

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”

08-10-2026

Saudi Food and Drug Authority (SFDA) – Safety Signal of Tozinameran and the Risk of Still's disease

*The Saudi Food and Drug Authority (SFDA) recommends that all healthcare professionals be aware of the safety signal of **Still's disease** associated with the use of **Tozinameran**. The signal originated as a result of routine pharmacovigilance monitoring activities.*

Introduction

Tozinameran is 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. Upon injection of tozinameran, the LNPs bind to the plasma membrane of nearby cells and release SARS-CoV-2 SP mRNA into the cell. The mRNA is then translated by the cellular protein translation machinery to produce SARS-CoV-2 SP. This may stimulate the immune system to induce an antibody and T-cell-mediated immune response. This may provide active immunization against SARS-CoV-2 infection. SP, usually found on the surface of SARS-CoV-2, plays an essential role in the infection pathway of the SARS-CoV-2 virus.^[1] Adult-onset Still's disease (AOSD) is an uncommon systemic inflammatory disorder characterized by inflammatory polyarthritis, daily fever, and a transient salmon-pink maculopapular rash.^[2] This review aims to evaluate this potential risk and to suggest regulatory recommendations if required.

Methodology

The Signal Detection Team at SFDA performed a signal review using the National Pharmacovigilance Center (NPC) database and the World Health Organization (WHO) database, Vigibase, along with a literature review to retrieve all relevant information and assess the potential link between still's disease and tozinameran use.

Results

Cases Review: The Signal Detection Team at SFDA searched the Saudi national database and the WHO database to identify individual case safety reports (ICSRs). The WHO database yielded 201 global case reports. The authors used the signal detection tool (VigiLyze) to retrieve global cases.^[3] The author applied WHO Causality assessment tool on the 29 extracted cases with completeness score (>0.8). 24 cases were considered possibly associated with tozinameran, 3 cases were assessed as unlikely to be associated, and the remaining 2 cases were unassessable.

Datamining: The disproportionality between the observed and expected reporting rates for a drug/adverse drug reaction (ADR) pair is estimated using the Information Component (IC), a tool developed by WHO-UMC to measure the reporting ratio. A positive IC reflects a higher statistical association, while negative values indicate a lower statistical association. The IC result for this drug/ADR combination was 1.5, reflecting a positive statistical association.^[3]



Conclusion

The cumulative weight of evidence identified from global cases, and disproportionality analysis suggests a potential causal association between tozinameran and still's disease. Healthcare professionals and health regulators should be aware of this potential risk in patients receiving tozinameran.

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- Cancer.gov. (2024). NCI Drug Dictionary. [online] Available at: <https://www.cancer.gov/publications/dictionaries/cancer-drug/def/tozinameran>
- 2- Bhargava, J. and Panginikkod, S. (2021). Still Disease. [online] PubMed. Available at: <https://www.ncbi.nlm.nih.gov/books/NBK538345/>.
- 3- Vigilyze.who-umc.org. 2026. [online] Available at: <https://vigilyze.who-umc.org/> (Accessed: 11 August 2026).