

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

01-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:** Latanoprost

**Requesting HA:** EMA (European Medicines Agency)

**Date received by Viatri:** 31 Mar 26

**Summary of HA query:** The Belgian assessors have come across the article of Alsoudi AF, Anderson JT, Wong TP, Scheffler AC. Prostaglandin-Induced Macular Hole: A Brief Report. Ophthalmic Surg Lasers Imaging Retina.2024;55 (2):112-115), reporting two cases of patients who had developed macular holes while using latanoprost. Additionally, the Lead Member State (LMS) identified 15 unique cases (in EVDAS and VigiBase) of macular holes possibly associated with latanoprost use, including the 2 literature cases above. These cases span from 1998 to 2024 and are considered serious; most were reported from Brazil (4), Japan (3), and the US (4). Out of these 15 cases, the LMS classified one as “probable” (with a positive dechallenge) and eight as “possible”, based on the WHO/UMC causality assessment. In the LMS view, there is at least a reasonable possibility that latanoprost could be linked to the development or recurrence of macular holes.

**Final Outcome:** LMS requested all Marketing Authorisation Holders of latanoprost-containing products to perform a cumulative review, covering at least the preferred terms (PTs) Macular hole, Macular rupture and Retinal tear, timely for inclusion in the next PSUR (DLP: 30/04/2028), to be evaluated in the framework of procedure PSUSA/00001832/202804.

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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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).