

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”

10-09-2024

Saudi Food and Drug Authority (SFDA) – Safety Signal of Tozinameran and the Risk of Suppressed lactation

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

Introduction

A formulation consisting of lipid nanoparticle (LNP) encapsulating a nucleoside modified messenger RNA (modRNA) encoding an optimized form of the full-length severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) spike glycoprotein (SP), with potential immunizing and anti-COVID-19 activities. ^[1] Suppression of lactation is the reduction and eventual stopping of breast milk production after childbirth. ^[2] The aim of this review is to evaluate the risk of Suppressed lactation associated with the use of Tozinameran 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 Suppressed lactation and Tozinameran use. The search conducted on August 2024.

Results

Case Review: Signal detection team at SFDA have searched Saudi national database and WHO database to find individual case safety reports (ICSRs). For the preferred term (Lactation insufficiency) the WHO database resulted in 773 global case-reports while only one local cases found. The authors used signal detection tool (Vigilyze) to retrieve all reported global cases. ^[3] Authors also applied WHO-UMC causality assessment criteria on the extracted 30 ICSRs with highest completeness score. ^[4]

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]

Literature: The signal team searched the literature to find related publications linking this ADR to Tozinameran. The search showed two published articles related to this signal [5,6]

Conclusion

The weighted cumulative evidence identified from assessed cases, literature and disproportionality analysis are suggestive for causal association between Tozinameran and Suppressed lactation. 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- National Institutes of Health (NIH). NCI Dictionaries (Tozinameran). Available at: <https://www.cancer.gov/publications/dictionaries/cancer-drug/def/tozinameran> [Accessed: 20/08/2024].
- 2- Children’s Health Queensland (2023) Suppressing lactation, Children’s Health Queensland. Available at: <https://www.childrens.health.qld.gov.au/health-a-to-z/breastfeeding/suppressing-lactation> . [Accessed: 20/08/2024].
- 3- Vigilyze.who-umc.org. 2024. [online] Available at: <https://vigilyze.who-umc.org/> [Accessed: 20/08/2024].
- 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> [Accessed: 21/08/2024].
- 5- Bertrand, K., Honerkamp-Smith, G. and Chambers, C.D. (2021) ‘Maternal and child outcomes reported by breastfeeding women following messenger RNA COVID-19 vaccination’, *Breastfeeding Medicine*, 16(9), pp. 697–701. doi:10.1089/bfm.2021.0169.
- 6- Lamers, M. et al. (2022) ‘Covid-19 vaccination during breastfeeding and its possible negative effect on milk production and supply: A preliminary observation’, *Breastfeeding Medicine*, 17(7), pp. 627–628. doi:10.1089/bfm.2022.0057.