

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”

08-09-2025

Saudi Food and Drug Authority (SFDA) – Safety Signal of Furosemide and the Risk of Cellulitis

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

Introduction

Furosemide Injection is indicated in adults and pediatric patients for the treatment of edema associated with heart failure, cirrhosis of the liver, and renal disease, including the nephrotic syndrome. Furosemide inhibits primarily the reabsorption of sodium and chloride not only in the proximal and distal tubules but also in the loop of Henle. ^[1] Cellulitis is a common bacterial skin infection. It is typically presents as a poorly demarcated, warm, erythematous area with associated edema and tenderness to palpation. It is an acute bacterial infection causing inflammation of the deep dermis and surrounding subcutaneous tissue. ^[2] The aim of this review is to evaluate the risk of Cellulitis associated with the use of Furosemide 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 Cellulitis and Furosemide use. The search conducted on July 2025.

Results

Cases 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 102 global case-reports while one local cases found which initiated this investigation. 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 0.8 and above (8 cases). ^[4] Among the cases, five were assessed as either probable or possible in relation to furosemide. The remaining three cases could not be adequately evaluated due to insufficient information necessary for causality assessment.

Conclusion

The weighted cumulative evidence identified from assessed local and global cases are suggestive for causal association between Furosemide and Cellulitis. 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:

- 1- Richards, D. M., Heel, R. C., Brogden, R. N., Speight, T. M., & Avery, G. S. (1984). Furosemide. A review of its antibacterial activity, pharmacological properties and therapeutic use. *Drugs*, 27(6), 469–527.
<https://doi.org/10.2165/00003495-198427060-00001>
- 2- Tanaja J, Lopez RA, Meer JM. Cellulitis. [Updated 2023 Aug 7]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK470440/>
- 3- Vigilyze.who-umc.org. 2025. [online] Available at: <https://vigilyze.who-umc.org/>
- 4- World Health Organization WHO (2013). WHO-UMC system for standardised case causality assessment. Available at <https://www.who.int/publications/m/item/WHO-causality-assessment>