

Update on Fluoroquinolone (FQ) Warnings – MHRA NEW WARNING JAN 2024

In Jan 2024, Medicines and Healthcare Regulatory Agency (MHRA) issued the most strongly worded warning to date on restriction of systemic and inhaled fluoroquinolones (FQs). Systemic FQs must now only be prescribed when other commonly recommended antibiotics are inappropriate. Prescribers must be aware of the risk of disabling and potentially long-lasting (up to months or years) or irreversible side effects, sometimes affecting multiple body systems and senses. Despite new restrictions and precautions introduced in 2019 by MHRA a study has shown no evidence of a change in FQ prescribing patterns in the UK, and the MHRA has continued to receive Yellow Card reports of these side effects.

- The FQs available in the UK are levofloxacin, ciprofloxacin, ofloxacin and moxifloxacin and in NHS Tayside all are RESTRICTED to use in certain specific infections.
- Prescribers should refer to most up to date warnings (below), the BNF and/or manufacturer's information when prescribing FQs and take account of all cautions, contraindications and interactions as well as the patient's medical history and reports of previous adverse drug reactions.
- Patients should be given advice about potential serious adverse drug reactions and to stop treatment and contact their doctor immediately, at the first signs of a serious
 adverse reaction, sucha as tendinitis or tendon rupture, muscle pain, muscle weakness, joint pain, joint swelling, peripheral neuropathy and central nervous system
 effects.

Musculoskeletal System

- Tendon damage (including rupture) has been reported which may occur within 48 hours or the effects can be delayed for several months and become apparent after stopping FQ treatment
 - Risk is increased in people older than 60 years and those with renal impairment or solid-organ transplants
 - Avoid use of a corticosteroid with a FQ since coadministration could exacerbate FQ-induced tendinitis and tendon rupture
 - Use in patients with previous tendon disorders related to FQ use is contra-indicated
- Other adverse effects include muscle pain or weakness and joint pain or swelling

Psychiatric and Nervous System Adverse Effects

- The Jan 2024 alert provides more detail about the range of psychiatric and nervous system symptoms that may occur including: sleep disorders, anxiety, depression, panic attacks, confusion, disorientation, memory impairment and suicidal thoughts or suicide attempts, neuropathies. Fatgue and changes in vision, taste, smell or hearing
- FQs can induce convulsions (with our without a history of convulsions) and risk is increased when co-prescribed with NSAIDs

Aortic Aneurysm and Dissection and Heart Valve Regurgitation

• December 2020 MHRA alert states that FQs have been associated with small increased risk of heart valve regurgitation and a 2018 MHRA alert states that patients, particularly older patients, taking FQs are at a small increased risk of aortic aneurysm and dissection. Please refer to alerts for full list of risk factors/predisposing conditions. Patients should be advised about the risk and told to seek immediate medical attention in the case of rapid onset of breathlessness or heart palpitations or sudden severe and constant pain in the abdomen, chest or back.

Other Adverse Effects (for complete information refer to the BNF and/or manufacturer's information)

• All FQs can prolong QT interval • In 2018, the <u>FDA</u> issued an additional warning that FQs can affect blood sugars

Recommendations:

- Follow <u>NHS Tayside Antibiotic Guidance</u> and limit prescribing of FQs to approved indications
- For all FQ prescribing consider recent warnings and all cautions, contraindications and interactions to determine whether risks outweigh benefits and advise patients re risks
- Ensure the patient has the MHRA PIL and risks have been explained
- Report any side effects via <u>Yellow Card</u> <u>Scheme</u>

Approved by AMG: Feb 2024 Review: Feb 2026