HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Aimovig▼ (erenumab) – Risk of serious hypersensitivity and anaphylaxis, and updates regarding the risk of constipation

Calcitonin gene-related peptide (CGRP) is a neuropeptide that modulates nociceptive signalling and a vasodilator that has been associated with migraine pathophysiology. CGRP levels have been shown to increase significantly during migraine and return to normal with headache relief. Aimovig ▼(erenumab)* is a human immunoglobulin G2 monoclonal antibody which binds with high affinity to the CGRP receptor and specifically competes with the binding of CGRP to inhibit its function at the CGRP receptor. Aimovig is formulated as a solution for injection to be administered subcutaneously, and is indicated for prophylaxis of migraine in adults who have at least four migraine days per month.

Recent periodic reviews of cumulative safety data for Aimovig by the European Medicines Agency's (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) have resulted in updates to the product information (Summary of Product Characteristics (SmPC) and Package Leaflet (PL)) in relation to hypersensitivity reactions and constipation. Whilst already known potential adverse effects of treatment with Aimovig, and previously described in the product information, evaluation of the available safety data has resulted in further characterisation of these risks. Important updates to the product information include additional detail on the risk of serious hypersensitivity and anaphylaxis, with a further update on the risk of constipation to follow. A summary of these updates is provided below:

Advice to Healthcare Professionals

Hypersensitivity reactions

- Serious hypersensitivity reactions, including rash, angioedema, and anaphylactic reactions, have been reported with Aimovig 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.
- If a serious or severe hypersensitivity reaction occurs, initiate appropriate therapy and discontinue treatment with Aimovig.

Constipation

- Constipation is a common undesirable effect of Aimovig and is usually mild or moderate in intensity.
- In the majority of reported cases, onset occurred after the first dose of Aimovig; however, patients have also experienced constipation later on in the course of treatment.
- In most cases constipation was reported to have resolved within three months. Constipation with serious complications has been reported with Aimovig in post-marketing experience. In some of these cases hospitalisation was required, including cases where surgery was necessary.
- History of constipation or the concurrent use of medicinal products 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, or if they develop severe constipation. For severe constipation, discontinuation of treatment should be considered.

Key Message

- Serious hypersensitivity reactions, including rash, angioedema, and anaphylactic reactions, have been reported with Aimovig (erenumab) in post-marketing experience, with onset in some cases occurring more than one week after treatment.
- Constipation is a common undesirable effect of Aimovig and whilst usually mild or moderate in intensity, cases with serious complications, including hospitalisation and/or surgery, have been reported in post-marketing experience. History of constipation or the concurrent use of medicinal products associated with decreased gastrointestinal motility may increase risk.
- ▼This medicinal product is subject to additional monitoring and as such, all suspected adverse reactions associated with its use should be reported to the HPRA via the available methods (www.hpra.ie/report). Further information on the additional monitoring of medicines is available at www.hpra.ie.

** Further details on Aimovig are available at www.hpra.ie and www.ema.europa.eu.*

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