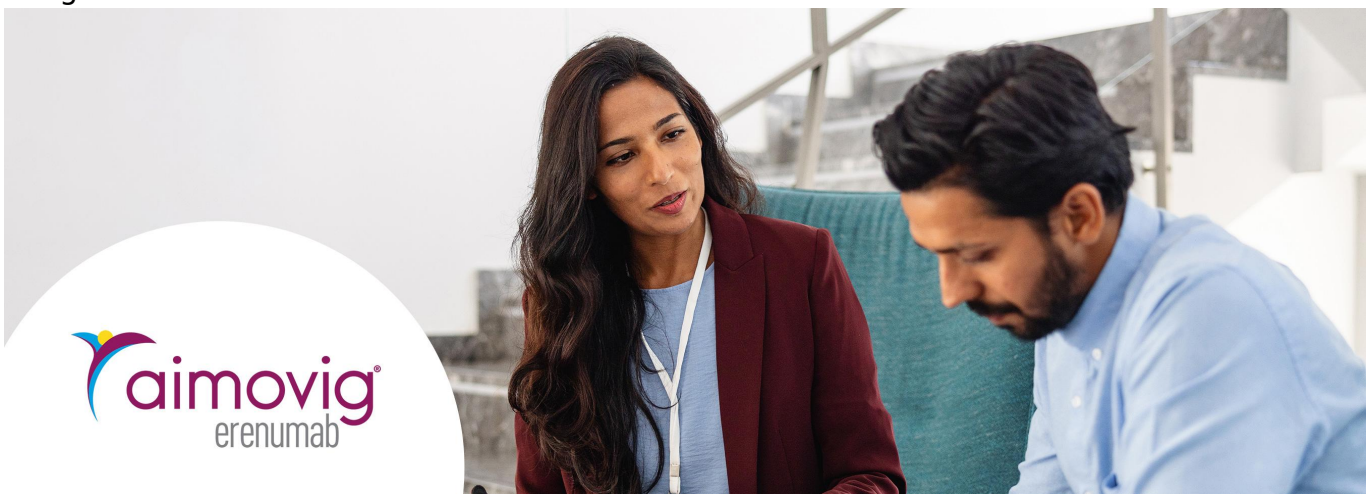
NOVARTIS

Aimovig - Safety profile - HCP

Prescribing information

Image



Image

AIMOVIG® (erenumab) safety profile

This page/content is for Great Britain healthcare professionals only. If you require information for Northern Ireland please refer to the Northern Ireland electronic medicines compendium (emc).

Aimovig is indicated for prophylaxis of migraine in adults who have at least 4 migraine days per month.[1]

The long-term safety and tolerability profiles of Aimovig have been studied for 5 years[2]

Image

No new safety signals were observed at 5 years[2]

Image

No increase in exposure-adjusted subject incidence rate per 100 subject-years in AEs or SAEs were observed compared with the 12-week double-blind treatment phase[2]

Summary of safety profile[1]

A total of over 2,500 patients (more than 2,600 patient years) have been treated with Aimovig in registration studies. Of these, more than 1,300 patients were exposed for at least 12 months and 218 patients were exposed for 5 years. The overall safety profile of Aimovig remained consistent for 5 years of long-term open-label treatment.

The reported adverse drug reactions for 70 mg and 140 mg were injection site reactions (5.6%/4.5%), constipation (1.3%/3.2%), muscle spasms (0.1%/2.0%) and pruritus (0.7%/1.8%). Most of the reactions were mild or moderate in severity. Less than 2% of patients in these studies discontinued due to adverse events.

List of adverse reactions in the SmPC[1]

Organ class	Adverse reaction	Frequency category
Immune system disorders	Hypersensitivity reactions* including anaphylaxis, angioedema, rash, swelling/oedema and urticaria	Common

Gastrointestinal disorders	Constipation	Common
	Oral sores[†]	Not known
Skin and subcutaneous tissue disorders	Pruritus[‡]	Common
	Alopecia Rash[§]	Not known
Musculoskeletal and connective tissue disorders	Muscle spasms	Common
General disorders and administration site conditions	Injection site reactions*	Common

*See section 'Description of selected adverse reactions' in the summary of product characteristics.[1]
[†]Oral sores includes preferred terms of stomatitis, mouth ulceration, oral mucosal blistering.[1]
[‡]Pruritus includes preferred terms of generalised pruritus, pruritus and pruritic rash.[1]
[§]Rash includes preferred terms of rash papular, exfoliative rash, rash erythematous, urticaria, blister.[1]

For further information about cautions and contraindication, please visit the summary of product characteristics.[1]

Clinical study safety profile

Ashina M et al, 2021:[2] 12-week double-blind, placebo-controlled clinical trial which continued in an open-label extension (OLE) of migraine[¶] patients treated with erenumab 70 mg every 4 weeks for up to 5 years.

Exposure-adjusted patient incidence rates of adverse event (per 100 patient-years)

	Double-blind treatment phase pooled data from four studies			**Open-label treatment phase of current study**	
	Erenumab			**Erenumab**	
	Placebo, N=1043, *n* [*r*]	70 mg, N=893, *n* [*r*]	140 mg, N=507 *n* [*r*]	70 mg, N=383, *n* [*r*]	140 mg, N=250 *n* [*r*]
All AEs	551 [280.2]	460 [261.2]	267 [230.5]	323 [142.0]	216 [109.9]
Grade ≥2	321 [126.5]	252 [108.7]	153 [100.4]	249 [68.7]	180 [57.7]
Grade ≥3	40 [12.8]	36 [12.9]	22 [11.7]	55 [8.8]	40 [6.4]
Serious AEs	20 [6.3]	18 [6.4]	10 [5.2]	30 [4.5]	25 [3.8]

AEs leading to discontinuation of investigational product	13 [4.1]	15 [5.3]	12 [6.3]	16 [2.3]	2 [0.3]
Fatal AEs	0 [0.0]	0 [0.0]	0 [0.0]	1 [0.1]	1 [0.1]
Nasopharyngitis**	77 [25.4]	61 [22.5]	42 [23.2]	82 [14.2]	59 [10.1]
Upper respiratory tract infection	40 [12.7]	46 [16.6]	21 [11.1]	52 [8.3]	53 [8.8]
Influenza	20 [6.3]	20 [7.1]	11 [5.8]	36 [5.5]	31 [4.8]

Adapted from Ashina M, et al. 2021.[2]

AEs, adverse events; *n*, number of patients reporting at least 1 occurrence of event; *r*, exposure-adjusted subject incidence rate per 100 subject-years.

¶Definition of migraine according to study protocol.[2]
**Nasopharyngitis was coded as viral upper respiratory tract infection in Medical Dictionary for Regulatory Activities version 20.0 used for double-blind treatment phase pooled analysis.

Posology and method of administration[1]

Treatment should be initiated by physicians experienced in the diagnosis and treatment of migraine.

Posology

Treatment is intended for patients with at least 4 migraine days per month when initiating treatment with erenumab.The recommended dose is 70 mg erenumab every 4 weeks. Some patients may benefit from a dose of 140 mg every 4 weeks.Each 140 mg dose is given either as one subcutaneous injection of 140 mg or as two subcutaneous injections of 70 mg.

Clinical studies have demonstrated that the majority of patients responding to therapy showed clinical benefit within 3 months. Consideration should be given to discontinuing treatment in patients who have shown no response after 3 months of treatment. Evaluation of the need to continue treatment is recommended regularly thereafter.

Special populations
Elderly (aged 65 years and over):
Aimovig has not been studied in elderly patients. No dose adjustment is required as the pharmacokinetics of erenumab are not affected by age.
Renal impairment/hepatic impairment:
No dose adjustment is necessary in patients with mild to moderate renal impairment or hepatic impairment.

Paediatric population
The safety and efficacy of Aimovig in children below the age of 18 years have not yet been established. No data are available.

Method of administration
Aimovig is for subcutaneous use.
Aimovig is intended for patient self-administration after proper training. The injections can also be given by another individual who has been appropriately instructed. The injection can be administered into the abdomen, thigh or into the outer area of the upper arm (the arm should be used only if the injection is being given by a person other than the patient. Injection sites should be rotated and injections should not be given into areas where the skin is tender, bruised, red or hard.

Pre-filled syringe
The entire contents of the Aimovig pre-filled syringe should be injected. Each pre-filled syringe is for single use only and designed to deliver the entire contents with no residual content remaining.
Comprehensive instructions for administration are given in the instructions for use in the package leaflet.

Pre-filled pen
The entire contents of the Aimovig pre-filled pen should be injected. Each pre-filled pen is for single use only and designed to deliver the entire contents with no residual content remaining.
Comprehensive instructions for administration are given in the instructions for use in the package leaflet.

Special warnings and precautions for use[1]

Cardiovascular effect
Patients with certain major cardiovascular diseases were excluded from clinical studies. No safety data are available in these patients.

Hypersensitivity reactions
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. In that context, patients should be warned about the symptoms associated with hypersensitivity reactions. If a serious or severe hypersensitivity reaction occurs, initiate appropriate therapy and do not continue treatment with erenumab.

Constipation
Constipation is a common undesirable effect of Aimovig and is usually mild or moderate in intensity. In a majority of the cases, the onset was reported after the first dose of Aimovig;

however patients have also experienced constipation later on in the treatment. In most cases constipation resolved within three months. In the post-marketing setting, constipation with serious complications has been reported with erenumab. 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. Patients should seek medical attention immediately if they develop severe constipation. Constipation should be managed promptly as clinically appropriate. For severe constipation, discontinuation of treatment should be considered.

Traceability
In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Latex-sensitive individuals
The removable cap of the Aimovig pre-filled syringe/pen contains dry natural rubber latex, which may cause severe allergic reactions in individuals sensitive to latex.

Sodium content
This medicinal product contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially “sodium free”.

Fertility, pregnancy and lactation[1]

Pregnancy
There are a limited amount of data from the use of Aimovig in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. As a precautionary measure, it is preferable to avoid the use of Aimovig during pregnancy.

Breast-feeding
It is unknown whether erenumab is excreted in human milk. Human IgGs are known to be excreted in breast milk during the first few days after birth, which is decreasing to low concentrations soon afterwards; consequently, a risk to the breast-fed infant cannot be excluded during this short period. Afterwards, use of Aimovig could be considered during breast-feeding only if clinically needed.

Fertility
Animal studies showed no impact on female and male fertility.

AMSM, acute migraine-specific medication; IgG, immunoglobulin G; MMD, monthly migraine days; OLE, open-label extension; OLTP, open-label treatment phase; SC, subcutaneous; SE, standard error.

References

1. Aimovig® (erenumab) Summary of Product Characteristics.

2. Ashina M, et al. *Eur J Neurol* 2021;28:1716–1725.

Dosing and administration

Dosing and administration

See more details

Hide details

Mode of action

Mode of action

See more details

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UK | October 2024 | FA-11214793

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Novartis online through the pharmacovigilance intake (PVI) tool at www.novartis.com/report, or alternatively email medinfo.uk@novartis.com or call 01276 698370.
