

Fluoroquinolone Antibiotic Safety Alert: Heart Valve Regurgitation

The Medicines and Healthcare products Regulatory Agency (MHRA) recently published (December 2020) a [safety alert](#) around the use of fluoroquinolones. Systemic (by mouth or injection) and inhaled fluoroquinolones have been associated with a small increased risk of heart valve regurgitation. One retrospective case-control study suggested a 2-fold increased relative risk with current oral fluoroquinolone use compared with the risk with use of amoxicillin or azithromycin ⁽¹⁾

Fluoroquinolones are antibiotics approved for treatment of certain bacterial infections including serious or life-threatening infections. UK authorised fluoroquinolones include: Ciprofloxacin, Levofloxacin, Moxifloxacin, Ofloxacin and Delafloxacin. As for all antibiotics, consideration should be given to [NICE/PHE Managing common infections: guidance for primary care](#) for guidance on the appropriate use of fluoroquinolones.

The MHRA advises that fluoroquinolones should only be used after careful benefit-risk assessment and after consideration of other therapeutic options in the following patients at risk for heart valve regurgitation:

- Patients with congenital heart valve disease or pre-existing heart valve disease
- Patients diagnosed with connective tissue disorders (for example, Marfan syndrome or Ehlers-Danlos syndrome)
- Patients with other risk factors or conditions predisposing for heart valve regurgitation (for example, hypertension, Turner's syndrome, Behçet's disease, rheumatoid arthritis, and infective endocarditis)

If systemic or inhaled fluoroquinolones have been initiated, healthcare professionals should advise patients, especially those at risk, of the importance of seeking immediate medical attention if they experience any of the following:

- a rapid onset of shortness of breath, especially when lying down flat in bed
- swelling of the ankles, feet, or abdomen
- new-onset heart palpitations

Reminder of previous MHRA safety concerns and warnings associated with fluoroquinolones

- Fluoroquinolones have also been associated with [disabling, long-lasting or potentially irreversible adverse reactions affecting musculoskeletal and nervous systems](#) – treatment should be discontinued at the first signs of a serious adverse reaction, including tendon pain or inflammation (MHRA safety alert, March 2019)
- Fluoroquinolones may be associated with a [small increased risk of aortic aneurysm and dissection](#). They should only be used after careful assessment of the benefits and risks in patients at risk of aneurysms and after consideration of other therapeutic options (MHRA safety alert, November 2018)

Refer to individual Summary of Product Characteristics (SPCs) on [electronic medicines compendium](#) for details of all adverse effects and for licensed indications, cautions, contraindications & monitoring requirements.

Please report suspected adverse drug reactions associated with fluoroquinolone antibiotics via the [Yellow Card scheme](#)

To contact the Medicines Optimisation Team please phone 01772 214302

Reference:

1. Etminan M and others. 'Oral Fluoroquinolones and Risk of Mitral and Aortic Regurgitation'. Journal of the American College of Cardiology 2019; volume 74, pages 1444–50