

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

09-Mar-2026

**RE: NEW SAFETY INFORMATION**

Dear Authority

*Please find attached new safety information from Viatriis 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 Viatriis. 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:** Pregabalin

**Requesting HA:** Therapeutic Goods Administration (TGA)

**Date received by Viatriis:** 03 Mar 2026

**Summary of HA query:** Swissmedic requested a safety update to product information for Pregabalin regarding adverse events of the liver and bile ducts on 31 Mar 25. This update was notified to the TGA as a part of cross-reporting activities and the TGA subsequently requested the same update to the product information. However, Viatriis submitted a review of clinical trial data, literature, and post-marketing data from 01-Sep-2016 to 31-Dec-2025 as well as a prior assessment and the conclusion that the supporting data did not warrant a label update. Additionally, Viatriis stated that Pregabalin undergoes negligible metabolism and is excreted predominantly unchanged drug in urine. Pregabalin does not have significant drug-drug interactions that would suggest a mechanism for hepatic toxicity. After evaluating the Viatriis response, the TGA slightly changed the original request but reiterated the requirement for the pregabalin product information to be updated to include adverse events of the liver: jaundice, hepatitis and liver failure.

**Final Outcome:** The Therapeutic Goods Administration (TGA) has requested to update Section 4.8 – to include adverse events of the liver, jaundice, hepatitis and liver failure.

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

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Viatriis 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).