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"

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Saudi Food and Drug Authority (SFDA) – Safety Signal of Rifampin and the Risk of Blood uric acid increased

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

Introduction

Rifampin, also known as rifampicin, belongs to the antimicrobial class of drugs. This medication is used to manage and treat diverse mycobacterial infections and gram-positive bacterial infections. Rifampin exhibits antibacterial activity against a wide range of gram-positive cocci, and specific gram-negative organisms. Rifampin exerts bactericidal antimicrobial effects by inhibiting DNA-dependent RNA polymerase (RNAP). [1] Hyperuricemia is a common disorder that affects patients of all ages and genders. The most common manifestation of hyperuricemia is gout, which can be very painful and is amenable to treatment. Hyperuricemia is also associated with uric acid and calcium nephrolithiasis. [2] The aim of this review is to evaluate the risk of Blood uric acid increased associated with the use of Rifampin 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 causality between Blood uric acid increased and Rifampin use. The search conducted on December 2024.

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 844 global case-reports while only one local case found. The authors used signal detection tool (Vigilyze) to retrieve global cases. [3] Authors also applied WHO-UMC causality assessment criteria on the extracted ICSRs with completeness score 1.0 (30 cases). [4] Among them, 28 cases were possibly linked to Rifampin, while the remaining two cases assessed as unlikely.

Datamining: The disproportionality of the observed and the expected reporting rate for drug/adverse drug reaction pair is estimated using information component (IC), a tool developed by WHO-UMC to measure the reporting ratio. Positive IC reflects higher statistical association while negative values indicates less statistical association. The IC result is (5.5) for this drug/ADR combination which reflects positive statistical association. [4]

Literature: The signal team searched the literature to find related publications linking this ADR to Rifampin. In a study done in 2015, that aimed to determine the effect of anti-tuberculous drugs on serum uric acid and urine uric acid (rifampicin is one of the medications). The result shows that 13 patients (81.25%) experienced hyperuricemia [5]

Conclusion

The weighted cumulative evidence identified from assessed cases and disproportionality analysis are suggestive for causal association between Rifampin and Blood uric acid increased. 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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