About Aimovig® (erenumab) in migraine prevention Media factsheet

About migraine

Migraine is a distinct neurological disease.¹ It involves recurrent attacks of moderate to severe head pain and may be associated with nausea, vomiting and sensitivity to light, sound and odors.² It is one of the top 10 causes of years lived with disability for men and women according to the World Health Organisation.³ It remains under-recognized and under-treated.¹

People with migraine are in urgent need of new preventive treatment options as up to 80% of patients with chronic migraine discontinue preventive medication within a year.⁴ Most of the currently available treatments aim to relieve symptoms rather than prevent migraine attacks. Frequent use of medications to treat headaches when they occur can lead to medication-overuse headache, which can result in entering a destructive cycle of medication use.⁵

About Aimovig®

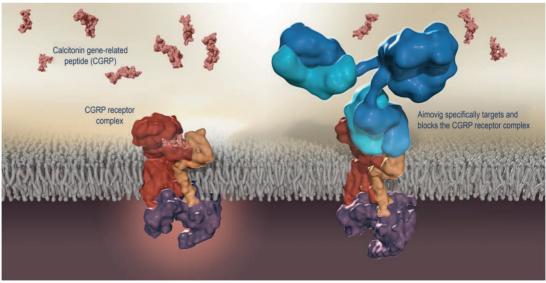
Overview

Aimovig is the first preventive migraine treatment approved by the FDA, EMA, Swissmedic and Australian TGA. It has also been approved in Canada, the UAE and Singapore. The European Commission (EC) approved Aimovig for the prevention of migraine in adults experiencing four or more migraine days per month. In the US, Aimovig is approved for the preventive treatment of migraine in adults. It is a novel therapeutic approach, the first and only medication specifically, developed to prevent migraine by blocking the calcitonin gene-related peptide receptor (CGRP-R), which is believed to play a critical role in migraine.⁶ Aimovig is self-administered or can be administered by another trained person once every four weeks via an autoinjector and does not require a loading dose. Some patients may benefit from a dosage of 140mg once every four weeks.

Aimovig's fast growing real world experience

Aimovig is the migraine prevention treatment with the largest and longest exposure in the market. As of April 2019, an estimated 200,000 patients worldwide have been prescribed Aimovig.

Aimovig's unique mode of action



© 2018 Amgen Inc. All rights reserved. Not for Reproduction. www.amgen.com. Used with permission

CGRP is a protein that binds to the CGRP receptor complex and is thought to be responsible for transmitting the pain signals associated with migraine.⁶ In people with migraine, CGRP levels increase at the onset of pain and return to normal when migrain pain subsides.⁷



Aimovig specifically blocks the CGRP receptor. It is the first and only human monoclonal antibody of its kind designed to do this.

What is the clinical evidence?

Data from clinical trials on Aimovig involving more than 3,000 patients have shown meaningful and sustained benefits in patients across the spectrum of migraine including reduced migraine days, even in difficult-to-treat patients. It has shown meaningful and sustained benefits in patients across the spectrum of migraine, with many experiencing a 50% or more reduction in monthly migraine days.⁸⁻¹¹

Growing clinical evidence on Aimovig's long-term efficacy and safety

More than two-thirds of chronic migraine patients converted to episodic migraine by the last dose received (Results from a 52-week, multicenter study, OLE, NCT02174861)¹² In the one-year extension of the Phase 3 STRIVE study, the efficacy data showed sustained benefits over 52 weeks.¹³

How was Aimovia developed?

Aimovig is being co-developed by Novartis and Amgen. In August 2015, Novartis entered into a global collaboration with Amgen to develop and commercialize pioneering treatments in the field of migraine and Alzheimer's disease. The collaboration focuses on investigational Amgen drugs in the migraine field, including Aimovig.

In April 2017, the collaboration was expanded to include co-commercialization of Aimovig in the United States. For the migraine program, Amgen retains exclusive commercialization rights in Japan, and Novartis has exclusive commercialization rights in all other countries worldwide.

References

- Migraine Research Foundation. Migraine facts. http://www.migraineresearchfoundation.org/fact-sheet.html. Accessed April 2019.
- National Institute for Neurological Disorders and Stroke. Migraine information Page. https://www.ninds.nih.gov/Disorders/All-Disorders/Migraine-Information-Page. Accessed April 2019.
- 3. World Health Organization. Headache disorders. http://www.who.int/mediacentre/factsheets/fs277/en/. Accessed April 2019.
- 4. Hepp Z, Dodick DW, Varon SF, et al. Adherence to oral migraine-preventive medications among patients with chronic migraine. Cephalalgia. 2015;35(6):478-88.
- 5. Headache Classification Committee of the International Headache Society, 2013.
- 6. Bigal ME, Walter S, Rapoport AM. Calcitonin gene-related peptide (CGRP) and migraine: Current understanding and state of development. Headache. 2013;53(8):1230-1244.
- 7. Lassen LH,Hadersley PA,Jacobsen VB, et al. CGRP may play a causative role in migraine. Cephalalgia. 2002;2(1):54-61.
- 8. Dodick DW, Ashina M, Brandes JL, et al. ARISE: A phase 3 randomized trial of erenumab for episodic migraine. Cephalalgia. 2018;38(6):1026-1037.
- Goadsby PJ, Reuter U, Hallström Y, et al. A controlled trial of erenumab for episodic migraine. N Engl J Med. 2017;30;377(22):2123-2132
- Tepper S, Ashina M, Reuter U, et al. Safety and efficacy of erenumab for preventive treatment of chronic migraine: a randomised, double-blind, placebo-controlled pahse 2 trial. Lancet Neurol.2017;16(6):425-434.
- 11. Reuter, U. et al. Efficacy and tolerability of erenumab in patients with episodic migraine in whom two-to-four previous preventive treatments were unsuccessful: a randomised, double-blind, placebo-controlled, phase 3b study. Lancet. 2018.
- 12. Lipton R, Tepper S, Silberstein S, et al. Presented at the 71st Annual Meeting of the American Academy of Neurology; May 4-10, 2019; Philadelphia, PA.
- 13. Chou D, Goadsby P, Reuter U, et al. Presented at the 71st Annual Meeting of the American Academy of Neurology; May 4-10, 2019; Philadelphia, PA.

GLNS/AMG/0319c - April 2019

Novartis Pharma AG Novartis Campus CH-4056 Basel Switzerland ©Novartis Pharma AG

