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Fluoroquinolone antibiotics: reminder of measures to reduce the risk of long-lasting, disabling and potentially irreversible side effects

EMA's safety committee, PRAC, is reminding healthcare professionals that the use of fluoroquinolone antibiotics, given by mouth, injection or inhalation, is restricted due to the risk of disabling, long-lasting and potentially irreversible side effects.

These restrictions were introduced in 2019 following an [EU-wide review](#) of these very rare, but serious side effects. An EMA funded study² has shown that although the use of fluoroquinolone antibiotics has reduced, these medicines may still be prescribed outside of their recommended uses.

Restrictions on the use of fluoroquinolone antibiotics mean that they should **not** be used:

- to treat infections that might get better without treatment or are not severe (such as throat infections);
- to treat non-bacterial infections, e.g., non-bacterial (chronic) prostatitis;
- for preventing traveller's diarrhoea or recurring lower urinary tract infections (urine infections that do not extend beyond the bladder);
- to treat mild or moderate bacterial infections unless other antibacterial medicines commonly recommended for these infections cannot be used.

Importantly, fluoroquinolones should be avoided in patients who have previously had serious side effects with a fluoroquinolone or quinolone antibiotic. They should be used with special caution in the elderly, patients with kidney disease and in those who have had an organ transplantation because these patients are at a higher risk of tendon injury. Since the use of a corticosteroid with a fluoroquinolone also increases this risk, combined use of these medicines should be avoided.

The study², which evaluated data from the primary care setting in six European countries (Belgium, France, Germany, the Netherlands, Spain and the United Kingdom) between 2016 and 2021, suggests

¹ This public health communication was amended on 22 May 2023 to clarify that these medicines should only be used in their approved indications rather than as last-line treatment.

² "Impact of European Union Label Changes for Fluoroquinolone Containing Medicinal Products for Systemic and Inhalation Use" ([EUPAS37856](#))

that the measures taken to restrict the use of these medicines as a result of the EU-wide review had a modest impact.

A Direct Healthcare Professional Communication (DHPC) will now be sent to healthcare professionals in the EU. The DHPC will emphasise that these products should only be prescribed for their approved indications and after a careful assessment of the benefits and risks in individual patients.

Information for patients

Fluoroquinolone antibiotics can cause serious side effects involving the nervous system, tendons, muscles and joints. Your doctor should only prescribe these medicines according to their approved uses.

- These very rare, but serious side effects include inflamed or torn tendons, muscle pain or weakness, joint pain or swelling, difficulty walking, feeling pins and needles, burning pain, tiredness, depression, problems with memory, sleeping, vision and hearing, and altered taste and smell.
- Tendon swelling and injury may occur within 2 days of starting treatment with a fluoroquinolone but may even occur several months after stopping treatment.
- If you are over 60 years of age, have a history of kidney problems or have had an organ transplantation, or if you are taking a corticosteroid (medicines such as prednisolone or hydrocortisone), you have a greater risk of developing tendon damage with a fluoroquinolone.
- If you experience the following side effects, stop treatment, and contact your doctor immediately:
 - tendon pain or swelling, particularly in the ankle or calf. If this happens, rest the painful area;
 - pain, numbness, tingling, swelling, or muscle weakness in different parts of the body, often beginning in the hands or feet, that gets worse over time;
 - severe tiredness, depression, poor memory or severe problems sleeping;
 - changes in vision, hearing, taste and smell;
 - swelling in your shoulders, arms or legs, or pains in your joints.

You and your doctor will decide if you can continue treatment or if you need another type of antibiotic

- You should not take a fluoroquinolone medicine if you have ever had a serious side effect with a fluoroquinolone or a quinolone medicine.
- If you have any questions or concerns about your medicines, speak to your doctor or pharmacist.

Information for healthcare professionals

- Findings of a study commissioned by EMA ([EUPAS37856](#)) suggest that fluoroquinolones continue to be prescribed outside of their recommended uses.
- EMA also notes that the study was subject to limitations and that caution should therefore be used when interpreting its data.
- Healthcare professionals are reminded of the outcome of an [EU-wide review](#) of inhaled and systemic quinolone and fluoroquinolone antibiotics that was conducted in 2018 by EMA. This review

led to significant restrictions on the use of these medicines due to the risk of rare but long-lasting (up to months or years), serious, disabling and potentially irreversible adverse reactions affecting different, sometimes multiple, body systems (musculoskeletal, nervous, psychiatric and senses).

- These adverse reactions can be limited by only prescribing these medicines within their approved indications and after a careful assessment of the benefits and risks in individual patients.
- Particular caution should be taken when prescribing fluoroquinolones in older patients, those with renal impairment, solid organ transplantation or on systemic corticosteroids as the risk of some adverse reactions (e.g. tendonitis, tendon rupture) are higher in these patients. Concomitant treatment with a fluoroquinolone and a corticosteroid should be avoided.
- Patients should be informed of the risks associated with fluoroquinolones prior to initiating treatment, including the potentially long-lasting and serious nature of these side effects, and advised to stop treatment and speak with their doctor at the first signs or symptoms of these adverse reactions.
- Fluoroquinolone treatment should be discontinued, and alternative treatment should be considered at the first sign of tendon pain or inflammation or of symptoms of neuropathy such as pain, burning, tingling, numbness, or weakness, so as to prevent development of potentially irreversible adverse reactions.

More about the medicine

Fluoroquinolone medicines are a family of broad-spectrum antibiotics that kill bacteria and fight infections. They are used to treat certain types of serious infections when other antibiotics are not suitable.

The EU-wide review, conducted in 2018 by EMA, concerned fluoroquinolone medicines given systemically (by mouth or injection) and inhaled medicines and covered medicines containing ciprofloxacin, flumequine, levofloxacin, lomefloxacin, moxifloxacin, norfloxacin, ofloxacin, pefloxacin, prulifloxacin and rufloxacin. Fluoroquinolone medicines are authorised in various EU Member States under different trade names.