

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 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: Pregabalin

Requesting HA: Therapeutic Goods Administration (TGA)

Date received by Viatri: 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, Viatri 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, Viatri 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 Viatri 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.

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Product Safety & Risk Management

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