



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”

29-09-2025

Saudi Food and Drug Authority (SFDA) – Safety Signal of Atorvastatin and the Risk of Anxiety

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

Introduction

Atorvastatin is a statin medication used to prevent cardiovascular disease in those at high risk and to treat abnormal lipid levels. Atorvastatin is a selective, competitive inhibitor of HMG-CoA reductase, the rate-limiting enzyme that converts 3-hydroxy-3-methylglutaryl-coenzyme A to mevalonate, a precursor of sterols, including cholesterol. ^[1] Anxiety disorders are a category of mental health diagnoses that involve excessive nervousness, fear, apprehension, and worry. These symptoms can interfere with a person's quality of life but are very treatable. ^[2] The aim of this review is to evaluate the risk of Anxiety associated with the use of Atorvastatin 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 Anxiety and Atorvastatin use. The search conducted on July 2025.

Results

Cases 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 813 global case-reports while nineteen 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 top 30 ICSRs with completeness score 1.0. ^[4] Among them, 23 cases were probably and possibly linked to Atorvastatin, while the remaining seven cases assessed as unlikely.

Conclusion

The weighted cumulative evidence identified from assessed local and global cases are suggestive for causal association between Atorvastatin and Anxiety. 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:

- 1- Nih.gov. (2024). DailyMed - ATORVASTATIN CALCIUM- atorvastatin calcium tablet, film coated. [online] Available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=25c8f92f-9cb6-482b-82e1-16ad7c94e7b3>
- 2- Felman, A. (2024). Anxiety: Overview, symptoms, causes, and treatments. [online] Medical News Today. Available at: <https://www.medicalnewstoday.com/articles/323454>.
- 3- Vigilyze.who-umc.org. 2025. [online] Available at: <https://vigilyze.who-umc.org/>
- 4- World Health Organization WHO (2013). WHO-UMC system for standardised case causality assessment. Available at <https://www.who.int/publications/m/item/WHO-causality-assessment>