

PRODUCT INFORMATION UPDATE HCP LETTER



24.10.2025

Opella Healthcare France S.A.S.
157 Avenue Charles De Gaulle
Neuilly-Sur-Seine
92200, France

Important information for healthcare professionals

**A new contraindication for Phenergan oral administration in patients
with known, documented long QT syndrome**

Phenergan 25mg film-coated tablets
Phenergan 5mg/5ml oral solution
(promethazine hydrochloride)
PA23180/011/001
PA23180/011/002

Dear Healthcare Professional,

Opella Healthcare France S.A.S. would like to inform you that a contraindication has been added to Section 4.3 of the SmPC and subsequently on the Package Leaflet as follows:

Phenergan should not be administered in patients with known, documented long QT syndrome, whether acquired or congenital (see sections 4.4 and 4.5).

This update follows the outcome of a variation for Phenergan film-coated tablets and oral solution, which examined the use of Phenergan and QT Prolongation. Subsequently changes were made to section 4.4 (Warnings and Precautions), section 4.5 (Interactions), section 4.8 (Undesirable effects) and section 4.9 (Overdose) of the SmPC. Corresponding sections of the Patient Information Leaflet (PIL) have also been updated.

Please ensure that all relevant staff are made aware of the content of this letter.

Pharmacists are advised to remind patients that if they have any concerns or questions regarding this update or their treatment, they should consult their physician or another qualified healthcare provider.

Communication of this information has been agreed with the Health Products Regulatory Authority (HPRA).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to HPRA Pharmacovigilance using the report form on the HPRA website, www.hpra.ie.

Adverse events should also be reported to:

Clonmel Healthcare Ltd.,
Waterford Road, Clonmel,
Co. Tipperary, Ireland.
Tel: +353 52 617 7777
Email: medicalinformation@clonmel-health.ie

If you have any questions, please contact:

Clonmel Healthcare Ltd.,
Waterford Road, Clonmel,
Co. Tipperary, Ireland.
Tel: +353 52 617 7777
Email: medicalinformation@clonmel-health.ie

Yours faithfully,

Electronically signed by: Gwenaelle
DEGROTTE
Reason: review and in agreement
Date: Oct 24, 2025 12:10:59 GMT+2


AUT-F0701 Product information update HCP letter v3d-Opella - Opella final

Final Audit Report

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