PRODUCT INFORMATION UPDATE HCP LETTER TEMPLATE

18.06.2025

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

Important information for healthcare professionals
Restriction of Phenergan oral formulation use in children less than 6 years of age (removal of posology, new adverse events and new warnings/precautions)

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 of the following:

Following the outcome of a recent variation for Phenergan film-coated tablets and oral solution, which examined new adverse events reported in children aged 2-5 years of age inclusive, changes to the product information have been agreed.

During the procedure, new adverse events of aggression, hallucination, and psychomotor hyperactivity in children aged 2-5 years were added to SmPC section 4.8. Due to safety concerns in this patient population, and on the basis that promethazine is a long-acting first-generation antihistamine with additional anti-emetic, central sedative, and anti-cholinergic properties, as well as the changes in therapeutic strategies over time (with the availability of non-sedating 2nd generation antihistamines for use in allergies, as well as available alternatives for nausea and vomiting), removal of the posology in the 2-5 year age group was agreed, with a recommendation that use in this population is not recommended due to safety concerns.

The following changes were made to the product information:

- Removal of use in children aged 2-5 years.
- Update the psychiatric and central nervous system adverse events section to include aggression, hallucination, and psychomotor hyperactivity in children less than 6 years of age.

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

The 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,

Gwenaelle Degrotte
Global INNs Regulatory Head Opella