Direct Healthcare Professional Communication

July 2023

Systemic and inhaled fluoroquinolone antibiotics – reminder on restrictions of use

Dear Healthcare Professional,

The General Administration for Pharmaceutical Vigilance of the Central Administration for Pharmaceutical Care at The Egyptian Drug Authority would like to inform you of the following:

Summary:

- Recent study data suggest that fluoroquinolones continue to be prescribed outside of the recommended uses.
- Systemic and inhaled fluoroquinolones should NOT be prescribed for:
  - Patients who have previously had serious adverse reactions with a quinolone or fluoroquinolone antibiotic;
  - Non-severe or self-limiting infections (such as pharyngitis, tonsillitis and acute bronchitis);
  - 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;
  - Non-bacterial infections, e.g. non-bacterial (chronic) prostatitis;
  - Preventing travellers' diarrhoea or recurrent lower urinary tract infections.
- Systemic and inhaled fluoroquinolones are associated with very rare, serious, disabling, long-lasting and potentially irreversible adverse reactions. These products should be prescribed only for approved indications and after careful assessment of the benefits and risks in the individual patient.

Background to safety concern:

The European Medicines Agency (EMA) made strong recommendations to restrict the use of systemic and inhaled fluoroquinolones following an EU-wide review conducted in 2018 to evaluate the risk of serious and long-lasting (lasting months or years), disabling and potentially irreversible adverse reactions mainly affecting the musculoskeletal and nervous system. As a consequence of the review conducted by EMA, the use of fluoroquinolone medicines was significantly restricted in 2019.

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These serious adverse reactions can include tendinitis, tendon rupture, arthralgia, pain in extremities, gait disturbance, neuropathies associated with paraesthesia, depression, fatigue, memory impairment, hallucinations, psychosis, sleep disorders and impaired senses (hearing, vision, taste and smell). Tendon damage (especially to Achilles tendon but other tendons can also be involved) can occur within 48 hours of commencing treatment or the effects can be delayed for several months after stopping treatment.
An EMA-funded study was carried out ("Impact of European Union Label Changes for Fluoroquinolone Containing Medicinal Products for Systemic and Inhalation Use" (EUPAS37856)) which was based on an analysis of prescribing rates for fluoroquinolones in six European healthcare databases (from Belgium, France, Germany, the Netherlands, Spain and the United Kingdom).
The study suggests that fluoroquinolones may still be used outside the authorised indications.
However, due to the limitations of the study no definitive conclusions can be drawn.

- Healthcare professionals are reminded to advise patients:
  - of the risk of these serious adverse reactions;
  - of the potential long-lasting and serious nature of these effects;
  - to immediately seek a physician at the first signs of these serious adverse reactions prior to continuing treatment
- Special caution should be taken in patients who concurrently are treated with corticosteroids, in elderly, patients with renal impairment and patients who have undergone solid organ transplants, as the risk of fluoroquinolone-induced tendinitis and tendon rupture may be exacerbated in these patients.

References

EMA https://www.ema.europa.eu/en/documents/dhpc/direct-healthcare-professional-communication-dhpc-systemic-inhaled-fluoroquinolone-antibiotics_en.pdf

BfArM https://www.bfarm.de/SharedDocs/Risikoinformationen/Pharmakovigilanz/DE/RHB/2023/rhb-fluorchinolone.pdf?__blob=publicationFile

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: General Administration for Pharmaceutical Vigilance

Email: pv.followup@edaegypt.gov.eg

Online reporting: https://primaryreporting.who-umc.org/EG
QR Code:

Hotline: 15301

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