

Xflox 400mg film-coated tablets

Moxifloxacin

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 more 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 signs of illness are the same as yours. If you get any 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:

- What Xflox is and what it is used for
- What you need to know before you take Xflox
- How to take Xflox
- Possible side effects
- How to store Xflox
- Contents of the pack and other information

1. What Xflox is and what it is used for

Xflox contains the active substance moxifloxacin, which belongs to a group of antibiotics called fluoroquinolones. Xflox works by killing bacteria that cause infections.

Xflox is used in patients aged 18 years and above for treating the following bacterial infections when caused by bacteria against which moxifloxacin is active. Xflox should only be used to treat these infections when usual antibiotics cannot be used or have not worked:

Infection of the sinuses, sudden worsening of long term inflammation of the airways or infection of the lungs (pneumonia) acquired outside the hospital (except severe cases).

Mild to moderate infections of the female upper genital tract (pelvic inflammatory disease), including infections of the fallopian tubes and infections of the uterus mucous membrane. Xflox tablets are not sufficient on their own for treating this kind of infection. Therefore, another antibiotic in addition to Xflox tablets should be prescribed by your doctor for the treatment of infections of the female upper genital tract (see section **2. What you need to know before you take Xflox, Warnings and precautions, Talk to your doctor before taking Xflox**).

If the following bacterial infections have shown improvement during initial treatment with moxifloxacin solution for infusion, Xflox tablets may also be prescribed by your doctor to complete the course of therapy: Infection of the lungs (pneumonia) acquired outside the hospital, infections of the skin and soft tissue.

Xflox tablets should not be used to initiate therapy for any type of infections of the skin and soft tissue or in severe infections of the lungs.

2. What you need to know before you take Xflox

Contact your doctor if you are not sure if you belong to a patient group described below.

Do not take Xflox

- If you are allergic to the active substance moxifloxacin, any other quinolone antibiotics or any of the other ingredients of this medicine (listed in section 6).
- If you are pregnant or are breast-feeding.
- If you are under 18 years of age.
- If you have previously had problems with your tendons related to treatment with quinolone antibiotics (see section **Warnings and Precautions** and section **4. Possible side effects**).
- If you were born with or have
 - any condition with abnormal heart rhythm (seen on ECG, electrical recording of the heart)
 - a salt imbalance in the blood (especially low levels of potassium or magnesium in the blood)
 - a very slow heart rhythm (called "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 (see section **Other medicines and Xflox**). This is because moxifloxacin can cause changes on the ECG, that is a prolongation of the QT-interval, i.e., delayed conduction of electrical signals.
- If you have a severe liver disease or increased liver enzymes (transaminases) higher than 5 times the upper normal limit.

Warnings and precautions

Before taking this medicine

You should not take fluoroquinolone/quinolone antibacterial medicines, including moxifloxacin, 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.

Talk to your doctor before taking Xflox

- moxifloxacin can **change your heart's ECG**, especially if you are female, or if you are elderly. If you are currently taking any medicine that decreases your blood potassium levels, consult your doctor before taking moxifloxacin (see also sections **Do not take Xflox and Other medicines and Xflox**).
- If you have ever developed a **severe skin rash or skin peeling, blistering and/or mouth sores** after taking moxifloxacin.
- If you suffer from **epilepsy** or a condition which makes you likely to have **convulsions** talk to your doctor before taking moxifloxacin.
- If you have or have ever had any **mental health problems**, consult your doctor before taking moxifloxacin.
- If you suffer from **myasthenia gravis** (abnormal muscle fatigue leading to weakness and in serious cases paralysis), taking moxifloxacin may worsen the symptoms of your disease. If you think you are affected consult your doctor immediately.
- 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, Behçet's disease, high blood pressure, or known atherosclerosis, rheumatoid arthritis (a disease of the joints) or endocarditis (an infection of the heart)).
- If you are **diabetic** because you may experience a risk of **change in blood sugar levels** with moxifloxacin.
- 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 moxifloxacin is suitable for you.
- If you have a **complicated infection of the female upper genital tract** (e.g. associated with an abscess of the fallopian tubes and ovaries or of the pelvis), for which your doctor considers an intravenous treatment necessary, treatment with moxifloxacin tablets is not appropriate.
- For the treatment of **mild to moderate infections of the female upper genital tract** your doctor should prescribe another antibiotic in addition to Xflox. If there is no improvement in symptoms after 3 days of treatment, please consult your doctor.

When taking Xflox

- If you experience **palpitations or irregular heart beat** during the period of treatment, you should inform your doctor immediately. He/she may wish to perform an ECG to measure your heart rhythm.
- The **risk of heart problems** may increase with increase of the dose. Therefore, the recommended dosage should be followed.
- There is a rare chance 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 Xflox and seek medical advice immediately.**
- moxifloxacin 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, dark urine, itching of the skin, a tendency to bleed or liver induced disease of the brain (symptoms of a reduced liver function or a rapid and severe inflammation of the liver) **please contact your doctor before taking any more tablets.**
- Serious skin reactions**

Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, and acute generalised exanthematous pustulosis (AGEP) have been reported with the use of moxifloxacin.

 - SJS/TEN can appear initially as reddish target-like spots or circular patches often with central blisters on the trunk. Also, ulcers of mouth, throat, nose, genitals and eyes (red and swollen eyes) can occur. These serious skin rashes are often preceded by fever and/or flu-like symptoms. The rashes may progress to widespread peeling of the skin and life-threatening complications or be fatal.
 - AGEP appears at the initiation of treatment as a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The most common

تتوقف فترة تناول موكسيفلوكساسين على مدى إصابتك. ما لم يبلغك طبيبك خلاف ذلك، سيكون علاجك كما يلي:

- لتعاقب المخاض/للتهاب الشعب الهوائية المزمن (التفاقم الحاد لمرض الانسداد الرئوي المزمن بما في ذلك التهاب الشعب الهوائية) من ٥ إلى ١٠ أيام.
- في حالة إصابة الرئتين (التهاب الرئوي) فيما عدا الانسداد الرئوي الذي يبدأ أثناء الإقامة في المستشفى ١٠ أيام.
- في حالة التهاب الحاد للجيوب الأنفية (التهاب الجيوب البكتيري الحاد) ٧ أيام.
- التهابات الحلقية إلى المتوسطة في الجهاز التناسلي العلوي للإناث (مرض التهاب الحوض)، بما في ذلك التهاب قنوات فالوب والتهاب المشاء المخاطي للرحم١٤ يوماً.

عند استخدام أقراص إكسفلوكس المغلفة لاستكمال دورة العلاج التي بدأت بحلول موكسيفلوكساسين الذي يجري تناوله عن طريق الحقن الوريدي، تكون فترات الاستخدام الموصى بها كما يلي:

- إصابة الرئتين (التهاب الرئوي) المكتسبة خارج المستشفى من ٧-١٤ يوماً.
- تحول معظم المرضى المصابين بالتهاب رئوي إلى العلاج عن طريق الفم باستخدام أقراص إكسفلوكس المغلفة في غضون ٤ أيام.
- إصابات البشرة والتسجج الرخو من ٧-٢١ يوماً.
- تحول معظم المرضى المصابين بإصابات في البشرة والتسجج الرخو إلى العلاج عن طريق الفم باستخدام أقراص إكسفلوكس المغلفة في غضون ٦ أيام.

ومن المهم أن تقوم باستكمال دورة العلاج حتى ولو بدأت تشعر بتحسن بعد بضعة أيام. إذا ما تحللت في التوقف عن تناول إكسفلوكس، فقد لا تشفى إصابتك تماماً وقد تعاودك الإصابة أو قد تسوء حالتك.

وقد تصبح البكتيريا المسببة لإصابتك مقاومة لموكسيفلوكساسين.

لا ينبغي تجاوز الجرعة وفترة العلاج الموصى بهما (انظر القسم ٢. **المعلومات التي تحتاج إلى معرفتها قبل تناول إكسفلوكس، التحذيرات والإحياطات**).

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