RWANDA FDA
Rwanda Food and Drugs Authority
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Kigali, 12/01/2021
Ref Nº: DIS/ 003 /FDA/2021

MEDICINE SAFETY COMUNICATION

Medicine: Clarithromycin

Re: Rwanda FDA warns on potential risk of heart problems in patients with heart disease treated with Clarithromycin

Reference is made to the new safety information published in the WHO Pharmaceutical NEWSLETTER Nº. 2/ 2018 **[1]** and further reference is made to drug safety communication published by US FDA on the risk of cardiovascular events and death associated with the use of Clarithromycin **[2];**

Clarithromycin is an antibiotic of macrolide class, commonly prescribed to treat respiratory tract infections, helicobacter pylori infection and duodenal ulcer disease, treatment and prophylaxis of disseminated mycobacterial infections.

Macrolides classes of drug including Clarithromycin have the greatest potential among antibiotics to cause QT interval prolongation, torsades de pointes and potentially increase the risk of cardiovascular events or lead to cardiac death **[3, 4].** Therefore, Clarithromycin acts by activating macrophages and initiate an inflammatory cascade and, as result to plaque rupture that lead to increase acute coronary syndrome.

Rwanda FDA is warning health professionals, marketing authorization holders and patients on the risk of cardiovascular events associated with QT prolongation, arrhythmia, myocardial infarction and death while using Clarithromycin in patients with heart diseases.

Information for Healthcare professionals

- ✓ Healthcare providers should be aware of significant risk and weight the benefits of prescribing clarithromycin to patient with heart disease because of a potential increased risk of heart problems or death that can occur later.

- ✓ Prescribers should advise patients with heart disease of the signs and symptoms of cardiovascular problems.
- ✓ Educate patients with heart disease about how to recognize the signs and symptoms of cardiovascular problems
- ✓ Patients with high risk factors for heart disease should not be treated with Clarithromycin

Information for patients

- ✓ Patients should contact their healthcare professionals if they experience any symptoms of heart problem while taking Clarithromycin.
- ✓ Do not stop taking Clarithromycin unless they talk to the healthcare professionals

Information for Marketing Authorization Holders

- ✓ Rwanda FDA requests Marketing Authorization Holders to add boxed warning to the prescribing information for risk of death and cardiac problems for the patient with heart diseases under clarithromycin treatment

Rwanda FDA urges patients and healthcare professionals to report the suspected serious adverse drug Clarithromycin and others medicines to Rwanda FDA 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 (s) should be sent to the email: pv-sm@rwandafda.gov.rw and copy to info@rwandafda.gov.rw

Sincerely,

Digitally signed by Rwanda FDA (Ag DG)
Date: 2021.01.13 18:24:55 +02'00'

Dr. Charles KARANGWA
Ag. Director General

References

1. WHO, WHO Pharmaceutical NEWSLETTER No 2/2018 accessible on https://www.who.int/publications-detail/who-pharmaceuticalsnewsletter

2. US FDA, Clarithromycin risk for patients with heart disease accessible on https://www.aafp.org/news/health-of-the-public/20180301clarithromycin.html

3. Xiang Li, et al. Macrolides use and the risk of sudden cardiac death, accessible on http://www.tandfonline.com/action/journallnformation?journalcode=ierz20
4. Malin Inghammar et al. American Journal of Epidemiology, accessible on https://doi.org/10.1093/aje/kwx359