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"

26-06-2025

Saudi Food and Drug Authority (SFDA) – Safety Signal of Nifedipine and the Risk of Shock

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

Introduction

Nifedipine is a calcium channel blocker in the dihydropyridine subclass. It is primarily used as an antihypertensive and as an anti-anginal medication. FDA-approved indications include chronic stable angina, hypertension. It also has other off-label indications. [1] Shock is a life-threatening manifestation of circulatory failure. Circulatory shock leads to cellular and tissue hypoxia resulting in cellular death and dysfunction of vital organs. Effects of shock are reversible in the early stages and a delay in diagnosis and/or timely initiation of treatment can lead to irreversible changes including multiorgan failure (MOF) and death. [2] The aim of this review is to evaluate the risk of Shock associated with the use of Nifedipine 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 causality between Shock and Nifedipine use. The search conducted on March 2025.

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 109 global case-reports while no local cases found. The authors used signal detection tool (Vigilyze) to retrieve global cases. [3] Authors also applied WHO-UMC causality assessment criteria on the extracted ICSRs with completeness score 0.6 and above (5 cases). [4] All the five cases were probably and possibly linked to Nifedipine.

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 (1.6) for this drug/ADR combination which reflects positive statistical association. [4]

Literature: The signal team conducted a literature search to identify publications linking this adverse drug reaction to Nifedipine. The search identified a published case report of shock occurring following the use of Nifedipine. [5]

Conclusion

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

References:

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2- Haseer Koya H, Paul M. Shock. [Updated 2023 Jul 24]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK531492/

3- Vigilyze.who-umc.org. 2025. [online] Available at: https://vigilyze.who-umc.org/

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5- Botta, I., Devriendt, J., Rodriguez, J. C., Morissens, M., Carling, A., Gutierrez, L. B., Preseau, T., De Bels, D., Honore, P. M., & Redant, S. (2018). Cardiogenic Shock after Nifedipine Administration in a Pregnant Patient: A Case Report and Review of the Literature. *Journal of translational internal medicine*, *6*(3), 152–156. https://doi.org/10.2478/jtim-2018-0029