

FDA/HPT/MVC/SMD/VGU/23/0224

4th July 2023

Dear Healthcare Professional,

FLUOROQUINOLONE ANTIBIOTICS: REMINDER OF MEASURES TO REDUCE THE RISK OF LONG-LASTING, DISABLING AND POTENTIALLY IRREVERSIBLE SIDE EFFECTS

The Food and Drugs Authority (FDA) wishes to remind you of the measures to reduce the risk of long-lasting, disabling and potentially irreversible side effects of fluoroquinolone medicines given by mouth, injection or inhalation, involving the nervous system, tendons, muscles and joints. This is an update to the precautions recommended by the FDA in 2019 regarding increased risk of raptures or tears in aorta blood vessel published on the FDA website <http://www.fdaghana.gov.gh/healthletter.php>

Fluoroquinolone medicines are antibacterial drugs approved to treat certain bacterial infections and they work by killing or stopping the growth of bacteria that can cause illness: they have activity against both gram negative and gram-positive bacteria. Fluoroquinolone containing medicines registered by the FDA are Ciprofloxacin, Levofloxacin, Moxifloxacin, Norfloxacin and Ofloxacin.

Advice for healthcare professionals

- Only prescribe fluoroquinolone containing medicine within their approved **indications** and after a careful assessment of the benefits and risks in individual patients.
- 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 is higher in these patients.
- Concomitant treatment with a fluoroquinolone and a corticosteroid should be avoided.
- 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, to prevent development of potentially irreversible adverse reactions.

Advice for patients

Patients should be informed of the risks associated with fluoroquinolones before initiating treatment and advised to seek immediate medical attention on seeing any of these signs if taking a fluoroquinolone-containing drug.

- tendon pain or swelling, particularly in the ankle or calf and to rest the painful area when any of these happen.
- pain, numbness, tingling, swelling, or muscle weakness in different parts of the body, often beginning in the hands or feet, that gets worse over time.
- severe tiredness, depression, poor memory or severe problems sleeping.
- changes in vision, hearing, taste and smell.
- swelling in your shoulders, arms or legs, or pains in your joints.

Healthcare professionals and the public are requested to report adverse reactions to fluoroquinolone medicines and all products including lack of therapeutic effect and medication errors through the following:

- Download and complete the Med Safety App from Google Play Store or App Store.
- Complete and submit the report online at <http://adr.fdaghana.gov.gh/>
- Download and complete the Adverse Reaction Reporting Form available on the FDA website at www.fda.gov.gh.

For additional information you may call the FDA on the hot line **0551112224/5** or the Safety Monitoring Department (National Pharmacovigilance Centre) on **+233 244 310 297**

Yours sincerely,



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CHIEF EXECUTIVE OFFICER