



RWANDA FDA
Rwanda Food and Drugs Authority
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Kigali, 08 JUL 2019
Ref N° 0691/Rwanda FDA/2019

RWANDA FDA SAFETY COMMUNICATION

Re: Information about serious low blood sugar levels and mental health side effects with fluoroquinolone antibiotics; requires label changes

Referring to the new safety information published by WHO Pharmaceuticals NEWSLETTER NO. 4/2018 reference also made to the USFDA safety communication about serious low blood sugar levels and mental health side effects with fluoroquinolone antibiotics that requires label changes, Rwanda FDA would like to inform you of the following:

- Current warnings in the prescribing information states that fluoroquinolone antibiotics may cause significant decreases in blood sugar and certain mental health side effects. The low blood sugar levels can result in serious problems, **including coma**, particularly in older people and patients with diabetes who are taking medicines to reduce blood sugar. These changes are due to that recent review found reports of life-threatening low blood sugar side effects and reports of additional mental health side effects.

Rwanda FDA is requiring updates in the drug labels and to the patient Medication Guides for the entire class of fluoroquinolones (**Available Fluoroquinolones associated with the highlighted events in Rwanda: levofloxacin, ciprofloxacin, ciprofloxacin extended-release tablets,**

moxifloxacin, ofloxacin). This affects only the fluoroquinolone formulations taken by mouth or given by injection. Blood sugar disturbances, including high blood sugar and low blood sugar, are already included as a warning in most fluoroquinolone drug labels; however, we are adding that low blood sugar levels, also called hypoglycaemia, **can lead to coma**.

- Across the fluoroquinolone antibiotic class, a range of mental health side effects are already described under *Central Nervous System Effects* in the *Warnings and Precautions* section of the drug label, which differed by individual drug. The new label changes will make the mental health side effects more prominent and more consistent across the systemic fluoroquinolone drug class. The mental health side effects to be added to or updated across all the fluoroquinolones are **disturbances in attention, disorientation, agitation, nervousness, memory impairment, and serious disturbances in mental abilities called delirium**

Information to Patients

Patients should tell their health care professionals if you are taking a diabetes medicine when the health care professional is considering prescribing an antibiotic, and also if you have low blood sugar or symptoms of it while taking a fluoroquinolone. For patients with **diabetes**, your health care professional may ask you to check your blood sugar more often while taking a fluoroquinolone. Early signs and symptoms of low blood sugar include: confusion, pounding heart or very fast pulse, dizziness, feeling shaky, unusual hunger, headaches, irritability, sweating, trembling, weakness, unusual anxiety and pale skin.

Information to Healthcare professionals

Health care professionals should be aware of the potential risk of hypoglycemia sometimes resulting in coma, occurring more frequently in the elderly and those with diabetes taking an oral hypoglycemic medicine or insulin. Alert patients of the symptoms of hypoglycemia and carefully monitor blood glucose levels in these patients, and discuss with them how to treat them if they have symptoms of hypoglycemia. Inform patients about the risk of psychiatric adverse reactions that can occur after just one dose. Stop fluoroquinolone treatment immediately if a patient reports any central

nervous system side effects, including psychiatric adverse reactions, or blood glucose disturbances and switch to a non-fluoroquinolone antibiotic if possible.

Health care professionals should not prescribe fluoroquinolones to patients who have other treatment options for acute bacterial sinusitis (ABS), acute bacterial exacerbation of chronic bronchitis (ABECB), and uncomplicated urinary tract infections (uUTI) because the risks outweigh the benefits in these patients.

Marketing Authorization Holders

- Rwanda FDA is requiring changes in the section of *Warnings and Precautions* of fluoroquinolones to include and describe **hypoglycemic coma**,
- The labels of fluoroquinolones currently include many psychiatric adverse reactions in the *Warnings and Precautions* section, for example, hallucination, psychoses, confusion, depression, anxiety, and paranoia. In an effort to harmonize the psychiatric adverse reactions described in the drug labels across the class of fluoroquinolones, Rwanda FDA is requiring that all fluoroquinolones include the new six psychiatric adverse reactions (**disturbance in attention, memory impairment, delirium, nervousness, agitation, and disorientation**)

We urge patients and health care professionals to report adverse events involving fluoroquinolones or other drugs to Rwanda FDA by completing the Adverse drug events reporting form and send it to: info@rwandafda.gov.rw or ltirenganya@rwandafda.gov.rw

Sincerely,



Dr. Charles KARANGWA
Ag. Director General of Rwanda FDA

Reference

1. WHO, *WHO Pharmaceuticals NEWSLETTER* No. 4, 2018 accessible on <http://www.who.int/medicines>

2. USFDA, *FDA reinforces safety information about serious low blood sugar levels and mental health side effects with fluoroquinolone antibiotics; requires label changes July 2018* Accessible on <https://www.fda.gov/news-events>

2. Dinesh Kumar Singal, Amit Mittal, and Anukalp Prakash, *Recurrent episodes of hypoglycaemia induced by moxifloxacin published Indian Journal of Pharmacology* accessed on <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3696308/>