Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Fluoroquinolone antibiotics (-oxacins): what you need to know about side effects of tendons, muscles, joints, and nerves

March 2019

- Fluoroquinolone medicines (ciprofloxacin, levofloxacin, moxifloxacin, and ofloxacin) are effective **antibiotics** that treat serious and life-threatening infections in the body

- Always take your doctor's advice on when and how to take antibiotics

- 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

Stop taking your fluoroquinolone antibiotic and contact your doctor 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 doctor**
- 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, or problems with your memory or severe problems sleeping
- Changes in your vision, taste, smell, or hearing

- Tell your doctor 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

- Doctors will take special care with these medicines if you are older than 60 years of age, if your kidneys do not work well, or if you have had an organ transplant; this is because these groups have a higher risk of side effects

- Talk to your doctor if you are taking or expect to take a corticosteroid (medicines such as hydrocortisone and prednisolone) – taking these medicines with a fluoroquinolone can increase the risk of tendon problems

- **Always read the leaflet** that comes with your medicines (ask your pharmacist for a leaflet if you did not receive one) and talk to your doctor or pharmacist if you are concerned about your medicines

- Please report side effects to the Yellow Card Scheme (see page 2 for more)

©Crown Copyright

Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Questions you may have about your medicine

What are fluoroquinolone antibiotics?
Fluoroquinolone antibiotics are a group of medicines that kill bacteria and fight infections.

Fluoroquinolones antibiotics are important for treating certain infections. Some of these infections can be life threatening.

In the UK, fluoroquinolones are ciprofloxacin, levofloxacin, moxifloxacin, and ofloxacin. This advice only applies to medicines that are swallowed, inhaled, or injected into the body.

Why has the advice about these medicines changed?
A European review has looked closely at the expected benefits and potential risks of fluoroquinolone antibiotics. The review identified very rare reports of serious and long-lasting side effects in people who had taken fluoroquinolones.

Although these reports have been rare, the medicines experts recommended that these medicines should not be used in conditions that are not serious or that get better on their own. This is because the expected benefits of using fluoroquinolones are low.

For more serious infections, the experts recommended that the benefits of these medicines in fighting infections are greater than the risks. However, healthcare professionals and patients should know about the risks. This is so side effects can be identified quickly.

What can I do if I think I'm having a side effect?
Tendon or muscle problems or feeling particularly unwell may be caused by events other than your medicines. The best person to talk to is your doctor. If you're unable to see your doctor, you can call 111 for advice.

Getting help for tendon or nervous system side effects early can prevent permanent problems. Don't delay in talking to your doctor if you think something is wrong.

Who can I tell about my side effects?
Please report any side effects to the MHRA via the Yellow Card Scheme. Reports are confidential and help to improve the safety of medicines.

Report side effects on the website (visit https://yellowcard.mhra.gov.uk/ or search for Yellow Card Scheme) and on the Yellow Card App on the Apple App Store or Google Play Store.

This sheet has been produced by the Medicine and Healthcare products Regulatory Agency (MHRA), an executive agency of the Department of Health and Social Care, to help healthcare professionals discuss new restrictions and advice for fluoroquinolone antibiotics. A large print sheet is also available online. Always read the leaflet that accompanies your medicines.

©Crown Copyright