

FDA/SMC/SMD/VGU/19/0087

27th February 2019

Dear Healthcare Professional,

RESTRICTIONS ON THE USE OF FLUOROQUINOLONES DUE TO INCREASED RISK OF RUPTURES OR TEARS IN THE AORTA BLOOD VESSEL IN CERTAIN PATIENTS

The Food and Drugs Authority (FDA) wishes to bring to your attention a new safety information relating to rare but serious adverse events of increased risk of ruptures or tears in aorta blood vessel (i.e. aortic dissections) in certain patients due to the use of systemic fluoroquinolone antibacterial agents given by mouth or through an injection. Aortic dissections can lead to dangerous bleeding or even death.

Persons at risk of aortic dissections include persons with history of blockages or aneurysms (abnormal bulges) of the aorta or other blood vessels, high blood pressure, certain genetic disorders that involve blood vessel changes and the elderly.

Fluoroquinolone 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.

In Ghana, fluoroquinolone antibacterial agents registered by the FDA are Ciprofloxacin, Levofloxacin, Moxifloxacin, Norfloxacin, and Ofloxacin. The list can also be accessed at the FDA website at <https://fdaghana.gov.gh/records/>.

Advise to Healthcare Professionals:

- Avoid prescribing fluoroquinolone antibiotics to patients who have an aortic aneurysm or are at risk for an aortic aneurysm, such as patients with peripheral atherosclerotic vascular diseases, hypertension, certain genetic conditions such as Marfan syndrome and Ehlers-Danlos syndrome, and elderly patients.
- Prescribe fluoroquinolones to above at risk patients only when no other treatment options are available.
- Advise all patients to seek immediate medical treatment for any symptoms associated with aortic aneurysm.
- Stop fluoroquinolone treatment immediately if a patient reports side effects suggestive of aortic aneurysm or dissection

Additionally, healthcare professionals should advise patients:

- To seek medical attention immediately by going to the hospital if you experience sudden, severe and constant pain in the stomach, chest or back.
- That symptoms of an aortic aneurysm often do not show up until the aneurysm becomes large or bursts, so report any unusual side effects from taking fluoroquinolones to your health care professional immediately.
- That before starting an antibiotic prescription, inform your health care professional if you have a history of aneurysms, blockages or hardening of the arteries, high blood pressure or genetic conditions such as Marfan syndrome or Ehlers-Danlos syndrome.
- Not to stop taking fluoroquinolone antibiotic without first talking to your health care professional if you have been prescribed one.

The FDA will like to advise healthcare professionals to educate patients on the possible side effect of all medicines and also report these to the FDA by completing the Adverse Reaction Reporting Form or online using the link <http://adr.fdaghana.gov.gh/> or call 024 431 0297 or send an email to drug.safety@fdaghana.gov.gh.

Yours faithfully,

Signed

DELESE A. A. DARKO (MRS)
CHIEF EXECUTIVE OFFICER