RWANDA FDA
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Kigali on; 24/06/2021
Ref N°: DIS/2290 /FDA/2021

MEDICINE SAFETY COMMUNICATION

Medicine: **Ceftriaxone**

RE: **Rwanda FDA warns on Increased risk of hypokalemia in patients treated with Ceftriaxone**

Reference is made to the new safety information published in the WHO Pharmaceutical NEWSLETTER N^0 1/2021, and further reference is made to safety signal published by Saudi Food and Drug Authority (SFDA) on hypokalemia associated with the use of Ceftriaxone

Ceftriaxone is a broad-spectrum third generation cephalosporin antibiotic indicated for the treatment of infections in various locations, such as in the respiratory tract, skin, soft tissue, and urinary tract. It acts by inhibiting the mucopeptide synthesis in the bacterial cell wall leading to the weakening of the bacterial cell wall and causes cell lysis.

Ceftriaxone increase the urinary potassium excretion, which cause hypokalemia. Hypokalemia defined, as a serum potassium concentration of less than 3.5 mEq/L is one of the most commonly encountered electrolyte abnormalities in clinical practice. Patients with mild hypokalemia are usually asymptomatic, whereas patients with moderate-to-severe hypokalemia present with generalized weakness, gastrointestinal disturbances associated with paralytic ileus, cardiac arrhythmias and acute respiratory failure, hepatic encephalopathy.

After conducting literature review and analysis of above safety information, Rwanda FDA is recommending health professionals patients/care givers and marketing authorization holders to consider the following on Ceftriaxone due to the risk of hypokalemia.

Information for healthcare professionals

- ✓ Health-care professionals should be aware of this potential adverse reaction and weight the benefits of prescribing Ceftriaxone to patients because of increased risk of hypokalemia.
- ✓ Rwanda FDA advice Health care professionals to consider monitoring serum potassium levels and any signs or symptoms of Hypokalemia when administered ceftriaxone parentally.
- ✓ Healthcare professionals should not prescribe Ceftriaxone when the patient is receiving concomitant medications known to cause hypokalemia such loop and thiazide diuretics.
- ✓ Educate patients how to recognize the signs and symptoms of hypokalemia

Information for caregivers and patients

- ✓ Rwanda FDA recommends patients to watch closely for signs of hypokalemia when they are taking Ceftriaxone
- ✓ Do not stop taking Ceftriaxone unless they talk to the healthcare professionals

Information for Marketing Authorization Holders

- ✓ Rwanda FDA requests Marketing Authorization Holders to update the patient leaflet or boxed information on the risk of hypokalemia to patients taking Ceftriaxone

Rwanda FDA urges patients and healthcare providers to report the suspected serious adverse drug events related to Ceftriaxone and other medicines to Rwanda FDA by filling information in online reporting system https://pvims.rwandafda.gov.rw/public/spontaneous or by completing ADR/AEFI reporting form accessible on Rwanda FDA website on the link http://w.w.w.rwandafda.gov.rw/web/fileadmin/adr-aefi_reporting_form.pdf and the filled form should be sent to the email: pv_sm@rwandafda.gov.rw and copy to info@rwandafda.gov.rw

Sincerely,

Dr. Charles KARANGWA
Ag. Director General

REFERENCES

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