



RWANDA FDA

Rwanda Food and Drugs Authority

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Kigali on; 11/08/2021

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DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Re: A drug interaction signal of Amiodarone and rivaroxaban resulting in gastrointestinal haemorrhage

Dear Health professionals,

Reference made to the WHO global database of individual cases safety report (Vigibase) [1] through its spontaneous reporting programme has received a variety noticed preliminary signal regarding the interaction between amiodarone and rivaroxaban resulting in gastrointestinal haemorrhage.

Amiodarone is an antiarrhythmic drug used for the conversion and prevention of supraventricular arrhythmias, known as atrial fibrillation. Amiodarone belongs to class III of the antiarrhythmic drugs family [2]. Rivaroxaban is an orally bioavailable, highly selective factor Xa inhibitor, blocking the intrinsic as well as the extrinsic pathway of the blood coagulation cascade.

Amiodarone increases levels of rivaroxaban by affecting hepatic/intestinal enzyme CYP3A4 metabolism. Patients with renal impairment receiving rivaroxaban with drugs that are combined weak or moderate CYP3A4 inhibitors may have significant increases in exposure compared with patients with normal renal function and no inhibitor use, since both pathways of rivaroxaban elimination are affected. Since these increases may increase bleeding risk, use rivaroxaban in this situation only if the potential benefit justifies the potential risk [3] . Considering the above, Rwanda FDA has analysed different reports from global database (Vigibase) on the mentioned signal and formulated the following recommendations:

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Information for healthcare professionals

- Healthcare professionals should be aware of this potential signal of drug-drug interaction and weigh the benefits of prescribing the combination of amiodarone and rivaroxaban, which increase the risk of gastrointestinal hemorrhage.
- Healthcare professionals are advised to take precautions for patients taking amiodarone and rivaroxaban in combination and monitor the occurrence of gastrointestinal hemorrhage.
- Healthcare providers should educate patients under treatment with amiodarone and rivaroxaban on signs and symptoms of gastrointestinal haemorrhage.

Rwanda FDA urges patients and healthcare providers to report the suspected serious adverse drug events related to amiodarone and rivaroxaban and other medicines to Rwanda FDA by filling information in online reporting system accessible on

<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-aeft-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



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References

1. WHO-UMC, Amiodarone, Rivaroxaban and gastro-intestinal hemorrhage- a drug interaction signal accessible on <https://www.who-umc.org/research-scientific-development/signal-detection/signal-library/>
2. S. Fernandez, C. Lenoir, C. F. Samer, and V. Rollason, "Drug-drug interactions leading to adverse drug reactions with rivaroxaban: A systematic review of the literature and analysis of vigibase," *J. Pers. Med.*, vol. 11, no. 4, 2021, doi: 10.3390/jpm11040250. accessible online <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8066515/>
3. G. R. M. College, " A study of drug interaction of glipizide with amiodarone on blood glucose level in diabetic mice ' Dr Devendra Singh Doneriya Dr Praveen Gautam ," no. 6, pp. 20–22, 2018 accessible on [https://www.worldwidejournals.com/international-journal-of-scientific-research-\(IJSR\)/article/a-study-of-drug-interaction-of-glipizide-with-amiodarone-on-blood-glucose-level-in-diabetic-mice/MTU2NzA=/?is=1&b1=897&k=225](https://www.worldwidejournals.com/international-journal-of-scientific-research-(IJSR)/article/a-study-of-drug-interaction-of-glipizide-with-amiodarone-on-blood-glucose-level-in-diabetic-mice/MTU2NzA=/?is=1&b1=897&k=225)

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