

## Fluoroquinolone Safety Alerts

### Prescribing tip for information only

Two recent safety alerts <sup>(1)</sup> <sup>(2)</sup> around the use of fluoroquinolone antibiotics (ciprofloxacin, ofloxacin, norfloxacin, levofloxacin and moxifloxacin) have been published in November 2018.

1. The European Medicines Agency (EMA) has recently reviewed the side-effects associated with quinolone antibiotics (not licensed for use in the UK) and fluoroquinolone antibiotics given by mouth, injection or inhalation.<sup>(1)</sup>

Fluoroquinolones are associated with prolonged (up to months or years) serious, disabling and potentially irreversible drug reactions including tendonitis, tendon rupture, arthralgia, pain in extremities, gait disturbance, neuropathies associated with paraesthesia, depression, fatigue, memory impairment, sleep disorders, and impaired hearing, vision, taste and smell. **NB Tendon damage (especially to Achilles tendon but also other tendons) can occur within 48 hours of starting fluoroquinolone treatment but the damage may be delayed several months after stopping treatment.**

**The EMA recommends that fluoroquinolone antibiotics should NOT be used in the following circumstances:**

- 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.
- fluoroquinolones should generally 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 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.**

**If prescribed, fluoroquinolone treatment should be discontinued at the first sign of tendon pain or inflammation. Patients should be advised to stop treatment with a fluoroquinolone and speak with the doctor in case of symptoms of neuropathy such as pain, burning, tingling, numbness or weakness to prevent development of potentially irreversible conditions.**

2. The Medicines and Healthcare Regulatory Agency (MHRA) issued a separate safety alert regarding fluoroquinolones <sup>(2)</sup> which states **systemic and inhaled fluoroquinolones may be associated with a small increased risk of aortic aneurysm and dissection, particularly in older patients.**

**The recommendations of the MHRA were:**

- Fluoroquinolones should only be used after careful benefit-risk assessment and after consideration of other therapeutic options in patients at risk for aortic aneurysm and dissection. See [link](#) for conditions predisposing to aortic aneurysm and dissection.
- Advise patients, particularly elderly people and those at risk, about rare events of aortic aneurysm and dissection and of the importance of seeking immediate medical attention in case of sudden-onset severe abdominal, chest or back pain.

**To contact the Medicines Optimisation Team please phone 01772 214302**

#### References:

1. Disabling and potentially permanent side effects lead to suspension or restrictions of quinolone and fluoroquinolone antibiotics. European Medicines Agency 16<sup>th</sup> November 2018. [EMA: Quinolone and Fluoroquinolone Review](#)
2. Systemic and inhaled fluoroquinolones: small increased risk of aortic aneurysm and dissection; advice for prescribing in high-risk patients. Drug safety update from MHRA. 14<sup>th</sup> November 2018. [Drug safety update: Fluoroquinolones](#)