



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”

26-04-2026

Saudi Food and Drug Authority (SFDA) – Safety Signal of Potassium chloride and the Risk of Arrest cardiac

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

Introduction

Potassium chloride is a medication used in the management and treatment of hypokalemia. This agent belongs to the electrolyte supplement class of medications. ^[1] Cardiac Arrest: As defined by the American Heart Association and the American College of Cardiology, "(sudden) cardiac arrest is the sudden cessation of cardiac activity so that the victim becomes unresponsive, with no normal breathing and no signs of circulation. If corrective measures are not taken rapidly, this condition progresses to sudden death. Sudden cardiac death should not be used to describe events that are not fatal." ^[2] The aim of this review is to evaluate the risk of Cardiac arrest associated with the use of Potassium chloride 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 Cardiac arrest and Potassium chloride use. The search conducted on April 2026.

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 278 global case reports while 1 local cases 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 19 extracted cases with completeness score (>0.8). ^[3] Among them, 8 case were probably linked to Potassium chloride, 8 cases resulted in possible association, while the remaining case 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 (2.3) 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 Potassium chloride. The search identified one published study suggesting a possible association between the drug and this potential risk. ^[4]

Conclusion

The cumulative weighted evidence from assessed local and global cases, supported by disproportionality analysis and published literature, suggests a potential causal association between potassium chloride and cardiac arrest. Healthcare professionals and regulatory authorities should be aware of this potential risk when prescribing and monitoring patients receiving this medication.

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

- 1- McMahon, R. S., & Bashir, K. (2020). Potassium Chloride
- 2- Patel K, Hipskind JE. Cardiac Arrest. [Updated 2023 Apr 7]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2026 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK534866/>
- 3- Vigilyze.who-umc.org. 2026. Available at: <https://vigilyze.who-umc.org/>
- 4- Reeve, J. F., Allinson, Y. M., & Stevens, A. (2005). High-risk medication alert: Intravenous potassium chloride. *Australian Prescriber*, 28(1), 14–16. <https://doi.org/10.18773/austprescr.2005.010>