

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

30-Jun-2026

RE: NEW SAFETY INFORMATION

Dear Authority

Please find attached new safety information from Viatris Middle East. The new safety information retrieved and shared below are mandated recommendations from global health authorities. 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: Methotrexate

Requesting HA: EMA (European Medicines Agency) / PSUSA/00002014/202510 – CHMP opinion

Date received by Viatris: 30 Jun 2026

Summary of HA query: Taking into account the PRAC Assessment Report on the PSUR(s) for methotrexate, it was concluded that in view of available data on epidermal necrosis from the literature and spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and in view of a plausible mechanism of action, the PRAC considers that a causal relationship between methotrexate and epidermal necrosis is at least a reasonable possibility. The PRAC concluded that the product information of products containing methotrexate should be amended accordingly

Final Outcome: To update SmPC and respective package leaflet

- to update SmPC sections 4.4 and 4.8 to add the adverse reaction epidermal necrosis with a frequency not known. The package leaflet is updated accordingly.
- Issues: to be addressed in the next PSUR

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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Affiliate Safety Representative