AJOVY™
(fremanezumab)
injection 225 mg/1.5 mL

A fully humanised monoclonal antibody that targets and blocks CGRP, a critical component in the pathogenesis of migraine[1,2]

The only anti-CGRP therapy offering the ***flexibility*** of quarterly or monthly dosing for ***migraine prevention***[1,3-5]

PRESCRIBER GUIDE

AJOVY is indicated for the preventive treatment of migraine in adults.[1]

CGRP: calcitonin gene-related peptide.

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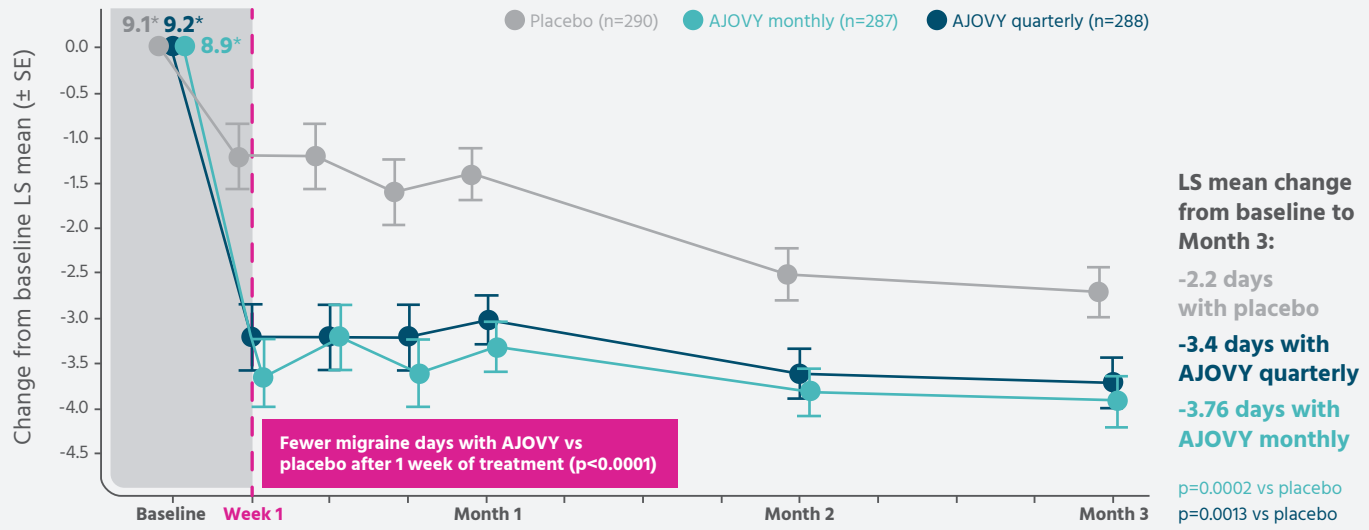
EPISODIC MIGRAINE

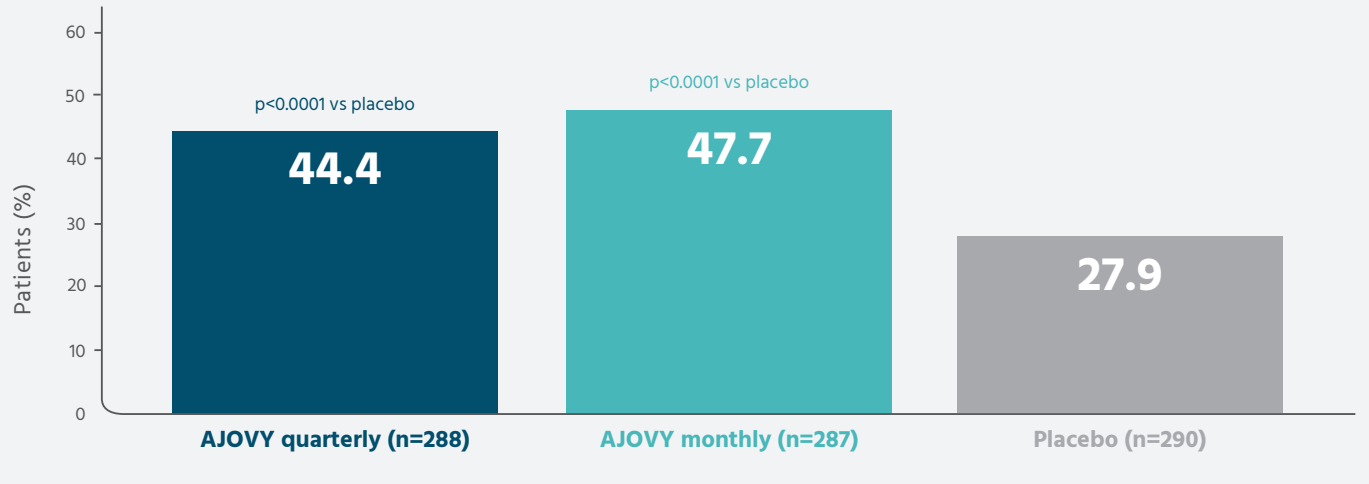
Start with AJOVY for fewer migraine days[1,6]

At Month 3, **patients† experienced 3.7 fewer migraine days** with AJOVY monthly vs placebo (p=0.0002)[1,6]



Adapted from Dodick et al. 2018.[6] *Measured during the 28-day pre-intervention period. Graph represents mean reduction from baseline in average monthly migraine days within the 12-week period following first dose (primary endpoint).[1,6]

47.7% of patients† achieved ≥50% reduction in migraine days with AJOVY monthly from baseline to Month 3 vs placebo (p<0.0001)[1,6]



Adapted from Dodick et al. 2018.[6] Graph represents patients with ≥50% reduction in monthly average number of migraine days (secondary endpoint).[1,6]

†Patients had episodic migraine defined as 6-14 headache days, with at least 4 migraine days per month.

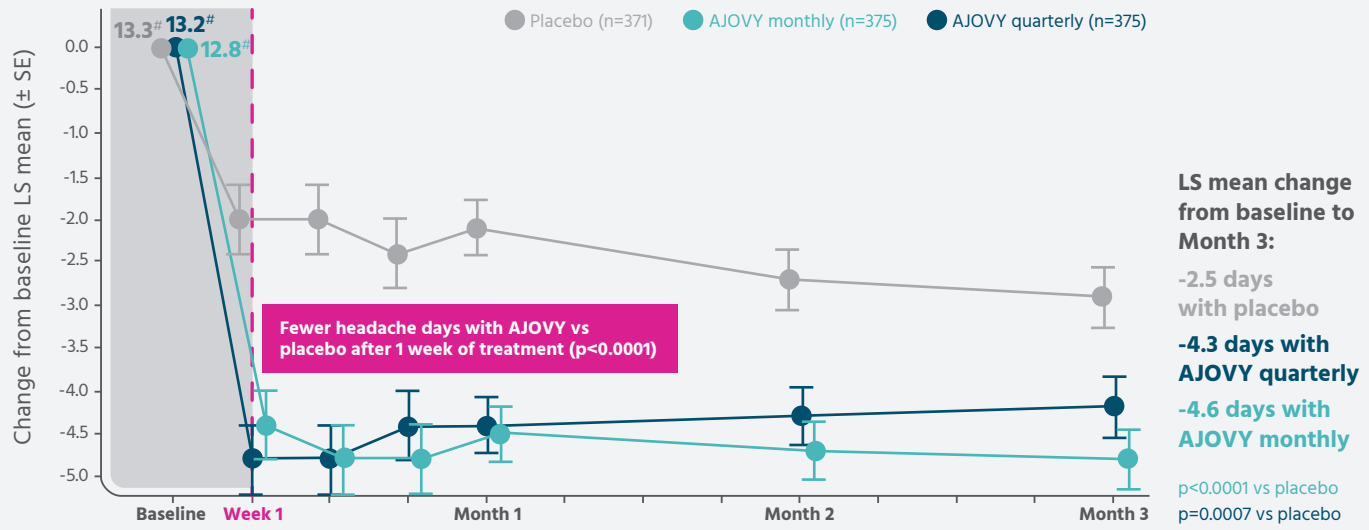
HALO EM study design: Randomised, 12-week, double-blind, placebo-controlled phase III study in adult patients with episodic migraine. Patients were randomised to one of three arms: AJOVY 675 mg every three months (quarterly), AJOVY 225 mg once a month, or monthly placebo. A total of 791 patients completed the 12-week double-blind treatment period. Primary efficacy endpoint was the mean change from baseline in the monthly average number of migraine days during the 12-week treatment period.[1,6]

EM, episodic migraine; LS, least squares; SE, standard error.

CHRONIC MIGRAINE

Start with AJOVY for fewer headache days[1,7]

At Month 3, **patients§ experienced 4.6 fewer headache days** with AJOVY monthly vs placebo (p<0.0001)[1,7]



Adapted from Silberstein et al. 2017.[7] #Measured during the 28-day pre-intervention period. Graph represents mean reduction from baseline in average monthly headache days of at least moderate severity within the 12-week period following first dose (primary endpoint).[1,7]

40.8% of patients§ achieved ≥50% reduction in headache days with AJOVY monthly from baseline to Month 3 (p<0.0001)[1,7]

Adapted from Silberstein et al. 2017.[7] Graph represents patients with ≥50% reduction in monthly average number of headache days (secondary endpoint).[1,7]

§Patients had chronic migraine defined as headache on ≥15 days per month and migraine on ≥8 days per month.

HALO CM study design: Randomised, 12-week, double-blind, placebo-controlled phase III study in adult patients with chronic migraine. Patients were randomised to one of three arms: AJOVY 675 mg for the starting dose followed by AJOVY 225 mg once a month (monthly), AJOVY 675 mg every 3 months (quarterly), or monthly placebo. A total of 1034 patients completed the 12-week double-blind treatment period. Primary efficacy endpoint was the mean change from baseline in the monthly average number of headache days of at least moderate severity during the 12-week treatment period.[1,7]

CM, chronic migraine; LS, least squares; SE, standard error.

AJOVY offers a safety profile comparable to placebo[1]

In patients treated with AJOVY in the pivotal Phase 3 trials:[1,6-8]

- **≤1%** of patients reported hypersensitivity reactions
- **≤2%** of patients discontinued therapy due to adverse events

Most common adverse events experienced among patients receiving AJOVY were injection-site reactions (pain, induration, erythema, pruritus):[1]

- Most injection-site reactions were rated as mild to moderate
- All injection site reactions resolved, mostly within a few hours or days
- Injection site reactions generally did not necessitate discontinuation of AJOVY.

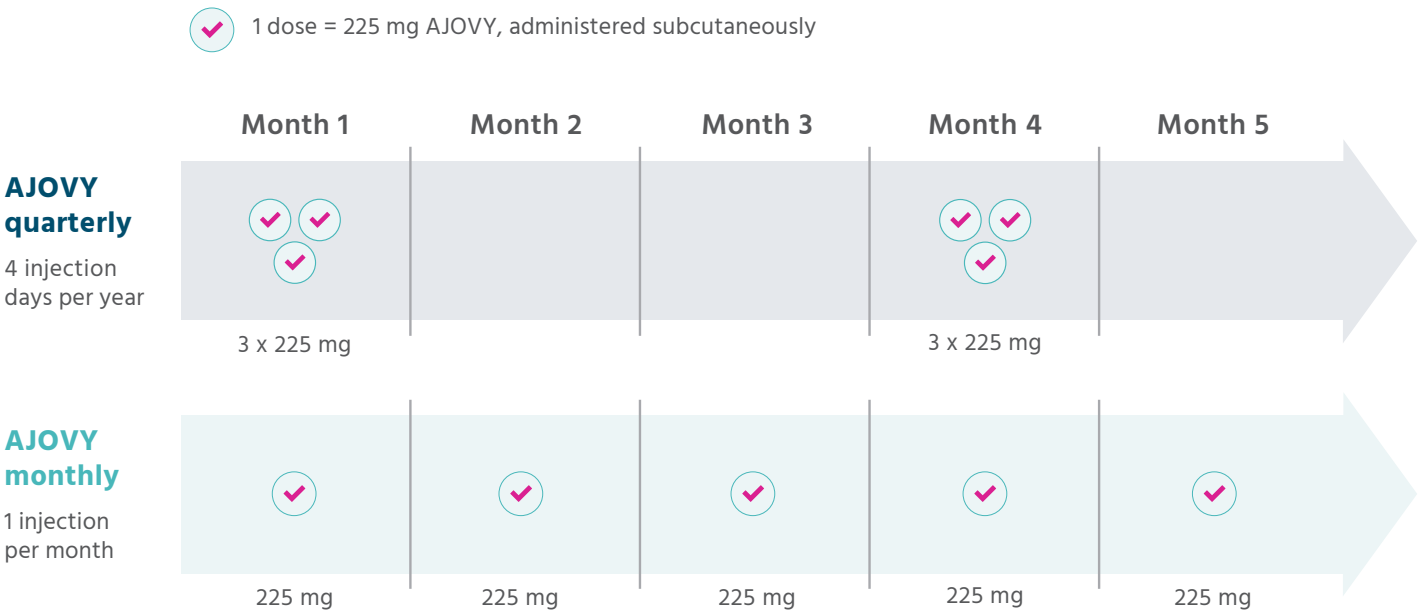
Treatment-emergent adverse events reported in ≥2% of episodic and chronic migraine patients[1a]

	Number of patients (%)				
	Placebo	AJOVY			
	Monthly (N=861)	225 mg monthly (N=386)	675 mg quarterly (N=667)	675/225 mg monthly[b] (N=467)	Total[c] (N=1702)
MedDRA PT	n (%)	n (%)	n (%)	n (%)	n (%)
Injection site pain	189 (22)	96 (25)	200 (30)	105 (22)	413 (24)
Injection site induration	113 (13)	71 (18)	131 (20)	90 (19)	292 (17)
Injection site erythema	104 (12)	55 (14)	135 (20)	76 (16)	273 (16)
Upper respiratory tract infection	35 (4)	20 (5)	29 (4)	17 (4)	68 (4)
Nasopharyngitis	35 (4)	13 (3)	30 (4)	16 (3)	62 (4)
Urinary tract infection	15 (2)	7 (2)	14 (2)	9 (2)	35 (2)
Dizziness	9 (1)	4 (1)	9 (1)	12 (3)	31 (2)
Injection site pruritus	2 (<1)	4 (1)	10 (1)	12 (3)	30 (2)
Sinusitis	22 (3)	4 (1)	12 (2)	8 (2)	29 (2)
Back pain	12 (1)	4 (1)	11 (2)	8 (2)	29 (2)
Injection site hemorrhage	16 (2)	4 (1)	16 (2)	8 (2)	28 (2)
Bronchitis	6 (≤1)	10 (3)	9 (1)	6 (1)	26 (2)

Adapted from Data Sheet.[1] [a]Double-blind, placebo-controlled studies (phase II and phase III) in patients with episodic and chronic migraine exposed to AJOVY. [b]Patients received AJOVY at 225 mg monthly with a starting dose of 675 mg. [c]Adverse events that occurred in patients in all AJOVY treatment groups, including the 675 mg monthly and 900 mg monthly treatment groups, are included in this total group.

MedDRA, Medical Dictionary for Regulatory Activities; PT, preferred term.

Start with AJOVY for the flexibility of quarterly or monthly dosing[1]



Post-hoc analysis from phase III study (n=1890) reported:

No evidence of wearing-off effect at the end of monthly or quarterly dosing intervals (no p-value reported)[9]*

Dosage and administration[1]

- AJOVY may be administered in the clinic by a healthcare professional or at home by the patient or caregiver[1]
- When switching dosing regimens, the first dose of the new regimen should be administered on the next scheduled dosing date of the prior regimen[1]
- No dose adjustment is required in patients with renal or hepatic impairment or elderly patients[1]

Storage[1]

- Store in a refrigerator (2-8°C). Do not freeze
- Keep the pre-filled syringe(s) in the outer carton to protect from light
- May be stored unrefrigerated for ≤7 days at ≤30°C; discard AJOVY if not used within 7 days of removal from refrigeration; AJOVY must remain in the outer carton when stored outside the refrigerator

*Post-hoc analysis of data from a 12-month phase III study that included chronic and episodic migraine patients who rolled over from the 12-week phase III HALO CM (n=917) and EM (n=661) trials, as well as an additional subset of 312 new patients. For selected months, the difference in the average number of migraine days between weeks 1-2 and weeks 3-4, between weeks 1-3 and week 4, and between weeks 1-2 and weeks 11-12 were calculated.[9]

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Scan here for resources
including the Injection Support Video and Migraine Diary for patients

CGRP: calcitonin gene-related peptide.

Before prescribing Ajovy™ (fremanezumab), a Prescription Medicine, please review the full Data Sheet for the product available at www.medsafe.govt.nz. Ajovy™ is an unfunded medicine – patients will need to pay for the medicine and any healthcare professional fees.

Ajovy™ (fremanezumab) 225 mg/1.5mL pre-filled syringe. **Indication**: Preventive treatment of migraine in adults. **Contraindications:** Hypersensitivity to the active substance or to any other component of the product. **Precautions:** Hypersensitivity; consider discontinuation and initiate appropriate treatment, Major Cardiovascular Disease; some patient groups with major cardiovascular disease were excluded from clinical trials. No safety data is available in these patients. No data available in elderly or paediatric patients. No data available in renal or hepatic impairment. Pregnancy Category B1; may cross placenta. Lactation, unknown whether fremanezumab is excreted in human milk. No or negligible influence on the ability to drive or operate machinery. **Interactions:** No formal clinical drug interaction studies have been performed. Concomitant Migraine Treatment; concomitant use of acute migraine treatments (analgesics, ergots and triptans) and preventive migraine medications did not influence safety and efficacy. CYP450 Substrates; pharmacokinetic interactions are not expected when co-administered. **Adverse Effects:** The most frequently reported adverse events were local reactions at the injection site [pain (24%), induration (17%), erythema (16%) and pruritus (2%)]. *Very Common:* Injection site pain, injection site induration, injection site erythema. *Common:* Injection site pruritus. *Uncommon:* Hypersensitivity reactions such as rash, pruritus, urticaria and swelling. **Dosage and Administration:** Ajovy™ should only be administered by subcutaneous injection. Treatment should be initiated by a physician experienced in the diagnosis and treatment of migraine. Available in a monthly dose; 225 mg once monthly or a quarterly dose; 675 mg every three months. The treatment benefit should be assessed 8-12 weeks after initiation of treatment. *Missed Dose;* resume dosing on the indicated dose and regimen. Do not administer a double dose. May be administered by healthcare professionals, as well as patients or caregivers upon proper training from their healthcare professional. Syringe is single use in one patient only. Discard any residue. Follow clean injection technique every time. Administer by subcutaneous injection only into areas of the abdomen, thigh, or upper arm that are not tender, bruised, red, or indurated. For multiple injections, do not use the same injection site. **Presentation:** 1.5 mL solution in a 2.25 mL Type I glass syringe with plunger stopper (bromobutyl rubber) and needle. The pre-filled syringe cap is not made with natural rubber latex. Pack sizes of one 225mg/1.5mL or three 225mg/1.5mL pre-filled syringes. Not all pack sizes may be marketed. **Storage:** Store in a refrigerator (2°C to 8°C). Do not freeze. Keep the pre-filled syringe(s) in the outer carton in order to protect from light. May be stored unrefrigerated for up to 7 days at a temperature up to 30°C. Must be discarded if not used within 7 days of removal from refrigeration. **Medical Classification:** Prescription Medicine. Based on Data Sheet v3.0 approved 28 January 2025. **Distributed in NZ by:** Teva Pharma (New Zealand) Limited (No. 1190198) of Tenancy B, Level 14, the AIG Building, 41 Shortland Street, Auckland Central, Auckland 1010 New Zealand. New Zealand Telephone: 0800 800 097

 Date of preparation: December 2025. Date of expiration: December 2027. TEV004. AJO-NZ-00003. TAPS MR12747.

References: 1. AJOVY™ (fremanezumab) Data Sheet. **2.** Urits I et al. Pain Ther 2020;9:195-215. **3.** EMGALITY (galcanezumab) Data Sheet. **4.** AIMOVIG (erenumab) Data Sheet. **5.** AQUIPTA (atogepant) Data Sheet. **6.** Dodick DW et al. JAMA 2018;319:1999-2008. **7.** Silberstein SD et al. N Engl J Med 2017;377:2113-2122. **8.** Ferrari MD et al. Lancet 2019;394(10203):1030-1040. **9.** Blumenfeld AM et al. Headache 2020;60:2431-2443.

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