



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”

17-06-2026

Saudi Food and Drug Authority (SFDA) – Safety Signal of Cefadroxil and the Risk of Dyspnea (Shortness Of Breath)

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

Introduction

Cefadroxil is bactericidal antibiotic used to treat certain infections of the skin, throat, tonsils, and urinary tract. Cefadroxil belongs cephalosporin class of antibiotics. ^[1] Dyspnea or Shortness Of Breath(SOB) is a subjective respiratory sensation characterized by insufficient air intake arising from complex physiologic, psychological, social, and environmental interactions. Acute presentations occur in pulmonary embolism, asthma exacerbation, pneumonia, or heart failure, whereas chronic manifestations develop in chronic obstructive pulmonary disease, interstitial lung disease, obesity, or neuromuscular weakness. The symptom may appear as air hunger, chest constriction, tachypnea, or increased respiratory effort, often restricting activity and diminishing functional capacity. ^[2] The aim of this review is to evaluate the risk of SOB 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 SOB and Cefadroxil 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 188 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 chooses to assess top 30 cases with completeness score 1.0. ^[3] Among them, 8 cases were probably linked to Cefadroxil, 17 cases resulted in possible association, and 5 cases resulted in unlikely association, while the remaining seven 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 (0.2) 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 one published study suggesting a possible association between the drug and this potential risk. ^[4]

Conclusion

The weighted cumulative evidence identified from assessed local and global cases, disproportionality analysis alongside with literature are suggestive for causal association between Cefadroxil and SOB. 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- U.S. National Library of Medicine. (2018, November 15). Cefadroxil. MedlinePlus. Retrieved March 4, 2026, from <https://medlineplus.gov/druginfo/meds/a682730.html>
- 2- Hashmi, M. F., Modi, P., Basit, H., & Sharma, S. (2018). Dyspnea.
- 3- Vigilyze.who-umc.org. 2026. [online] Available at: <https://vigilyze.who-umc.org/>
- 4- Lamba, G., & Aswani, V. (2011). A severe laryngeal angioedema reaction from cefadroxil in a patient with no known allergies to penicillins. West Indian Medical Journal, 60(3), 346–347.