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Systemic and inhaled quinolone and fluoroquinolone antibiotics – risk of disabling and potentially long-lasting side effects and restrictions on use

Ciprofloxacin

Dear Healthcare professional,

Marketing authorisation holders of quinolone and fluoroquinolone antibiotics products in agreement with the European Medicines Agency (EMA) and the Pharmacy and Poisons Board would like to inform you on the following:

Summary

- Disabling, long-lasting and potentially irreversible but very rare, adverse reactions mainly affecting musculoskeletal and nervous systems have been reported with quinolone and fluoroquinolone antibiotics.
- As a consequence, the benefits and risks of all quinolone and fluoroquinolone antibiotics and their indications across the EU were reviewed. (Also, the medicinal products containing nalidixic acid, pipemidic acid, cinoxacin and flumequine will be removed from the market.)
- Do not prescribe these medicines
    - for treating non-severe or self-limiting infections (such as pharyngitis, tonsillitis and acute bronchitis)
    - for preventing travellers' diarrhoea or recurrent lower urinary tract infections
    - for patients who have previously had serious adverse reactions with a quinolone or fluoroquinolone antibiotic
    - for mild to moderate infections (including uncomplicated cystitis, acute exacerbation of chronic bronchitis and chronic obstructive pulmonary disease (COPD), acute bacterial rhinosinusitis and acute otitis media) unless other antibiotics that are commonly recommended for these infections are considered inappropriate.
- Caution should be used especially when prescribing for the elderly, patients with renal impairment, patients with solid organ transplants, and those concurrently treated with corticosteroids, as the risk of fluoroquinolone-induced tendinitis and tendon rupture may be exacerbated in these patients.
- **Advise patients to stop treatment immediately** at the first signs of a serious adverse reaction, such as tendinitis and tendon rupture, muscle pain, muscle weakness, joint pain, joint swelling, peripheral neuropathy and central nervous system effects and to contact their doctor for further advice.

Background to safety concern

EMA has reviewed systemic and inhaled quinolone and fluoroquinolone antibiotics to evaluate the risk of serious and persistent (lasting months or years), disabling and potentially irreversible adverse reactions mainly affect the musculoskeletal and nervous systems.

Serious adverse reactions of the musculoskeletal system include tendinitis, tendon rupture, myalgia, muscle weakness, arthralgia and joint swelling.

Serious peripheral and central nervous system effects include peripheral neuropathy, psychosis, anxiety, insomnia, depression, hallucinations, suicidal thoughts, confusion, as well as impairment of vision, hearing, smell and taste.

Only a few cases of these disabling and potentially irreversible adverse reactions have been reported, but underreporting can be assumed. Due to the seriousness of these reactions in previously healthy persons, any decision to prescribe quinolones and fluoroquinolones should be taken after a careful assessment of the benefits and risk.

The product information for fluoroquinolones containing medicines will be updated with this new information.

Call for reporting

Healthcare professionals are encouraged to report adverse events in patients taking quinolone or fluoroquinolone antibiotics to Pharmacy and Poisons Board according to the national pharmacovigilance guidelines

Company contact point

Kindly contact the undersigned should you require further clarification.

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Yours Faithfully,

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Yours faithfully,

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