Safety Communication

[19/06/2023]

Reminder of the Potential Musculoskeletal Complications with the Use of Systemic and Inhaled Fluoroquinolone Antibiotics

The Saudi Food and Drug Authority (SFDA) would like to remind healthcare professionals that fluoroquinolone antibiotics given orally, intravenously, or inhaled have potential side effects of disabling, long-lasting, and irreversible effects. Fluoroquinolone medicines are a family of broad-spectrum antibiotics that are active against bacteria of both Gram-negative and Gram-positive classes. Fluoroquinolones can be used in certain infections, including some life-threatening ones, where alternative antibiotics are not sufficiently effective. Medications containing fluoroquinolones approved by the SFDA include ciprofloxacin, gemifloxacin, levofloxacin, lomefloxacin, moxifloxacin, norfloxacin, delafloxacin and ofloxacin.

The fluoroquinolone antibiotics should not be used:

- To treat non-sever infections such as throat infections.
- To treat non-bacterial infections such as non-bacterial (chronic) prostatitis.
- For preventing traveler's diarrhea or recurring lower urinary tract infections.
- To treat mild or moderate bacterial infections unless other antibacterial medicines commonly recommended for these infections cannot be used.

Please visit the SFDA website to look at registered Fluoroquinolones in Saudi Arabia via this link https://www.sfda.gov.sa/en/drugs-list.

In 2018, the SFDA evaluated the potential risk of serious and long-lasting, disabling and potentially irreversible adverse reactions mainly affecting the musculoskeletal and nervous system with fluoroquinolone antibiotics.

These serious adverse reactions can include tendinitis, tendon rupture, arthralgia, pain in extremities, gait disturbance, neuropathies associated with paranesthesia, 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.

Based on the available evidence from all post marketing sources, the SFDA recommended labeling update of all fluoroquinolone containing products to include warnings and precautions that fluoroquinolones should be avoided in patients with previous serious side effects to fluoroquinolone or quinolone antibiotic. They should be used with special caution in the elderly, patients with kidney disease and in those who have had an organ transplantation because these patients are at a higher risk of tendon injury. Concomitant use of corticosteroids and fluoroquinolones also increases this risk and should be avoided.

Advice for healthcare professionals:

- The use of inhaled and systemic quinolone and fluoroquinolone antibiotics due to the risk of rare but long-lasting , serious, disabling and potentially irreversible adverse reactions affecting different, sometimes multiple, body systems (musculoskeletal, nervous, psychiatric and senses).
- To reduce the risk of side effects, these antibiotics should only be prescribed for approved indications in the product information after a thorough evaluation of the benefits and risks for a particular individual.
- Specific caution should be taken when prescribing fluoroquinolones in older patients, those with renal impairment, solid organ transplantation or on systemic corticosteroids as the risk of some adverse reactions (e.g. tendonitis, tendon rupture) are higher in these patients. Concomitant treatment with fluoroquinolones and corticosteroids should be avoided.
- Patients should be well-informed of the risks associated with fluoroquinolones earlier before initiating treatment, including the potentially long-lasting and serious nature of these side effects, and counseled to stop treatment and speak with their doctor at the first signs or symptoms of these adverse reactions.

- Fluoroquinolone treatment should be discontinued, and alternative treatment should be considered at the first sign of tendon pain or inflammation or of symptoms of neuropathy such as pain, burning, tingling, numbness, or weakness, so as to prevent development of potentially irreversible adverse reactions.

- **Please see the Summary of Product Characteristics (SPC) for further information.**

Call for reporting:

The SFDA urges both healthcare professionals and patients to report ADRs related to use of any medication to the SFDA using the following contact information:

The National Pharmacovigilance Centre (NPC):

Fax: +966-11-205-7662

SFDA Call Center: 19999

E-mail: npc.drug@sfda.gov.sa

Website: https://ade.sfda.gov.sa

aRMM: