



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 Cefadroxil and the Risk of Erythema

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

Introduction

Cefadroxil is indicated for the treatment of the following infections (skin, UTI, ENT) caused by; *S. pneumoniae*, *H. influenzae*, staphylococci, *S. pyogenes* (group A beta-hemolytic streptococci), *E. coli*, *P. mirabilis*, *Klebsiella* sp, coagulase-negative staphylococci and *Streptococcus pyogenes*. It works by binds to specific penicillin-binding proteins (PBPs) located inside the bacterial cell wall, causing the inhibition of the third and last stage of bacterial cell wall synthesis.^[1] Erythema: Redness of the skin, caused by hyperemia of the capillaries in the lower layers of the skin. ^[2] The aim of this review is to evaluate the risk of Erythema associated with the use of Cefadroxil 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 Erythema and Cefadroxil use. The search conducted on March 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 128 global case reports while one 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 21 extracted cases with completeness score (1). ^[3] Among them, 16 cases were probably linked to Cefadroxil, 4 cases resulted in possible association, and one case resulted in unlikely association.

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 (0.6) 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 Cefadroxil. The search identified two published studies suggesting a possible association between the drug and this potential risk. ^{[4][5]}

Conclusion

The cumulative evidence from evaluated local and global cases, supported by disproportionality analysis and published literature, suggests a potential causal association between cefadroxil and erythema. Healthcare professionals and regulatory authorities should remain aware of this potential risk when prescribing or 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@sfd.gov.sa

References

- 1- PubChem (n.d.). Cefadroxil. [online] pubchem.ncbi.nlm.nih.gov. Available at: <https://pubchem.ncbi.nlm.nih.gov/compound/Cefadroxil>.
- 2- Nih.gov. (2015). Erythema (Concept Id: C0041834) - MedGen - NCBI. [online] Available at: <https://www.ncbi.nlm.nih.gov/medgen/11999#Definition>.
- 3- Vigilyze.who-umc.org. 2026. [online] Available at: <https://vigilyze.who-umc.org/>
- 4- Mian, Sundus MD1; Bilal, Hiba DO1; Bernshteyn, Michelle MD2; Perl, Andras MD, PhD1. S2721 A Rare Case of Cefadroxil-Induced DRESS Syndrome Leading to Severe Acute Liver Failure Necessitating Liver Transplantation Evaluation. The American Journal of Gastroenterology 115():p S1422, October 2020. | DOI: 10.14309/01.aig.0000712932.63438.ae
- 5- Nahata, M.C., Jackson, D.S. and Powell, D.A. (1990). Cefadroxil Kinetics and Dynamics in a Pediatric Patient with Acute Osteomyelitis. Chemotherapy, [online] 36(6), pp.392–395. doi:<https://doi.org/10.1159/000238794>.