



EUROPEAN MEDICINES AGENCY
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Fluoroquinolone and quinolone antibiotics: PRAC recommends restrictions on use

New restrictions follow review of disabling and potentially long-lasting side effects

EMA's Pharmacovigilance Risk Assessment Committee (PRAC) has recommended restricting the use of fluoroquinolone and quinolone antibiotics (used by mouth, injection or inhalation) following a review of disabling and potentially long-lasting side effects reported with these medicines. The review incorporated the views of patients, healthcare professionals and academics presented at EMA's public hearing on fluoroquinolone and quinolone antibiotics in June 2018.

Very rarely, patients treated with fluoroquinolone or quinolone antibiotics have suffered long-lasting and disabling side effects, mainly involving muscles, tendons and bones and the nervous system.

Following its evaluation of these side effects, the PRAC has recommended that some medicines, including all those that contain a quinolone antibiotic, should be removed from the market. This is because they are authorised only for infections that should no longer be treated with this class of antibiotics.

The PRAC recommended that the remaining fluoroquinolone antibiotics should:

- **not** be used
 - to treat infections that might get better without treatment or are not severe (such as throat infections);
 - for preventing traveller's diarrhoea or recurring lower urinary tract infections (urine infections that do not extend beyond the bladder);
 - to treat patients who have previously had serious side effects with a fluoroquinolone or quinolone antibiotic;
 - to treat mild or moderately severe infections unless other antibacterial medicines commonly recommended for these infections cannot be used;
- be used **with caution** especially for the elderly, patients with kidney problems, patients who have had an organ transplantation or those who are being treated with a systemic corticosteroid. These patients are at higher risk of tendon injury caused by fluoroquinolone and quinolone antibiotics.



The PRAC also recommended that healthcare professionals should advise patients to stop treatment with a fluoroquinolone antibiotic at the first sign of a side effect involving muscles, tendons or bones (such as inflamed or torn tendon, muscle pain or weakness, and joint pain or swelling) or the nervous system (such as feeling pins and needles, tiredness, depression, confusion, suicidal thoughts, sleep disorders, vision and hearing problems, and altered taste and smell).

Prescribing information of individual fluoroquinolone antibiotics will be updated to reflect the restricted use.

The PRAC recommendations will now be sent to EMA's Committee for Medicinal Products for Human Use (CHMP), which will adopt the Agency's final opinion.

More about the medicine

Fluoroquinolones and quinolones are a class of broad-spectrum antibiotics that are active against bacteria of both Gram-negative and Gram-positive classes.

The review covered the following medicines: ciprofloxacin, flumequine, levofloxacin, lomefloxacin, moxifloxacin, norfloxacin, ofloxacin, pefloxacin, prulifloxacin and rufloxacin (fluoroquinolone antibiotics); cinoxacin, nalidixic acid, pipemidic acid (quinolone antibiotics).

The review concerned only medicines given systemically (by mouth or injection) and inhaled medicines.

More about the procedure

The review of fluoroquinolones and quinolones was initiated on 9 February 2017 at the request of the German medicines authority (BfArM), under [Article 31 of Directive 2001/83/EC](#).

The review has been carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which has made a set of recommendations. The PRAC recommendations will now be sent to the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt the Agency's opinion.

The final stage of the review procedure is the adoption by the European Commission of a legally binding decision applicable in all EU Member States. The new restrictions on the use of fluoroquinolones and quinolones will become applicable after a Commission decision is issued.