

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”

27-08-2025

Saudi Food and Drug Authority (SFDA) – Safety Signal of Prednisolone and the Risk of Respiratory failure

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

Introduction

Prednisolone inhibit the inflammatory response to a variety of inciting agents and probably delay or slow healing. They inhibit the edema, fibrin deposition, capillary dilation, leukocyte migration, capillary proliferation, fibroblast proliferation, deposition of collagen, and scar formation associated with inflammation. ^[1] Respiratory failure is defined by the inability of the respiratory system to adequately deliver oxygen or remove carbon dioxide from the pulmonary circulation resulting in hypoxemia, hypercapnia or both. ^[2] The aim of this review is to evaluate the risk of Respiratory failure associated with the use of Prednisolone 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 Respiratory failure and Prednisolone use. The search conducted on May 2025.

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 491 global case-reports while only one local case found. The authors used signal detection tool (Vigilyze) to retrieve global cases. ^[3] Authors also applied WHO-UMC causality assessment criteria on the extracted ICSR with completeness score 1.0 (30 cases). ^[4] Among the reported cases, 16 were assessed as probably or possibly linked to Prednisolone, one case was considered unlikely, and the remaining 13 could not be assessed due to insufficient information.

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 (2.0) for this drug/ADR combination which reflects positive statistical association. ^[4]



Conclusion

The weighted cumulative evidence identified from assessed cases and disproportionality analysis are suggestive for causal association between Prednisolone and Respiratory failure. 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. (2006, September 11). ECONOPRED® (Prednisolone acetate) suspension. DailyMed. Retrieved from <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=2d6c3ea4-5189-4f6e-bb6a-c9379f441d7a>
- 2- ScienceDirect. (2019). Respiratory failure – an overview. In Topics in Medicine and Dentistry. ScienceDirect. Retrieved from <https://www.sciencedirect.com/topics/medicine-and-dentistry/respiratory-failure>
- 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>