HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Product information updates recommended by the EMA's Pharmacovigilance Risk Assessment Committee (PRAC)

The HPRA wishes to highlight a selection of recent recommendations, made by the EMA's Pharmacovigilance Risk Assessment Committee (PRAC), to update product information* for medicines in clinical use. The PRAC, in which the HPRA participates, are responsible for assessing and monitoring the safety of medicines. Healthcare professionals (HCPs) are reminded to regularly check the HPRA (www.hpra.ie) or EMA (www.ema.europa.eu) websites for current product information concerning medicines they prescribe or dispense.

Ibuprofen-containing medicines: Acute Generalised Exanthematous Pustulosis (AGEP)
Ibuprofen is a non-steroidal anti-inflammatory drug (NSAID), commonly used for the reduction of pain, inflammation and fever.

- Product information for ibuprofen-containing medicines already include a warning regarding very rare reports of serious skin reactions, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis. This warning will be updated to reflect that cases of AGEP have also been reported. HCPs are reminded that treatment with ibuprofen-containing medicines should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.

Aimovig▼(erenumab): constipation and hypersensitivity
Aimovig is an IgG2 monoclonal antibody which binds to the calcitonin gene-related peptide (CGRP) and is indicated for prophylaxis of migraine in adults who have at least four migraine days per month.

- Constipation, which is usually mild to moderate, is a known and common adverse reaction associated with Aimovig (erenumab). In the majority of reported cases, onset was after the first dose, however, patients have also experienced constipation later on in treatment. In most cases constipation resolved within three months. Product information has been updated to reflect that, in the post-marketing setting, constipation with serious complications has been reported with erenumab. In some cases hospitalisation was required, including cases where surgery was necessary. History of constipation or the concurrent use of medicines associated with decreased gastrointestinal motility may increase the risk for more severe constipation and the potential for constipation-related complications. Patients should be warned about the risk of constipation and advised to seek medical attention in case constipation does not resolve or worsens and immediately so if they develop severe constipation. Constipation should be managed promptly as clinically appropriate. For severe constipation, discontinuation of treatment should be considered.

- A warning in product information will reflect that serious hypersensitivity reactions, including rash, angioedema, and anaphylactic reactions, have been reported with erenumab in post-marketing experience. These reactions may occur within minutes, although some may occur more than one week after treatment. Patients should be warned about the symptoms associated with hypersensitivity reactions. HCPs are advised to discontinue erenumab immediately if serious hypersensitivity occurs.

Emgality▼(galcanezumab): hypersensitivity reactions, including delayed onset hypersensitivity reactions
Emgality is an IgG4 monoclonal antibody which binds to the calcitonin gene related peptide (CGRP) and is indicated for prophylaxis of migraine in adults who have at least four migraine days per month.

- Product information for Emgality (galcanezumab) already contains a warning that serious hypersensitivity reactions including cases of anaphylaxis, angioedema and urticaria have been reported. Serious hypersensitivity reactions may occur within a day after galcanezumab administration, however cases with a delayed onset have also been reported. The product information will be updated to reflect that cases of hypersensitivity reactions with onset ranging from more than 1 day to 4 weeks after administration have been reported. In some cases, hypersensitivity reactions had a prolonged duration. HCPs are advised to discontinue galcanezumab immediately if serious hypersensitivity occurs. Patients should be advised of the possibility of a delayed onset hypersensitivity reaction, and instructed to seek medical attention immediately should they develop signs and/or symptoms of a serious hypersensitivity reaction.

** The approved product information is made up of the Summary of Product Characteristics (SmPC) and Package Leaflet (PL) and is available at www.hpra.ie or www.ema.europa.eu*