



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”

18-05-2026

Saudi Food and Drug Authority (SFDA) – Safety Signal of Rosuvastatin and the Risk of Peripheral coldness

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

Introduction

Rosuvastatin is indicated for the treatment of hypercholesterolaemia, Prevention of Cardiovascular Events. Its mechanism of action is a selective and competitive inhibitor of HMG-CoA reductase, the rate-limiting enzyme that converts 3-hydroxy-3-methylglutaryl coenzyme A to mevalonate, a precursor for cholesterol. ^[1] Peripheral coldness defined as a set of symptoms including pain, tingling, numbness, chills, stiffness, weakness, swelling or skin color changes on exposure to cold. ^[2] The aim of this review is to evaluate the risk of Peripheral coldness associated with the use of Rosuvastatin 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 Peripheral coldness and Rosuvastatin use. The search conducted on April 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 75 global case reports while 1 local case found which triggers this investigation. The authors used signal detection tool (Vigilyze) to retrieve global cases. ^[3] The author applied WHO Causality assessment tool on the 11 extracted cases with completeness score (>0.8). ^[3] Among them, 6 cases resulted in possible association, and 3 cases resulted in unlikely association, while the remaining 2 cases lacked sufficient information for a proper assessment.



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

Conclusion

The weighted cumulative evidence identified from assessed local and global cases alongside with literature are suggestive for causal association between Rosuvastatin and Peripheral coldness. 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

- 1- Medicines.ie. (2024). Crestor 5mg/10mg/20mg/40mg film-coated tablets. [online] Available at: <https://www.medicines.ie/medicines/crestor-5mg-10mg-20mg-40mg-film-coated-tablets-35417/spc>.
- 2- Khabbazi A, Farzaneh R, Mahmoudi M, Shahi M, Jabbaripour Sarmadian A, Babapour E, Alizadeh L, Khabbazi R, Nouri-Vaskeh M. Cold intolerance and associated factors: a population study. Sci Rep. 2022 Oct 27;12(1):18029. doi: 10.1038/s41598-022-21842-9. PMID: 36302950; PMCID: PMC9613912.
- 3- Vigilyze.who-umc.org. 2026. [online] Available at: <https://vigilyze.who-umc.org/>
- 4- Huynh, N. T., & Huot, P. (2014). A generalised sensation of coldness following introduction of rosuvastatin therapy. Case Reports, 2014, bcr2014205987.