

Erenumab

Approved indication: migraine

Aimovig (Novartis)

pre-filled pen containing 70 mg/mL

Australian Medicines Handbook section 16.3.2

Patients who have frequent attacks of migraine may benefit from prophylaxis. Drugs that have been used for prophylaxis include amitriptyline, pizotifen and propranolol. Injections of erenumab add to these choices.

Erenumab is a monoclonal antibody against the calcitonin gene-related peptide (CGRP) receptor. During an attack of migraine there is an increase in the concentration of CGRP. This peptide causes vasodilation and is thought to modulate pain. By competing with CGRP for the receptor, erenumab could prevent attacks.

After subcutaneous injection the peak concentration of erenumab is reached after 4–6 days. The effective half-life is 28 days so monthly injections are recommended. Renal and hepatic impairment are not expected to affect the pharmacokinetics. There is also no effect on the pharmacokinetics of the combined oral contraceptive pill. The safety of erenumab in pregnancy is unknown.

A double-blind, phase II clinical trial studied 667 adults with chronic migraine. They had an average of 18 days of migraine every month. There were 191 patients randomised to erenumab 70 mg, 190 to 140 mg and 286 to placebo. After receiving monthly injections for 12 weeks, 40–41% of the patients taking either dose of erenumab had a 50% or greater reduction in migraine days per month, compared with 23% of the placebo group. On average the reduction was 6.6 days with erenumab and 4.2 days with placebo.¹

The same doses were studied in a placebo-controlled phase III trial involving 955 patients with episodic migraine. In this trial the double-blind treatment was for 24 weeks. At the start of the trial the patients were having an average of 8.3 days of migraine per month. This was reduced by at least half in 43.3% (135/312) of the patients given erenumab 70 mg and 50% (159/318) of those given erenumab 140 mg. In the placebo group 26.6% (84/316) responded. The mean number of migraine days per month fell by 3.2 days with erenumab 70 mg, 3.7 days with 140 mg and by 1.8 days with placebo.²

In another phase III trial 286 patients with episodic migraine were randomised to receive erenumab 70 mg while 291 received monthly injections of placebo. After a 12-week double-blind treatment

phase, the mean number of migraine days fell by 2.9 days, from a baseline of 8.3 days, with erenumab, and by 1.8 days with placebo. A reduction of 50% or more in monthly migraine days was achieved by 39.7% of the erenumab group and 29.5% of the placebo group.³

During the clinical trials a total of 1400 patients were treated with erenumab. Injection site reactions were common, affecting 4–6% of patients. Pruritus, muscle spasm and constipation were also commonly reported. While some of the patients continued treatment with erenumab after the trials, its long-term safety is unknown. Some patients will develop anti-erenumab antibodies.^{2,3}

In its approved indication of migraine prophylaxis, erenumab is significantly more effective than placebo. Although the phase III trials reported that the difference is only 1–2 days per month, this can be important for patients having frequent migraine attacks. There were corresponding reductions in the number of days patients needed to take drugs for acute treatment. While there were some improvements in everyday functioning, these were not always significantly different from placebo.³

Erenumab will not benefit everyone. Less than half the patients injecting 70 mg monthly will get a 50% or greater reduction in the number of days they have migraine. Initially erenumab is likely to be tried in people who have not benefited from other drugs. Around 40% of the patients in the phase III trials had taken prophylaxis previously, but patients who had not responded to more than two preventive drugs were excluded from some trials.^{2,3} A monthly injection could overcome some of the problems with adhering to a prophylactic regimen, but the long-term effectiveness of erenumab needs to be established.

T [manufacturer provided the product information](#)

REFERENCES

1. Tepper S, Ashina M, Reuter U, Brandes JL, Doležil D, Silberstein S, et al. Safety and efficacy of erenumab for preventive treatment of chronic migraine: a randomised, double-blind, placebo-controlled phase 2 trial. *Lancet Neurol* 2017;16:425-34. [https://doi.org/10.1016/S1474-4422\(17\)30083-2](https://doi.org/10.1016/S1474-4422(17)30083-2)
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NEW DRUGS

The Transparency Score is explained in [New drugs: transparency, Vol 37 No 1, Aust Prescr 2014;37:27](#).

At the time the comment was prepared, information about this drug was available on the websites of the [Food and Drug Administration](#) in the USA, and the [European Medicines Agency](#).