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 Venlafaxine 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 **Venlafaxine**. The signal has been originated as a result of routine pharmacovigilance monitoring activities.*

Introduction

Venlafaxine is categorized as a serotonin-norepinephrine reuptake inhibitor (SNRI). It is approved by the US Food and Drug Administration (FDA) to treat major depressive disorder (unipolar), social anxiety disorder, and panic disorder. [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 Venlafaxine 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 Venlafaxine 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 586 global case reports while no local cases found. The authors used signal detection tool (Vigilyze) to retrieve global cases. [3] The author applied WHO causality assessment tool on the top 17 cases with completeness score of (0.80) and above. [3] Among them, two cases were probably linked to Venlafaxine, six cases resulted in possible association, five cases resulted in unlikely association, while the remaining four cases lacked sufficient information for a proper assessment.

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. [3]

Literature: The signal team conducted a literature search to identify publications linking this adverse drug reaction to Venlafaxine. The search identified three published studies suggesting a possible association between the drug and this potential risk. [5], [6], [7]

Conclusion

The weighted cumulative evidence identified from assessed cases, disproportionality analysis and literature are suggestive for causal association between Venlafaxine and Cardiac arrest. 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

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