems even when taking/ using fluoroquinolone antibiotics, including Flonoxin 400mg Tablet 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 Flonoxin 400mg Tablet and inform your doctor immediately.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Flonoxin.

If you are about to start taking any new medicine tell your doctor and pharmacist that you are taking Flonoxin.

Tell your doctor immediately if you become pregnant while taking Flonoxin.

- Things you must not do

Do not stop taking your medicine unless advised by your doctor. Talk to your doctor if you wish to stop taking the medicine before the end of the course of treatment.

Do not take any new medicines without first consulting your doctor.

Do not give your medicine to anyone else, even if they have the same condition as you.

- Things to be careful of

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 Flonoxin, 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 Flonoxin therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking Flonoxin, 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 Flonoxin and inform your healthcare providers immediately in order to prevent the development of potentially irreversible condition.

Driving or using machines

This medicine may affect your ability to drive or use machines. If you feel dizzy, drowsy or have blurry vision, do not drive or use machines until these symptoms have worn off.

Side effects

Like all medicines, Flonoxin can cause side effects, although not everybody gets them. Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Common side effects include:

- Infections due to resistant bacteria or fungi e.g. oral and vaginal candidiasis
- Headache
- Dizziness
- Change in heart rhythm in patients with low blood potassium level
- Nausea
- Vomiting
- Stomachache
- Diarrhoea
- Increase in liver enzyme (transaminases) in blood

Rare: Depression (in very rare cases leading to self-harm, such as suicidal ideations/thoughts (desire to kill oneself), or suicide attempts), hallucinations

Very rare: Psychotic reactions (potentially leading to self-harm, such as suicidal ideations/ thoughts (desire to kill oneself), or suicide attempts)

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).

Ask for the advice of your doctor or pharmacist if you have any concerns about the effects of taking this medicine.

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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.moh.gov.my (Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI).

Storage and Disposal of Flonoxin

- Storage

Keep your medicine in its original packaging until it is time to take them.

If you take the tablets out of the pack, they may not keep well.

Keep your medicine in a dry place where the temperature will stay below 30°C.

Do not store your Flonoxin in the bathroom or near a sink.

Keep it where children cannot reach it.

- Disposal

Do not use this medicine after the expiry date which is stated on the container, and the carton. 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.

Product Description

- What it looks like

Dull red, 17 mm oblong shaped, plain on both sides, film-coated tablet.

- Ingredients

Active ingredient:

- Moxifloxacin

Inactive ingredients:

- Povidone
- Lactose monohydrate
- Croscarmellose sodium
- Magnesium stearate
- Opadry

- MAL number

MAL19096015AZ

Manufacturer

Duopharma Manufacturing (Bangi) Sdn. Bhd

Lot No. 2&4, Jalan P/7, Section 13, Bangi Industrial Estate, 43650 Bangi Industrial Estate, Selangor, Malaysia

Product Registration Holder

Duopharma Marketing Sdn. Bhd

Lot No. 2,4,6,8 &10, Jalan P/7, Section 13, 43650 Bangi Industrial Estate, Selangor, Malaysia

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