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"

26-02-2026

Saudi Food and Drug Authority (SFDA) – Safety Signal of TOZINAMERAN and the Risk of Cardiac arrest

*The Saudi Food and Drug Authority (SFDA) recommends all health care professionals to be aware of the safety signal of **Cardiac arrest** 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] As defined by the American Heart Association and the American College of Cardiology, "(sudden) cardiac arrest is the sudden cessation of cardiac activity so that the person becomes unresponsive, with no normal breathing and no signs of circulation. If corrective measures are not taken rapidly, this condition progresses to sudden death. [2] The aim of this review is to evaluate the risk of Cardiac arrest 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 Cardiac arrest 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 3671 global case reports while the NPC database resulted in 5 local case reports 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 30 cases with completeness score 1.0. [3] Among them, twenty cases were possibly linked to TOZINAMERAN, ten cases resulted in unlikely association.

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 (-0.7) for this vaccine/ADR combination which reflects negative statistical association. [3]

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

Conclusion

The weighted cumulative evidence identified from assessed local and global cases, in addition to the published literature are suggestive for causal association between TOZINAMERAN and Cardiac arrest. 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

1. National Cancer Institute. (n.d.). tozinameran. In NCI Drug Dictionary. National Institutes of Health. Retrieved January 27, 2026, from https://www.cancer.gov/publications/dictionaries/cancer-drug/def/tozinameran
2. Patel, K., & Hipskind, J. E. (2023). Cardiac arrest. In StatPearls [Internet]. StatPearls Publishing.
3. Vigilyze.who-umc.org. 2026. [online] Available at: https://vigilyze.who-umc.org/
4. Paknahad, M. H., Yancheshmeh, F. B., & Soleimani, A. (2023). Cardiovascular complications of COVID-19 vaccines: A review of case-report and case-series studies. Heart & Lung, 59, 173-180.