

Iran Food and Drug Administration (IFDA)
Office for Regulatory & Monitoring of Health Products Use
Islamic Republic of Iran

14-Apr-2026

RE: NEW SAFETY INFORMATION

Dear Authority

Please find attached new safety information from Viatri Middle East. The new safety information retrieved and shared below are mandated recommendations from global health authorities. As these are mandated recommendations, the company consider these already as valid, and no further assessment/validation is made by Viatri. The recommended actions are taken within the local market of which this new safety information has been made available. Following your review, please inform us of any local actions/recommendations, for the local Iran market as required:

INN: Atorvastatin (as calcium trihydrate)

Requesting HA: Therapeutic Goods administration (TGA), Australia

Date received by Viatri: 14 Apr 2026

Summary of HA query: Therapeutic Goods Administration (TGA) has agreed to update Product Information (PI) for Atorvastatin to ensure that health professionals and consumers have access to this information and this information was published in the product information safety updates-March 2026.

Final Outcome: The Therapeutic Goods Administration (TGA) has agreed to the update of following sections of product information:

Section - 4.4 (Special warnings and precautions for use) - to add new warning under subheading 'Skeletal Muscle'. The risk of myopathy and/or rhabdomyolysis may be increased by concomitant administration of HMG-CoA reductase inhibitors (e.g. atorvastatin) and daptomycin. Consideration should be given to temporarily suspend LIPITOR in patients taking daptomycin unless the benefits of concomitant administration outweigh the risk. If co-administration cannot be avoided, CK levels should be measured 2-3 times per week, and patients should be closely monitored for any signs or symptoms that might represent myopathy

Section - 4.5 Interactions with other medicines and other forms of interactions to add new interaction under subheading 'Daptomycin'. Cases of myopathy and/or rhabdomyolysis have been reported with HMG-CoA reductase inhibitors (e.g. atorvastatin) co-administered with daptomycin. If co-administration cannot be avoided, appropriate clinical monitoring is recommended.

Section 4.8 Adverse effects (undesirable effects) – to add lichenoid drug reaction and vasculitis

Viatri Middle East FZ-LLC, Licence no. 95499

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تأسست كشركة منطقة حرة ذات مسؤولية محدودة بموجب اللوائح المنظمة للشركات الخاصة في المناطق الحرة لسلطة دبي للتطوير لسنة 2016 الصادرة بموجب القانون رقم (1) لسنة 2000 بإمارة دبي (وتعديلاته).

This is safety notification from the pharmacovigilance department; any regulatory action will be taken as per regulatory procedure and as per safety update approval at reference country.

Affiliate Safety Representative
Product Safety & Risk Management