Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

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Fluoroquinolone antibiotics: ciprofloxacin, levofloxacin, moxifloxacin, ofloxacin

New restrictions and precautions due to very rare reports of disabling and potentially long-lasting or irreversible side effects

- Disabling, long-lasting or potentially irreversible adverse reactions affecting musculoskeletal (including tendonitis and tendon rupture) and nervous systems have been reported with fluoroquinolone antibiotics – see Drug Safety Update for more information

- Prescribers and dispensers of fluoroquinolones should advise patients to stop 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 for further advice – see MHRA sheet to discuss measures with patients

- Fluoroquinolone treatment should be discontinued at the first sign of tendon pain or inflammation in patients and the affected limb or limbs appropriately treated (for example with immobilisation)

Fluoroquinolones should not be prescribed for:

- non-severe or self-limiting infections, or non-bacterial conditions
- mild to moderate infections (such as in acute exacerbation of chronic bronchitis and chronic obstructive pulmonary disease) unless other antibiotics that are commonly recommended for these infections are considered inappropriate*
- uncomplicated cystitis (for which ciprofloxacin or levofloxacin were previously authorised) unless other antibiotics that are commonly recommended are considered inappropriate*

*For example, when first-line antibiotics are unsuitable due to resistance, contraindications, or intolerance, or if first-line treatments have failed.

- Avoid coadministration with corticosteroids since this could exacerbate fluoroquinolone-induced tendinitis and tendon rupture
- Avoid use in patients who have previously had serious adverse reactions with a quinolone or fluoroquinolone antibiotic
- Prescribe with special caution in 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

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Trigger for the advice on fluoroquinolones

An EU review of the safety fluoroquinolone and quinolone antibiotics was triggered by reports of disabling and potentially long-lasting, irreversible side effects mainly affecting the musculoskeletal and nervous systems. See Drug Safety Update for characteristics of reactions reported.

The review identified 286 cases of serious adverse reactions reported as disabling and lasting for 30 days or more, without any alternative explanations, from across the EU over a 21-year period. Although cumulative fluoroquinolone patient exposure data are not available for this time period, it is estimated that more than 300 million daily doses of fluoroquinolone antibiotics are dispensed every year in the EU.

Although relatively few cases have been reported, under-reporting is likely. Due to the seriousness of these reactions sometimes reported in previously healthy people, any decision to prescribe a fluoroquinolone should be taken after a careful assessment of the benefits and risks in each case.

If fluoroquinolones are to be used, prescribers should ensure they consult the Summary of Product Characteristics and national guidance, and inform patients of the actions they should take at the first signs of a serious adverse reaction.

Report any suspected adverse event reactions to fluoroquinolones to the Yellow Card Scheme online (https://yellowcard.mhra.gov.uk/) or the Yellow Card App (download via iTunes Yellow Card for iOS devices or via PlayStore Yellow Card for Android devices).

Nalidixic acid

The quinolone nalidixic acid was authorised for urinary tract infections, which is no longer a permitted indication. Therefore, the licence for nalidixic acid has been cancelled.

Yours sincerely,

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