



Viatis Middle East FZ – LLC
Atlas Business Center -4th Floor
Al Falak St. Dubai Media City
PO Box 502049
Dubai United Arab Emirates
Tel: +971.4.512.1500

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

22-Sep-2026

RE: NEW SAFETY INFORMATION

Dear Authority

Please find attached new safety information from Viatis 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: Antidepressants

Requesting HA: Medicines and Healthcare Products Regulatory Agency (MHRA)

Date received by Viatis: 22 Sep 2026

Summary of HA query: MHRA gathered patient feedback on the updates to the antidepressants' patient information leaflets (PILs) regarding the risk of suicidal behaviors and has agreed text for update of PIL and SmPC on the risk of suicidal behaviour and the description of the mechanism of action which applies to all antidepressants. The text agreed on sexual dysfunction where symptoms continue despite stopping applies only to specific medicines. MHRA requested to submit variation regarding update in SmPC section 4.4 and respective sections in PIL regarding self-harm, suicidal behaviour (box warning) and long-lasting sexual dysfunction and MAH should use exact MHRA-agreed wording.

Final Outcome: Update in SmPC section 4.4 and respective sections in PIL regarding self-harm, suicidal behaviour (box warning) and long-lasting sexual dysfunction and MAH should use exact MHRA-agreed wording.

Company position for recommended actions: The topic is currently under evaluation. Viatis conducts a thorough assessment and will provide an update as soon as the evaluation is completed and the impact for the local label can be confirmed.

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.

Jayaprakash
Penumudi-M567265
Digitally signed by Jayaprakash
Penumudi-M567265
Date: 2026.09.24 12:34:49 +04'00'

Affiliate Safety Representative
Product Safety & Risk Management