

Fluoroquinolone antibiotics: must now only be prescribed when other commonly recommended antibiotics are inappropriate

Systemic fluoroquinolones must now only be prescribed when other commonly recommended antibiotics are inappropriate. This follows a review by the MHRA which looked at the effectiveness of current measures to reduce the identified risk of disabling and potentially long-lasting or irreversible side effects.

Advice for healthcare professionals:

- systemic (by mouth, injection, or inhalation) fluoroquinolones can cause long-lasting (up to months or years), disabling and potentially irreversible side effects, sometimes affecting multiple body systems and senses
- the UK indications for systemic fluoroquinolones have been updated so they must only be used in situations when other antibiotics, that are commonly recommended for the infection, are inappropriate
- situations in which other antibiotics are considered to be inappropriate and where a fluoroquinolone may be indicated are where:
 - there is resistance to other first-line antibiotics recommended for the infection
 - other first-line antibiotics are contraindicated in an individual patient
 - other first-line antibiotics have caused side effects in the patient requiring treatment to be stopped
 - treatment with other first-line antibiotics has failed
- this goes further than previous measures which set out that fluoroquinolones should not be prescribed for non-severe or self-limiting infections, or non-bacterial conditions, for example non-bacterial (chronic) prostatitis. These measures are still in place.
- as a reminder, patients should be advised to stop fluoroquinolone treatment at the first signs of a serious adverse reaction, such as tendinitis or tendon rupture, muscle pain, muscle weakness, joint pain, joint swelling, peripheral neuropathy and central nervous system effects, and to contact their doctor immediately
- refer to MHRA's sheet for patients ([regular print](#) or [large print](#)) for further advice
- remain alert to the risk of suicidal thoughts and behaviours with use of fluoroquinolone antibiotics. A reminder about these risks was published in the [September 2023 issue](#) of Drug Safety Update.
- as a reminder of advice published in our [August 2023 issue](#) of Drug Safety Update:
 - avoid fluoroquinolone use in patients who have previously had serious adverse reactions with a quinolone antibiotic (for example, nalidixic acid) or a fluoroquinolone antibiotic
 - prescribe fluoroquinolones with special caution for people older than 60 years and for those with renal impairment or solid-organ transplants, because they are at a higher risk of tendon injury

- avoid coadministration of a corticosteroid with a fluoroquinolone since this could exacerbate fluoroquinolone-induced tendinitis and tendon rupture
- report suspected adverse drug reactions to fluoroquinolone antibiotics on the [Yellow Card website](#) or via the Yellow Card app (download it from the [Apple App Store](#), or [Google Play Store](#))

Advice for healthcare professionals to provide to patients:

- fluoroquinolones are a class of antibiotics that include ciprofloxacin, delafloxacin, levofloxacin, moxifloxacin, and ofloxacin – these medicines may also have a brand name so patients should check the details of all antibiotics prescribed to them
- fluoroquinolone antibiotics have been reported to cause serious side effects involving tendons, muscles, joints, nerves, or mental health – in some patients, these side effects have caused long-lasting or permanent disability
- stop taking your fluoroquinolone antibiotic and contact your doctor immediately if you have any of the following signs of a side effect:
 - tendon pain or swelling – if this happens, rest the painful area until you can see your doctor
 - pain in your joints or swelling in joints such as in the shoulders, arms, or legs
 - abnormal pain or sensations (such as persistent pins and needles, tingling, tickling, numbness, or burning), weakness 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 doctor if you have had any of the above effects at any point while taking a fluoroquinolone – this means you should avoid them in the future

Side effects of systemic fluoroquinolones

Systemic and inhaled fluoroquinolones are associated with a risk of serious, disabling, long-lasting and potentially irreversible adverse reactions, estimated to occur in at least between 1 and 10 people in every 10,000 who take a fluoroquinolone. These may affect multiple body systems and include musculoskeletal, nervous, psychiatric and sensory reactions. These adverse reactions have been reported in patients irrespective of their age and potential risk factors.

Patients have reported that experiencing long-lasting or disabling reactions can affect their mental health, particularly when they perceive healthcare professionals fail to adequately acknowledge the reactions or the possibility that they are associated with a fluoroquinolone. Tendon damage can occur within 48 hours of commencing treatment, or the effects can be delayed for several months and become apparent after stopping treatment.

There are no proven drug treatments for these side effects. However, it is important that fluoroquinolones are stopped immediately at the first signs of a musculoskeletal, neurological or psychiatric side effect, such as those described above to avoid further

exposure, which could potentially worsen adverse reactions. These symptoms should be appropriately investigated.

MHRA review and further limits to the use of fluoroquinolones

[Restrictions to the use of fluoroquinolones](#) were introduced in 2019 to minimise the risk of these reactions. The MHRA has reviewed the effectiveness of these measures in the UK and sought the advice of the Commission on Human Medicines (CHM). As a result of this review a reminder about these risks was published in the [August 2023 issue of Drug Safety Update](#).

The MHRA has now taken additional regulatory action to update the indications for all systemic fluoroquinolones to state they should only be used when other commonly recommended antibiotics are inappropriate. Situations where other antibiotics are considered to be inappropriate are where:

- there is resistance to other first-line antibiotics recommended for the infection
- other first-line antibiotics are contraindicated in an individual patient
- other first-line antibiotics have caused side effects in the patient requiring treatment to be stopped
- treatment with other first-line antibiotics has failed

The description of disabling and potentially long-lasting or irreversible side effects in the safety information has also been updated, to include more detail about the range of psychiatric symptoms that may occur as part of these reactions. These may include sleep disorders, anxiety, panic attacks, confusion or depression. While the frequency of disabling and potentially long-lasting or irreversible side effects cannot be estimated precisely using available data, the updated reporting incidence indicates a minimum frequency of between 1 and 10 per 10,000 patients.

Report any suspected adverse drug reactions

Please continue to report suspected adverse drug reactions to fluoroquinolones via the [Yellow Card Scheme](#). Your report will help us safeguard public health.

Healthcare professionals, patients, and caregivers are asked to submit reports using the Yellow Card scheme electronically using:

- the [Yellow Card website](#)
- the Yellow Card app; download from the [Apple App Store](#) or [Google Play Store](#)
- some clinical IT systems for healthcare professionals (EMIS, SystmOne, Vision, MiDatabank, and Ulysses)

When reporting, please provide as much information as possible, including information about batch numbers, medical history, any concomitant medication, onset timing, treatment dates, and product brand name.

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