IMAGINE WHAT'S POSSIBLE FOR YOUR PATIENTS WITH FEWER MIGRAINE DAYS

Emgality is indicated for the prevention of migraine in adults[1]

Emgality®
(galcanezumab) injection

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Effective migraine prevention is still needed for many patients[2]

Migraines disrupt patients' lives at home and work[2,3]

REDUCED QUALITY TIME

with friends and family[2]

REDUCED PRODUCTIVITY

with an average of **4 and 8 hours of lost productivity time per week** in people with episodic and chronic migraine, respectively[3]

Current oral migraine preventive treatments aren't satisfying patients' needs[4,5]

LESS THAN HALF

of eligible patients receive preventive treatment[4]

50%

50% DISCONTINUE

their first oral migraine preventive **within ~60 days**[5]

Meet Jessica

Jessica, 38
Working mother of one

Migraine frequency:

4 or more migraine headache days per month

Disease burden:

- Migraine attack lasting 4-72 hours and can be disabling[6,7]
- Migraine negatively impacts her productivity at home and work[8]
- She has discontinued other migraine preventives due to lack of efficacy and/or intolerable side effects[2]

"I can't go to his swimming class. I can't go to work. I can't do what I want to do when I have a migraine"

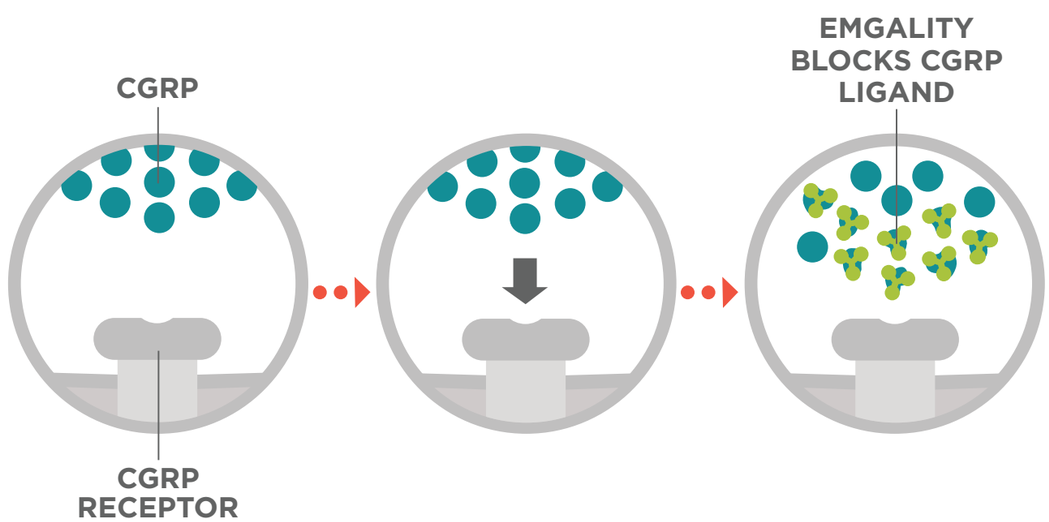
"I have a lot going on with my family, friends and career. I try my best to be present but often, my migraines are so painful it is difficult to leave the house"

Hypothetical patient.

Emgality is specifically developed to prevent migraine by targeting the CGRP ligand[1,9,10]

Emgality is a humanised IgG4 monoclonal antibody that targets the CGRP ligand[1,11]

Emgality binds to the CGRP ligand with high affinity and high specificity[1,11]



Calcitonin gene-related peptide (CGRP) is thought to play a central role in the pathophysiology of migraine:[12]

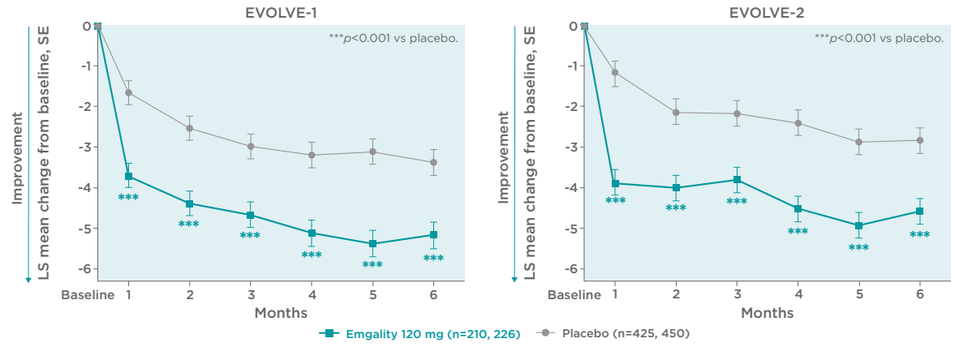
- CGRP is widely expressed throughout the central and peripheral nervous system. It is released by stimulation of the trigeminal sensory nerves and acts as a sensory neurotransmitter, vasodilator, and mediator of neurogenic inflammation[9–11]
- CGRP was found to be significantly elevated during migraine attacks in the external jugular vein[1,9,10]
- An infusion of CGRP can induce migraine attacks in individuals with a history of migraine[1,9,10]

Emgality prevents the biological activity of CGRP without blocking the CGRP receptor[11]

More migraine free days are possible vs placebo for patients with episodic migraine[1,11,13,14]*

*Emgality reduced mean monthly MHDs vs placebo from month 1 and maintained response up to month 6[11,13]

Mean change from baseline in number of MHDs (month 1 to 6)[11,13]



Adapted from Stauffer VL *et al.* 2018[11] and Skljarevski V *et al.* 2018.[13]
Baseline mean MHDs for Emgality and placebo, respectively: EVOLVE-1: 9.2 and 9.1; EVOLVE-2: 9.1 and 9.2.[11,13]

Primary endpoint: Emgality reduced mean monthly MHDs by 4.7 and 4.3 from baseline vs 2.8 and 2.3 for placebo in EVOLVE-1 and EVOLVE-2, respectively (p<0.001)[11,13]

~3 IN 5

patients achieved a **≥50% reduction** in migraine days per month (p<0.001)[11,13]

EVOLVE-1: 62.3% vs placebo 38.6%[11]

EVOLVE-2: 59.3% vs placebo 36.0%[13]

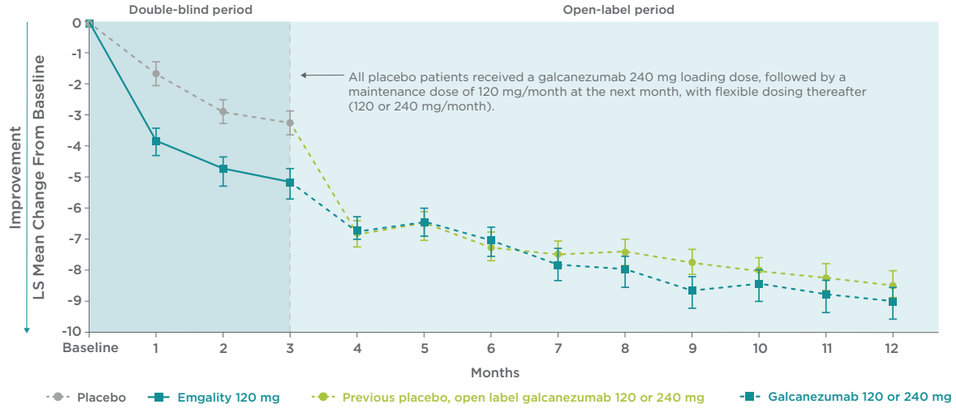
More migraine free days are possible with Emgality for patients with episodic migraine[11,13]*

*Emgality demonstrated higher ≥50%, ≥75%, and 100% response rates vs placebo in reduction of mean monthly MHDs from month 1 to 6

More migraine free days are possible vs placebo for patients with chronic migraine[15,16]*

*Emgality reduced mean monthly MHDs vs placebo from month 1 to 3 and maintained response up to 1 year[15,16]

Mean change from baseline in number of MHDs per month across 12 months[15,16]



Adapted from Detke HC *et al.* 2018.[16] Patients who entered the 9-month open-label extension received a 240 mg loading dose of glacanezumab, followed by a maintenance dose of 120 mg/month at the next month, with flexible dosing thereafter (120 or 240 mg/month) at the discretion of the investigator. Previous placebo (n=501), previous glacanezumab 120 mg (n=259), previous galcanezumab 240 mg (n=262). The final results support the observation that galcanezumab appears effective, safe, and well tolerated for the preventive treatment of chronic migraine.[16]

Only galcanezumab 120 mg is registered in Australia and New Zealand.[1]

Chronic migraine was defined as ≥15 headache days per month for more than 3 months, of which at least 8 had the features of migraine.[15]

Primary endpoint: Emgality reduced mean monthly MHDs across months 1 to 3 by 4.8 vs 2.7 for placebo (p<0.001, baseline mean: 19.4 vs 19.6, respectively)[15]

~1 IN 4

patients achieved a **≥50% response** in migraine days per month (p<0.001)[15]

REGAIN:
27.6% vs. placebo 15.4% (mean % of patients from month 1 to 3)[15]

Imagine what your patients could achieve with fewer migraine days

Emgality significantly reduced the functional impact of migraine on the lives of patients over months 4 to 6 vs placebo[1,11,13]

In the Emgality clinical trials of patients with episodic migraine, the quality of life measurements were based on MIDAS and MSQ questionnaires:[11,13]

- The MIDAS Questionnaire was developed to assess headache-related disability with the aim of improving migraine care. Headache sufferers answer five questions, scoring the number of days, in the past 3 months, of activity limitations due to migraine.[19] A decrease in MIDAS score represents an improvement in quality of life[17]
- The MSQ-Role Function-Restrictive (RF-R) domain is a 7-item questionnaire that measures the functional impact of migraine on relationships with family and friends, leisure time, work or daily activities, productivity, concentration, tiredness, and energy. An increase in MSQ score indicates better health status[18]

As assessed by the MSQ-RF-R, patients treated with Emgality saw statistically significant improvements from baseline:[11,13,20]

63% increase

54% increase

Relative improvement in MSQ score from baseline (month 4 to 6):

63% in EVOLVE-1, 32.4-point improvement from baseline (51.4 points) vs 24.7 points with placebo (baseline: 52.9 points) over months 4 to 6 (difference 7.7. p<0.001)[11]

54% in EVOLVE-2, 28.5-point improvement from baseline (52.5 points) vs 19.7 points with placebo (baseline: 51.4 points) over months 4 to 6 (difference 7.8. p<0.001)[13]

As assessed by the MIDAS questionnaire, patients treated with Emgality saw statistically significant improvements from baseline:[19]

Up to 80%

73–80% of patients on Emgality saw their overall disability cut in half (≥50% response) at Month 6 based on MIDAS total score vs 55–56% for placebo (p<0.001)[19]

7–9 days

to

2–4 days

Emgality decreased the number of days that patients experienced reduced productivity at work or school at month 6. Baseline 6.9 to 8.7 days. Mean change from baseline -4.8 to -5.2 days with Emgality vs -3.1 to -3.3 days with placebo[19]

Improvements relevant across the following domains:

- Work or daily activities
- Leisure time
- Concentration
- Relationships with family and friends
- Productivity
- Energy
- Tiredness

Emgality has a favourable safety profile with low rates of discontinuation[1,11,13,15]

The safety of Emgality has been evaluated vs placebo in >2500 patients across three phase 3 trials[1,11,13,15]

Treatment-emergent adverse events occurring in ≥1.0% of patients treated with Emgality and significantly more than placebo (pooled data)[21]

Event, % (n)	Emgality 120 mg (n=705)	Placebo (n=1451)
Injection site reaction	3.1% (22)*	1.0% (14)
Injection site erythema	2.8% (20)	1.4% (20)
Injection site pruritus	2.1% (15)*	0.1% (2)
Injection site swelling	1.1% (8)*	0.1% (1)

Adapted from Stauffer VL *et al.* 2018.[21]
*p<0.001, †p<0.05

Less than 2.5% DISCONTINUED

<2.5% of patients discontinued Emgality due to treatment-emergent adverse events (n=1435)[1,21*]

*Pooled discontinuation rate from the double-blind treatment phase of the three phase 3 studies (1.8% for 120 mg; 3.0% for 240 mg).[1,21]

- The majority of injection site reactions were reported within 1 day and on average resolved within 5 days[1]
- Most cases of injection site pain (86%) occurred within 1 hour of injection and resolved the same day[1,11,13,15]
- The majority of injection site-related events were mild to moderate and did not lead to discontinuation of Emgality[1]

Emgality safety profile

Treatment-emergent adverse events occurring in ≥1.0% of patients treated with Emgality and more frequently than placebo (pooled data)[21]

Event, % (n)	Emgality 120 mg (n=705)	Placebo (n=1451)
Injection site pain	10.1% (71)	9.5% (138)
Nasopharyngitis	7.4% (52)	6.5% (94)
Upper respiratory tract infection	4.4% (31)	4.1% (60)
Injection site reaction	3.1% (22)*	1.0% (14)
Injection site erythema	2.8% (20)†	1.4% (20)
Sinusitis	2.8% (20)	2.1% (31)
Urinary tract infection	2.7% (19)	2.3% (33)
Fatigue	2.4% (17)	2.3% (34)
Injection site pruritus	2.1% (15)*	0.1% (2)
Neck pain	2.1% (15)	1.5% (21)
Abdominal pain	1.8% (13)	1.7% (24)
Cough	1.7% (12)	1.3% (19)
Oropharyngeal pain	1.4% (10)	0.9% (13)
Bronchitis	1.3% (9)	1.2% (17)
Constipation	1.0% (7)	0.6% (8)
Weight increased	1.3% (9)	0.8% (12)
Hypertension	1.1% (8)	1.0% (15)
Anxiety	1.3% (9)	0.9% (13)
Injection site swelling	1.1% (8)*	0.1% (1)
Viral infection	1.1% (8)	0.8% (11)

Please see the Emgality Product Information for further safety information.

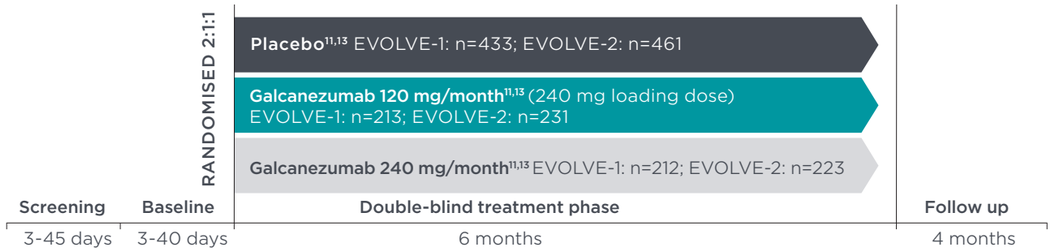
Only galcanezumab 120 mg is registered in Australia and New Zealand[1]

Study design (episodic migraine): EVOLVE-1 and EVOLVE-2[11,13]

EVOLVE-1 and EVOLVE-2 were 6-month, phase 3, multicentre, randomised, double-blind, placebo-controlled trials (n=1773)[11,13]

Patient criteria[1,11,13]

- Patients who met the ICHD-3β criteria for migraine and had 4-14 MHDs per month
- Patients were allowed to use medication for the acute treatment of migraine
- Patients who failed 3 or more classes of preventives were excluded



Primary endpoint[1,11,13]

- Overall mean change from baseline in the number of monthly MHDs over months 1 to 6

Key secondary endpoints[1,11,13]

- Proportion of patients with ≥50%, ≥75%, and 100% reduction in monthly MHDs over months 1 to 6
- Overall mean reduction in monthly MHDs in which acute medication was taken over months 1 to 6
- Mean change from baseline in MSQ Role Function-Restrictive domain over months 4 to 6*

*The MSQ Role Function-Restrictive domain (v2.1) measures impact of migraine on work or daily activities, relationships with family and friends, leisure time, productivity, concentration, energy, and tiredness. Scoring ranges from 0 to 100, with higher scores indicating less impairment; i.e. patients experience fewer restrictions on the performance of day-to-day activities.[11,13]

Baseline demographics[11,13]

	EVOLVE-1[11]		EVOLVE-2[13]	
	Emgality 120 mg (n=213)	Placebo (n=433)	Emgality 120 mg (n=231)	Placebo (n=461)
Age, years, mean (SD)	40.9 (11.9)	41.3 (11.4)	40.9 (11.2)	42.3 (11.3)
Sex (female), %	85.0	83.6	85.3	85.3
Race (white), %	79.3	82.2	71.9	70.5
Disease characteristics				
Duration of migraine, mean (SD)	21.1 (13.0)	19.9 (12.3)	19.9 (11.7)	21.2 (12.8)
MHDs per month, mean (SD)	9.2 (3.1)	9.1 (3.0)	9.1 (2.9)	9.2 (3.0)
Migraine attacks per month, mean (SD)	5.6 (1.7)	5.8 (1.7)	5.5 (1.8)	5.7 (1.8)
MHD category, ≥8, %	65.7	65.8	66.7	66.6
MHDs with acute medication use per month, mean (SD)	7.4 (3.7)	7.4 (3.5)	7.5 (3.3)	7.6 (3.4)
Prior preventive treatment, %	62.4	59.4	68	64.6
MSQ RF-R, mean (SD)	51.4 (16.2)	52.9 (15.4)	52.5 (14.8)	51.4 (15.7)
PGI-S, mean (SD)	4.4 (1.1)	4.2 (1.1)	4.1 (1.2)	4.3 (1.2)
MIDAS total score, mean (SD)	32.9 (28.2)	31.8 (27.3)	30.9 (27.9)	34.3 (31.0)
Geography*				
North America, %	100.0	100.0	48.5	48.6
Europe, %	0	0	26.0	26.5
Other, %	0	0	25.5	25.0

Adapted from Stauffer VL *et al.* 2018[11] and Skljarevski V *et al.* 2018.[13]

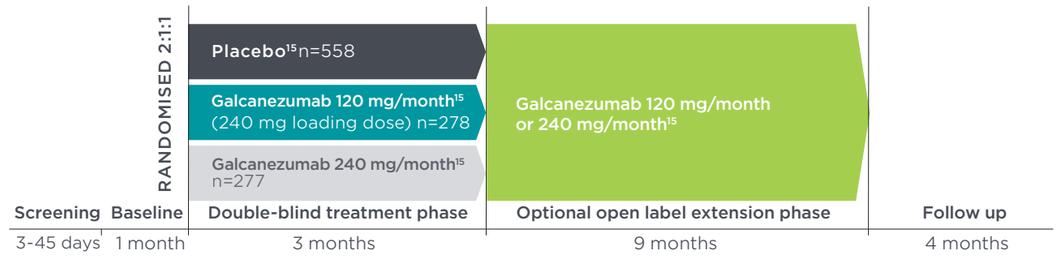
*Percentage for the EVOLVE-2 placebo group does not equal 100% as the result of rounding.

Study design (chronic migraine): REGAIN[1,15]

REGAIN was a 3-month, phase 3, multicentre, randomised, double-blind, placebo-controlled trial, followed by a 9-month open-label extension period (n=1113)[15]

Patient criteria[15]

- Patients who met the ICHD-3β criteria for migraine and had ≥15 headache days per month, of which at least 8 had the features of migraine
- Patients were allowed to use medication for the acute treatment of migraine
- Patients who failed 3 or more classes of preventives were excluded



Primary endpoint (double-blind phase)[15]

- Overall mean change from baseline in the number of monthly MHDs over months 1 to 3

Key secondary endpoints (double-blind phase)[15]

- Proportion of patients with ≥50%, ≥75%, and 100% reduction of monthly MHDs over months 1 to 3
- Overall mean reduction in monthly MHDs on which acute medication was taken over months 1 to 3
- Mean change from baseline in MSQ Role Function-Restrictive domain at month 3*

*The MSQ Role Function-Restrictive domain (v2.1) measures impact of migraine on work or daily activities, relationships with family and friends, leisure time, productivity, concentration, energy, and tiredness. Scoring ranges from 0 to 100, with higher scores indicating less impairment; i.e., patients experience fewer restrictions on the performance of day-to-day activities.[15]

Baseline demographics[15]

	REGAIN[15]	
	Emgality 120 mg (n=278)	Placebo (n=558)
Age, years, mean (SD)	39.7 (11.9)*	41.6 (12.1)
Sex (female), %	85.0	87.0
Race (white), %	80.0	77.0
Disease characteristics		
Duration of migraine, mean (SD)	20.4 (12.7)	21.9 (12.9)
MHDs per month, mean (SD)	19.4 (4.3)	19.6 (4.6)
Migraine attacks per month, mean (SD)	21.2 (4.0)	21.5 (4.1)
Prior preventive treatment in past 5 years (%)	76.0	78.0
MDH with acute medication use per month, mean (SD)	15.1 (6.3)	15.5 (6.6)
Failed ≥2 preventives in past 5 years (%)	24.0	29.0
MSQ RF-R, mean (SD)	39.3 (17.3)	38.4 (17.2)
PGI-S, mean (SD)	4.8 (1.2)	4.9 (1.2)
MIDAS total score, mean (SD)	62.5 (49.5)	68.7 (57.4)

Adapted from Detke HC *et al.* 2018.[15]

*p≤0.05 vs placebo.

Convenient and simple administration

The 3 key administration steps to teach your patients:[22]

1. Uncap

Uncap the auto-injector

2. Place and unlock

Place firmly against injection site and unlock the auto-injector

3. Press and hold, look and listen

Press the button (a click is heard) and hold until a second click is heard, and check that the grey plunger has descended

CGRP: calcitonin gene-related peptide. **ICHD-3B:** International Classification of Headache Disorders-3rd edition beta. **MSQ:** Migraine-Specific Quality of Life Questionnaire. **PGI-I:** Patient Global Impression of Improvement. **PGI-S:** Patient Global Impression of Severity. **LS:** least squares. **MHD:** migraine headache day. **SD:** standard deviation. **SE:** standard error. **MIDAS:** Migraine Disability Assessment.

References: 1. Emgality Approved Product Information, 06 March 2023/Data Sheet, 03 September 2020. **2.** Piechal A *et al. Pharmacol Rep* 2019;71:624–35. **3.** Serrano D *et al. Value Health* 2013;16(1):31–8. **4.** Rizzoli P. *Headache* 2014;54:364–9. **5.** Hepp Z *et al. Cephalalgia* 2017;37(5):470–85. **6.** Leroux E and Ducros A. *Orphanet J Rare Dis* 2008;3:20. **7.** IHS. *Cephalalgia* 2013;33:629–808. **8.** Gladstone JP and Dodick DW. *Expert Rev Neurother* 2003;3:845–72. **9.** Durham PL. *N Engl J Med* 2004;350(11):1073–5. **10.** Goldberg SW and Silberstein SD. *CNS Drugs* 2015;29(6):443–52. **11.** Stauffer VL *et al. JAMA Neurol* 2018;75(9):1080–8. **12.** Villalón CM and Olesen J. *Pharmacol Ther* 2009;124(3):309–23. **13.** Skljarevski V *et al. Cephalalgia* 2018;38(8):1442–54. **14.** Förderreuther S *et al. J Headache Pain* 2018;19:121. **15.** Detke HC *et al. Neurology* 2018;91:e2211–21. **16.** Detke HC *et al.* One-year treatment with galcanezumab in patients with chronic migraine: results from the open-label phase of the REGAIN study. Poster presented at the 17th Biennial Migraine Trust International Symposium; September 6–9, 2018; London, UK. **17.** Stewart WF *et al. Neurology* 2001;56(6 Suppl 1):S20–8. **18.** Speck RM *et al. Headache* 2019;59(5):756–74. **19.** Ford JH *et al. Neurology* 2019;93(5):e508–e517. **20.** Rendas-Baum R *et al. Qual Life Res* 2013;22(5):1123–33. **21.** Stauffer VL *et al.* Safety data from phase 3 clinical studies comparing galcanezumab and placebo in patients with episodic and chronic migraine. Poster presented at the 12th European Headache Federation Congress; September 28-30, 2018; Florence. Italy. **22.** Emgality Instructions for Use.

Lilly

Emgality® (galcanezumab) injection

Australian mandatories:

PBS Information: Emgality is PBS listed for chronic migraine. Authority Required (STREAMLINED). Criteria apply, see www.pbs.gov.au for details.

Before prescribing, please review approved Product Information available at www.lilly.com.au/en/products/ or on request by calling 1800 454 559.

▼ **EMGALITY® Minimum Product Information: INDICATIONS** – EMGALITY is indicated for the prophylaxis of migraine in adults. **CONTRAINDICATIONS** – Hypersensitivity to galcanezumab or any of the excipients. **PRECAUTIONS** – Serious hypersensitivity reactions including cases of anaphylaxis, angioedema and urticaria have been reported. **ADVERSE EFFECTS Clinical Trials Experience** – Very Common (≥10%) Injection site pain and reactions (erythema, pruritus, bruising and swelling), Common (≥1 and <10%) vertigo, constipation and pruritus. **Postmarketing data** - Common (≥1 and <10%) rash. **DOSAGE AND ADMINISTRATION** – Dosage: The recommended dose is 120 mg galcanezumab injected subcutaneously once monthly, with a 240 mg loading dose as the initial dose. EMGALITY should be initiated by physicians experienced in the diagnosis and treatment of migraine. Treatment response should be evaluated by the prescriber after 8-12 weeks as recommended by the current Australian treatment guideline. Elderly Patients (≥65 years): Dose adjustments for patients aged 65 years and older are not recommended due to insufficient data to determine whether they respond differently from younger subjects. Children and adolescents (<18 years): safety and effectiveness have not been established. Renal or Hepatic Impairment: Specific clinical pharmacology studies to evaluate the effects of renal impairment and hepatic impairment on the PK of galcanezumab were not conducted. Administration: subcutaneous injection in the abdomen, thigh, back of the upper arm and buttocks. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use EMGALITY if it is cloudy, or there are visible particles. Single-use in one patient only. Discard any residue. Please review full PI before prescribing. Full PI is available on request from Eli Lilly. Eli Lilly Australia Pty Ltd, Level 9, 60 Margaret St, Sydney NSW 2000. Based on PI last amended 06 March 2023.

▼ This medicinal product is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems.

New Zealand mandatories:

EMGALITY® (galcanezumab 120mg/mL prefilled pen).
PRESCRIPTION MEDICINE. Emgality is not funded on the New Zealand Pharmaceutical Schedule.

INDICATIONS – EMGALITY is indicated for the prophylaxis of migraine in adults. **CONTRAINDICATIONS** – Hypersensitivity to galcanezumab or any of the excipients. **PRECAUTIONS** – Serious hypersensitivity reactions including cases of anaphylaxis, angioedema and urticaria have been reported. **ADVERSE EFFECTS Clinical Trials Experience** – Very Common (≥10%) Injection site pain and reactions (erythema, pruritus, bruising and swelling), Common (≥1 and <10%) vertigo, constipation and pruritus, **Postmarketing data** - Common (≥1 and <10%) rash. **DOSE AND METHOD OF ADMINISTRATION** – Dosage: The recommended dose is 120 mg galcanezumab injected subcutaneously once monthly, with a 240 mg loading dose as the initial dose. Emgality should be initiated by physicians experienced in the diagnosis and treatment of migraine. Treatment response should be evaluated by the prescriber after 8-12 weeks as recommended by the current American Headache Society Consensus Statement. Elderly Patients (≥65 years): Dose adjustments for patients aged 65 years and older are not recommended due to insufficient data to determine whether they respond differently from younger subjects. Children and adolescents (<18 years): safety and effectiveness have not been established. Renal or Hepatic Impairment: Specific clinical pharmacology studies to evaluate the effects of renal impairment and hepatic impairment on the PK of galcanezumab were not conducted. Method of administration: subcutaneous injection in the abdomen, thigh, back of the upper arm and buttocks. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use EMGALITY if it is cloudy, or there are visible particles. Single-use in one patient only. Discard any residue. Please review full Data Sheet before prescribing. Full Data Sheet is available on request from Eli Lilly and Company (NZ) Limited. PO Box 109 197 Newmarket, New Zealand. Telephone 0800 500 056 or www.medafe.govt.nz. Based on Datasheet last amended 03 September 2020.

Date of preparation: April 2023. PP-GZ-AU-0128. TAPS: MR8380. FR10396.

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