

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 more 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”

12-08-2026

Saudi Food and Drug Authority (SFDA) – Safety Signal of Glucose and the Risk of Hyperkalemia

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

Introduction

Glucose is defined as a simple sugar that plays a critical role in energy metabolism, and its monitoring is essential for managing conditions such as diabetes. Continuous glucose sensors (CGS) are utilized to track glucose levels, influencing insulin treatment decisions in diabetes management. ^[1] Hyperkalemia is a condition in which characterized by high potassium levels in the blood. The person may not have any symptoms, or they may be easy to dismiss. Severe symptoms may cause muscle weakness or affect the heart. ^[2] The aim of this review is to evaluate the risk of Hyperkalemia associated with the use of Glucose 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 Hyperkalemia and Glucose 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 36 global case reports while 1 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 cases with completeness 0.6 and above (9 cases). ^[3] Among them, 5 cases resulted in possible association, while the remaining 4 cases lacked sufficient information for a proper assessment.

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 (0.7) for this drug/ADR combination which reflects positive statistical association. ^[3]



Literature: The signal team conducted a literature search to identify publications linking this adverse drug reaction to Glucose. The search identified two published studies suggesting a possible association between the glucose and this potential risk. ^[4,5]

Conclusion

The weighted cumulative evidence identified from assessed local and global cases, disproportionality analysis and literature are suggestive for causal association between Glucose and Hyperkalemia. Health care professionals and health regulators must be aware of the potential risk in this product 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@sfd.gov.sa

References

- 1- Elsevier. (n.d.). Glucose. In ScienceDirect Topics. Retrieved March 1, 2026, from <https://www.sciencedirect.com/topics/agricultural-and-biological-sciences/glucose>
- 2- Cleveland Clinic. (2023, May 11). Hyperkalemia (high potassium). Cleveland Clinic. <https://my.clevelandclinic.org/health/diseases/15184-hyperkalemia-high-blood-potassium>
- 3- Vigilyze.who-umc.org. 2025. [online] Available at: <<https://vigilyze.who-umc.org/>> (Accessed: 8 September 2025).
- 4- Goldfarb, S., Strunk, B., Singer, I., & Goldberg, M. (1975). Paradoxical glucose-induced hyperkalemia: Combined aldosterone-insulin deficiency. The American Journal of Medicine, 59(5), 744-750.
- 5- Nicolis, G. L., Kahn, T., Sanchez, A., & Gabrilove, J. L. (1981). Glucose-induced hyperkalemia in diabetic subjects. Archives of Internal Medicine, 141(1), 49-53.