SFDA SAFETY SIGNAL

"A signal is defined by the SFDA as reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously. Usually m ore than a single report is required to generate a signal, depending upon the seriousness of the event and the quality of the information. A signal is a hypothesis together with data and arguments and it is important to note that a signal is not only uncertain but also preliminary in nature"

17-06-2026

Saudi Food and Drug Authority (SFDA) – Safety Signal of Apixaban and the Risk of Hyperacidity

*The Saudi Food and Drug Authority (SFDA) recommends all health care professionals to be aware of the safety signal of **Hyperacidity** associated with the use of **Apixaban**. The signal has been originated as a result of routine pharmacovigilance monitoring activities.*

Introduction

Apixaban is a novel oral anticoagulant approved by the US Food and Drug Administration (FDA) in 2012 for use in patients with nonvalvular atrial fibrillation to reduce the risk of stroke and blood clots. Later, in 2014, apixaban gained approval for the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), as well as for reducing the risk of blood clots (DVT and PE) in patients who have undergone knee or hip replacement surgery. The drug is also approved for reducing the risk of recurrent DVT and PE after initial therapy. [1] Hyperchlorhydria is a medical condition characterized by excessive secretion of hydrochloric acid in the gastric mucosa. This condition leads to an increased level of hydrochloric acid in the gastric juice, resulting in symptoms that resemble those of Amlapitta. It is marked by an overproduction of gastric acid, which can cause discomfort and other related symptoms. Understanding hyperchlorhydria is important for recognizing its connection with gastrointestinal ailments and managing its effects effectively. [2] The aim of this review is to evaluate the risk of Hyperacidity associated with the use of Apixaban and to suggest regulatory recommendations if required.

Methodology

Signal Detection team at SFDA performed a signal review using National Pharmacovigilance Center (NPC) database, and World Health Organization (WHO) database, VigiBase, with literature screening to retrieve all related information to assess the potential link between Hyperacidity and Apixaban use.

Results

Case Review: Signal detection team at SFDA have searched Saudi national database and WHO database to find individual case safety reports (ICSRs). The WHO database resulted in 20 global case reports while one local case found which triggers this investigation. The authors used signal detection tool (Vigilyze) to retrieve global cases. [3] The author applied Who Causality assessment tool on the extracted all cases. Among them, 1 case resulted in possible association, while the remaining 19 cases lacked sufficient information for a proper assessment.

Literature: The signal team conducted a literature search to identify publications linking this adverse drug reaction to Apixaban. The search revealed one article related to this signal. [4]

Conclusion

The weighted cumulative evidence identified from assessed local and global cases alongside with literature are suggestive for causal association between Apixaban and Hyperacidity. Health care professionals and health regulators must be aware of the potential risk in drug recipients.

Report Adverse Drug Events (ADRs) to the SFDA

The SFDA urges both healthcare professionals and patients to continue reporting adverse drug reactions (ADRs) resulted from using any medications to the SFDA either online, by regular mail or by fax, using the following contact information:

National Pharmacovigilance Center (NPC)
Saudi Food and Drug Authority-Drug sector
4904 northern ring branch rd
Hittin District
Riyadh 13513 – 7148
Kingdom of Saudi Arabia
Toll free number: 19999
Email: NPC.Drug@sfda.gov.sa

References

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