



**MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD**

Ref. PPB/MIP/PMS/CIR/005/18-19

14th January ,2019

Dear Healthcare Provider,

Re: Systemic and inhaled quinolone and fluoroquinolone antibiotics

Fluoroquinolones and quinolones are a class of broad-spectrum antibiotics that are active against bacteria of both Gram-negative and Gram-positive classes. Fluoroquinolones are of value in certain infections, including some life-threatening ones, where alternative antibiotics are not sufficiently effective.

The Pharmacy and Poisons Board in agreement with the European Medicines Agency and Marketing Authorization Holders of quinolone and fluoroquinolone antibiotics products and would like to inform you on two major updates on the use of quinolones and fluoroquinolones

1. Systemic and inhaled quinolones and fluoroquinolones:
Risk of disabling and potentially irreversible serious side effects and restrictions on use.
2. Systemic and inhaled quinolones and fluoroquinolones:
New warning about the risk of aortic aneurysm and dissection

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

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

Summary

Applicable to Quinolones and Fluoroquinolones

- Disabling, long-lasting and potentially irreversible 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 were reviewed.

- **Do not** prescribe these medicines
 - for treating non-severe or self-limiting infections (such as pharyngitis, tonsillitis and acute bronchitis)
 - for preventing travelers' diarrhoea or recurrent lower urinary tract infections
 - for non-bacterial infections, e.g. non-bacterial (chronic) prostatitis
 - 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.
 - for patients who have previously had serious adverse reactions with a quinolone or fluoroquinolone antibiotic
- **Prescribe these medicines with special caution** 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. Concomitant use of corticosteroids with fluoroquinolones should be avoided.
- Advise patients to **stop treatment** 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.

Applicable to Fluoroquinolones

- Systemic and inhaled Fluoroquinolones may increase the risk of aortic aneurysms and dissection, particularly in older people. Fluoroquinolones should only be used in patients at risk after careful benefit-risk assessment and consideration of other therapeutic options.
- Patients should be advised about the risk of aortic aneurysm and dissection and told to seek immediate medical attention in case of sudden severe abdominal, chest or back pain.

Background to safety concern

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

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

Serious peripheral and central nervous system effects include peripheral neuropathy, insomnia, depression, fatigue, memory impairment, 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 in each case.

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

Call for reporting

Reporting suspected adverse reactions is important as it allows continued monitoring of the benefit/risk balance of medicinal product.

Healthcare professionals are encouraged to report adverse events in patients taking quinolone or fluoroquinolone antibiotics to Pharmacy and Poisons Board in accordance with the national pharmacovigilance reporting system.

Any suspected adverse events should be reported to Pharmacy and Poisons Board, Lenana Road. P.O. Box 27663-00506 Nairobi. Email: pv@pharmacyboardkenya.org or report directly online at www.pv.pharmacyboardkenya.org



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