# 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 m ore 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"*

**19-04-2026**

## Saudi Food and Drug Authority (SFDA) – Safety Signal of TOZINAMERAN and the Risk of Troponin I increased

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

**Introduction**

Tozinameran a formulation consisting of lipid nanoparticle (LNP) encapsulating a nucleoside modified messenger RNA (modRNA) encoding an optimized form of the full-length (SARS-CoV-2) spike glycoprotein (SP), with potential immunizing and anti-COVID-19 activities. 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] Cardiac troponin I (TnI), a part of the troponin complex that is present in cardiac muscle tissues, has been known as a reliable biomarker of cardiac muscle tissue injury and was widely used in the early diagnosis of Acute Myocardial Infarction. It will release in the bloodstream when cardiac muscle is damaged or dead. [2] The aim of this review is to evaluate the risk of Troponin I increased 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 potential link between Troponin I increased and Tozinameran use. The search conducted on February 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 677 global case reports while the NPC database resulted in one local case report which started this investigation. The authors used signal detection tool (Vigilyze) to retrieve global cases. [3] The author applied WHO Causality assessment tool on top 31 cases with completeness score 0.9 and above. [3] Among them, twenty four cases were possibly linked to Tozinameran, four cases resulted in unlikely association while the remaining three cases were unable to be assessed due to lack of important information.

**Datamining**: The disproportionality of the observed and the expected reporting rate for vaccine/adverse 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 (1.9) for this vaccine/ADR combination which reflects positive statistical association. [3]

**Literature**: The signal team conducted a literature search to identify publications linking this adverse reaction to Tozinameran. The search identified two published studies suggesting a possible association between the vaccine and this potential risk. [4]

**Conclusion**

The weighted cumulative evidence identified from assessed local and global cases, alongside with literature and disproportionality analysis are suggestive for causal association between Tozinameran and Troponin I increased. Health care professionals and health regulators must be aware of the potential risk in vaccine 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


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3. Vigilyze.who-umc.org. 2026. [online] Available at: https://vigilyze.who-umc.org/
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5. Kelly, M. A., & Mills, R. L. (2021). Post-vaccination myocarditis and elevated troponin in adolescents following the Pfizer-BioNTech COVID-19 vaccine. Circulation, 143(10), 946-957. https://doi.org/10.1161/CIRCULATIONAHA.121.055725.