



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”

19-04-2026

Saudi Food and Drug Authority (SFDA) – Safety Signal of MELATONIN and the Risk of Cardiac failure

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

Introduction

Melatonin is a naturally occurring hormone produced by the pineal gland and is structurally related to serotonin. The activity of melatonin at the MT1, MT2 and MT3 receptors is believed to contribute to its sleep-promoting properties, as these receptors (mainly MT1 and MT2) are involved in the regulation of circadian rhythms and sleep regulation. ^[1] Heart failure (HF), also known as congestive heart failure (CHF), is a complex clinical syndrome characterized by the heart's inability to pump blood effectively due to structural or functional impairments. ^[2] The aim of this review is to evaluate the risk of Cardiac failure associated with the use of MELATONIN 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 failure and Melatonin use. The search conducted on March 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 4 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 all cases. ^[3] Among them, four cases were linked to Melatonin, but lacked sufficient information for a proper assessment.

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

Conclusion

The weighted cumulative evidence identified from assessed cases and literature are suggestive for causal association between Melatonin and Cardiac failure. 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@sfd.gov.sa

References

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2. Shams P, Malik A, Chhabra L. Heart Failure (Congestive Heart Failure) [Updated 2025 Feb 26]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK430873/>
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