

Ref: B/279/35/9/2018

9th August 2018

Circular 9 of 2018

To:

- 1) Zimbabwe Medical Association
- 2) Medical and Dental Practitioners Council of Zimbabwe
- 3) Retail and Hospital Pharmacies
- 4) Pharmaceutical Society of Zimbabwe
- 5) Retail Pharmacists Association

Dear All

RE: SAFETY NOTIFICATIONS FOR FLUOROQUINOLONE ANTIBIOTICS – LOW BLOOD SUGAR LEVELS AND MENTAL HEALTH SIDE EFFECTS

The Authority wishes to notify health care professionals of the reinforcement of safety information about serious low blood sugar levels and mental health side effects associated with fluoroquinolone antibiotics after reviewing a notification recently issued by the US FDA.

Health care professionals are therefore being advised as follows:

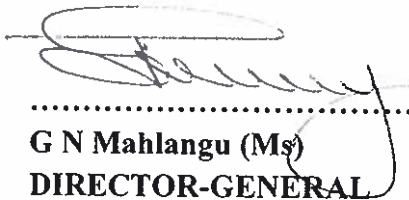
1. Health care professionals should be aware of the potential risk of hypoglycemia sometimes resulting in coma, occurring more frequently in the elderly and those with diabetes taking an oral hypoglycemic medicine or insulin.
2. Alert patients of the symptoms of hypoglycemia and carefully monitor blood glucose levels in these patients, and discuss with them how to treat themselves if they have symptoms of hypoglycemia.
3. Inform patients about the risk of psychiatric adverse reactions that can occur after just one dose.
4. 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.

5. Stop fluoroquinolone treatment immediately if a patient reports serious side effects involving the tendons, muscles, joints, or nerves, and switch to a non-fluoroquinolone antibiotic to complete the patient's treatment course.
6. 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.

The Authority urges health care professionals to report side effects involving fluoroquinolones or other medicines to the Medicines Control Authority of Zimbabwe using the available reporting tools.

Yours faithfully

MEDICINES CONTROL AUTHORITY OF ZIMBABWE



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G N Mahlangu (Ms)
DIRECTOR-GENERAL