INDICATION

Emgality is a calcitonin gene-related peptide antagonist indicated for the preventive treatment of migraine in adults.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Emgality is contraindicated in patients with serious hypersensitivity to galcanezumab-gnlm or to any of the excipients.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Hypersensitivity reactions (e.g., rash, urticaria, and dyspnea) have been reported with Emgality in clinical studies. If a serious or severe hypersensitivity reaction occurs, discontinue administration of Emgality and initiate appropriate therapy. Hypersensitivity reactions can occur days after administration and may be prolonged.

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥2% and at least 2% greater than placebo) in Emgality clinical studies were injection site reactions.

Please see accompanying Full Prescribing Information. See Instructions for Use included with the device.

GZ HCP ISI 27SEP2018

References: 1. Emgality [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC. **2.** Diamond S, Bigal ME, Silberstein S, et al. Patterns of diagnosis and acute and preventive treatment for migraine in the United States: results from the American Migraine Prevalence and Prevention study. *Headache*. 2007;47:355-363. **3.** Lipton RB, Bigal ME, Diamond M, et al; for the AMPP Advisory Group. Migraine prevalence, disease burden, and the need for preventive therapy. *Neurology*. 2007;68:343-349. **4.** Data on File. Lilly USA, LLC. DOF-GZ-US-0028. **5.** US Census Bureau. Quick facts. https://www.census.gov/quickfacts/fact/table/US/PST045217. Accessed January 12, 2019. **6.** Lipton RB, Bigal ME, Kolodner K, et al. The family impact of migraine: population-based studies in the USA and UK. *Cephalalgia*. 2003;23:429-440. **7.** Durham PL. CGRP-receptor antagonists—A fresh approach to migraine therapy? *N Engl J Med*. 2004;350(11):1073-1075. **8.** Lassen LH, Haderslev PA, Jacobsen VB, et al. CGRP may play a causative role in migraine. *Cephalalgia*. 2002;22:54-61. **9.** Oku R, Satoh M, Fujii N, et al. Calcitonin gene-related peptide promotes mechanical nociception by potentiating release of substance P from the spinal dorsal horn in rats. *Brain Res*. 1987;403:350-354. **10.** Stauffer V, Dodick DW, Zhang Q, et al. Evaluation of galcanezumab for the prevention of episodic migraine: the EVOLVE-1 randomized clinical trial. *JAMA Neurol*. 2018;75(9):1080-1088. **11.** Skljarevski V, Matharu M, Millen BA, et al. Efficacy and safety of galcanezumab for the prevention of episodic migraine: results of the EVOLVE-2 Phase 3 randomized controlled clinical trial. *Cephalalgia*. 2018;38(8):1442-1454. **12.** Data on File. Lilly USA, LLC. DOF-GZ-US-0001. **13.** Bagley CL, Rendas-Baum R, Maglinte GA, et al. Validating Migraine-Specific Quality of Life Questionnaire v2.1 in episodic and chronic migraine. *Headache*. 2012;52:409-421. **14.** Data on File. Lilly USA, LLC. DOF-GZ-US-0002. **15.** Data on File. Lilly USA, LLC. DOF-GZ-US-0010. **16.** Data on File. Lilly USA, LLC. DOF-GZ-US-0025. **17.** Data on File. Lilly USA, LLC. DOF-GZ-US-0015. **18.** Data on File. Lilly USA, LLC. DOF-GZ-US-0016. **19.** Silberstein SD, Holland S, Freitag F, et al. Evidence-based guideline update: Pharmacologic treatment for episodic migraine prevention in adults. *Neurology*. 2012;78:1337-1345. **20.** Data on File. Lilly USA, LLC. DOF-GZ-US-0012. **21.** Data on File. Lilly USA, LLC. DOF-GZ-US-0008. **22.** Data on File. Lilly USA, LLC. DOF-GZ-US-0026. **23.** Data on File. Lilly USA, LLC. DOF-GZ-US-0013. **24.** Data on file. Lilly USA, LLC. DOF-GZ-US-0020. **25.** Data on file. Lilly USA, LLC. DOF-GZ-US-0060. **26.** Emgality [Instructions for Use]. Indianapolis, IN: Lilly USA, LLC. **27.** Data on File. Lilly USA, LLC. DOF-GZ-US-0019.

Lilly

Emgality® (galcanezumab-gnlm) 120 mg injection | MORE IS POSSIBLE

For your patients with episodic migraine (4-14 migraine headache days [MHDs] per month),

ONE OF THESE IS POSSIBLE WITH EMGALITY®

THE WALRUS THAT **WENT TO THE MOON**

THE WOMAN WHO EXPERIENCED **A MONTH OF TOTAL MIGRAINE HEADACHE FREEDOM**

Emgality can give some patients the chance to be totally migraine-free for a month[1]

With Emgality, a significantly greater mean percentage of patients with episodic migraine experienced a **100% reduction in monthly MHDs** from baseline vs placebo over Months 1 to 6.[1]

EVOLVE-1:
16% with Emgality (N=210) vs 6% with placebo (N=425) ($p<0.001$)

EVOLVE-2:
12% with Emgality (N=226) vs 6% with placebo (N=450) ($p<0.001$)

In the REGAIN study, in patients with chronic migraine (≥15 headache days per month), the mean percentage of patients achieving a 100% reduction in monthly MHDs from baseline was not significant vs placebo over Months 1 to 3.[1]

Please see study design for EVOLVE-1 and EVOLVE-2 on page 7 and for REGAIN on page 22.

INDICATION

Emgality is a calcitonin gene-related peptide antagonist indicated for the preventive treatment of migraine in adults.

SELECT IMPORTANT SAFETY INFORMATION

Contraindications

Emgality is contraindicated in patients with serious hypersensitivity to galcanezumab-gnlm or to any of the excipients.

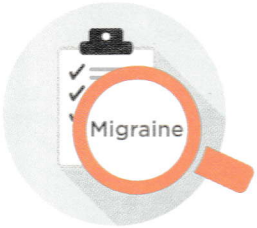
Please see Important Safety Information on back cover and accompanying Full Prescribing Information. See Instructions for Use included with the device.

Emgality® (galcanezumab-gnlm) 120 mg injection | MORE IS POSSIBLE

Migraine is under-recognized and undertreated[2,3]

More than 30 million adults suffer with migraine in the US[3-5]

In the American Migraine Prevalence and Prevention (AMPP) study, which surveyed households to identify people with migraine[2]:



~50%

of people with migraine had **received a migraine diagnosis**

Preventive treatment is underutilized in migraine[3]

According to the AMPP study[3]:

MORE THAN 35% of people with migraine were candidates for a preventive

YET ONLY ABOUT 10% were using a preventive

Migraine can have a profound impact on people's lives[3,6]

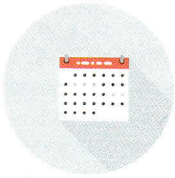
Migraine can lead to reduced productivity and cost people valuable time for work, household tasks, and leisure[3,6]

Migraine may affect a person's productivity at work[3]

- Nearly **30% of people** with migraine reported that their productivity at work was reduced by at least 50% in the previous 3 months in the AMPP study

Migraine may affect a person's productivity at home[3,6]

- **85% of people** reported substantial reductions in their ability to do household work or chores due to migraine in a survey of 389 people with migraine living with a household partner as reported in the family impact of migraine study
- **More than one-third of people** with migraine reported that household productivity was reduced by at least 50% in the previous 3 months in the AMPP study



Migraine may cause a person to miss leisure time and activities[6]

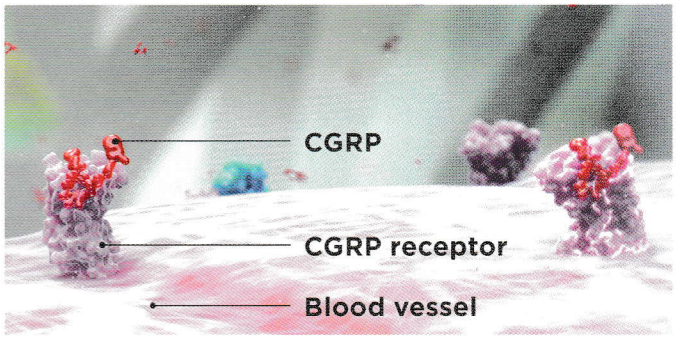
- **45% of people** reported missing family, social, and leisure activities due to migraine in a survey of 389 people with migraine living with a household partner as reported in the family impact of migraine study

Please see Important Safety Information on back cover and accompanying Full Prescribing Information for Emgality® (galcanezumab-gnlm). See Instructions for Use included with the device.

CGRP is thought to play a central role in migraine pathogenesis[7]

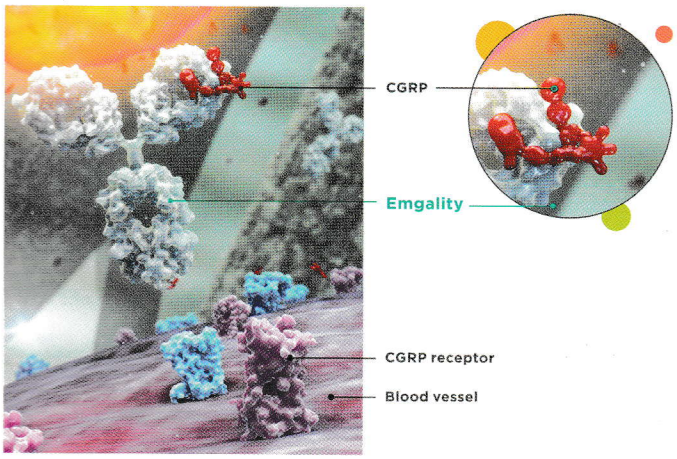
Elevated levels of calcitonin gene-related peptide (CGRP) can lead to a cascade of vasodilation and pain associated with migraine attacks, as observed in preclinical studies of CGRP[7]

- CGRP, released from the trigeminal ganglia, **is elevated during migraine[7]**
- An infusion of CGRP **can induce migraine attacks** in susceptible individuals, and CGRP is involved in the transmission of pain[8,9]
- Perivascular release of CGRP has been **shown to induce vasodilation** and plasma protein leakage from tissues[7]



Emgality is a CGRP binding antibody specifically developed to prevent migraine[1]

Emgality is a humanized monoclonal antibody that **binds to CGRP and blocks its binding** to the receptor[1]



There are no relevant data on the pharmacodynamic effects of galcanezumab-gnlm.[1]

SELECT IMPORTANT SAFETY INFORMATION

Hypersensitivity Reactions

Hypersensitivity reactions (e.g., rash, urticaria, and dyspnea) have been reported with Emgality in clinical studies. If a serious or severe hypersensitivity reaction occurs, discontinue administration of Emgality and initiate appropriate therapy. Hypersensitivity reactions can occur days after administration and may be prolonged.

Please see Important Safety Information on back cover and accompanying Full Prescribing Information. See Instructions for Use included with the device.

Emgality® (galcanezumab-gnlm) 120 mg injection

Consider Emgality for patients like Jessica[a]

Nonclinical profile

"I have a lot going on with my family, friends, and career."

"I don't have time to lose to migraine, so I power through it, but it's difficult that I can't be as productive as I want to be."

Clinical profile

Age: 38

Migraine frequency: **4-14** MHDs per month

Treatment history:

- Has implemented lifestyle modifications
- Has tried various acute treatment options
- May have tried preventives

[a]Not an actual patient.

SELECT IMPORTANT SAFETY INFORMATION

Adverse Reactions

The most common adverse reactions (incidence ≥2% and at least 2% greater than placebo) in Emgality clinical studies were injection site reactions.

Please see Important Safety Information on back cover and accompanying Full Prescribing Information. See Instructions for Use included with the device.

PATIENT PROFILE & STUDY DESIGN

The efficacy and safety of Emgality were evaluated in two large Phase 3 trials[1,10,11]

EVOLVE-1 (North America) and **EVOLVE-2 (Global)** were 6-month, randomized, multicenter, double-blind, placebo-controlled studies in patients with episodic migraine[1,10,11]

Patients with 4-14 MHDs per month (N=1773)[1,10,11]

- Meeting International Classification of Headache Disorders (ICHD-3) criteria for diagnosis of migraine
- Participants were randomized to once-monthly placebo, Emgality 120 mg after an initial loading dose of 240 mg, or Emgality 240 mg. 240 mg is an unapproved dose
- The studies excluded patients on any other migraine preventive treatment, patients with medication overuse headache, patients with electrocardiogram (ECG) abnormalities compatible with an acute cardiovascular event, and patients with a history of stroke, myocardial infarction, unstable angina, percutaneous coronary intervention, coronary artery bypass grafting, deep vein thrombosis, or pulmonary embolism within 6 months of screening

6-month treatment period[1]

- Acute headache treatments including migraine-specific medications (ie, triptans, ergotamine derivatives), nonsteroidal anti-inflammatory drugs (NSAIDs), and acetaminophen were allowed

Primary endpoint[1]

- Mean change from baseline in the number of monthly MHDs over Months 1 to 6

Key secondary endpoint[1]

- Response rates (the mean percentages of patients reaching at least 50%, 75%, and 100% reduction from baseline in the number of monthly MHDs over Months 1 to 6)

Additional key secondary endpoints[1,12]

- Mean change from baseline in the number of monthly MHDs with use of any acute headache medication during the 6-month treatment period
- Impact of migraine on daily activities, as assessed by the mean change from baseline in the average Migraine-Specific Quality of Life version 2.1 (MSQ v2.1) Role Function-Restrictive (RF-R) domain score over Months 4 to 6[b]
- Mean change from baseline in the Patient Global Impression of Severity (PGI-S) score over Months 4 to 6

[b]MSQ v2.1 is a self-administered tool developed to assess the impact of migraine on patients' health-related quality of life. Areas measured included: relationships with family and friends, leisure time, productivity, concentration, energy, and tiredness. Scores are scaled from 0 to 100, with higher scores indicating less impact of migraine on daily activities.[1,13]

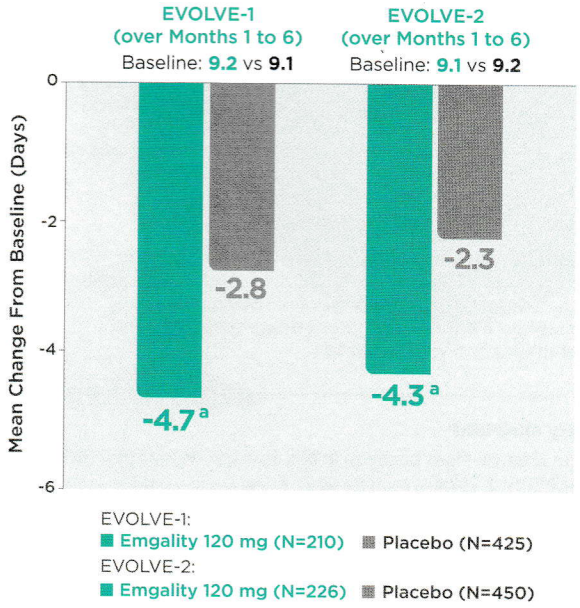
Emgality® (galcanezumab-gnlm) 120 mg injection

For your patients with 4-14 MHDs per month,

Emgality delivered significantly more migraine-free days vs placebo[1]

Emgality **prevented up to 4.7 MHDs per month** vs up to **2.8 MHDs per month with placebo**, on average ($p<0.001$)[1]

Mean Reduction in Monthly MHDs[1]



[a]$p<0.001$ vs placebo.

Please see study design for EVOLVE-1 and EVOLVE-2 on page 7.

SELECT IMPORTANT SAFETY INFORMATION

Contraindications

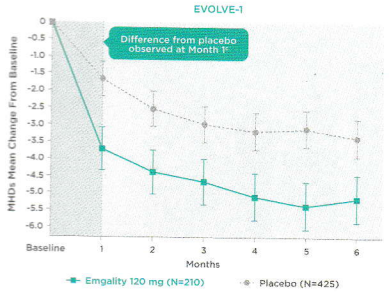
Emgality is contraindicated in patients with serious hypersensitivity to galcanezumab-gnlm or to any of the excipients.

Please see Important Safety Information on back cover and accompanying Full Prescribing Information. See Instructions for Use included with the device.

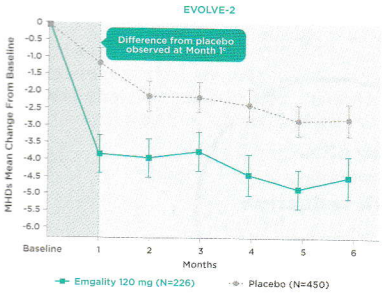
Emgality reduced mean monthly MHDs in the first month and every following month[1]

Emgality **demonstrated reductions in MHDs in every month** of the 6-month treatment period, on average[1]

Change From Baseline in Monthly MHDs[1,14b]



EVOLVE-1:
-3.7 mean MHDs with Emgality in the first month vs **-1.7 mean MHDs** with placebo[14]



EVOLVE-2:
-3.9 mean MHDs with Emgality in the first month vs **-1.2 mean MHDs** with placebo[14]

[b]Least-square (LS) means and 95% confidence intervals are presented.
[c]Earliest post-baseline, prespecified assessment.

Emgality **significantly reduced the mean number of monthly MHDs that acute medication was used** vs placebo over Months 1 to 6 ($p<0.001$)[1]

- EVOLVE-1: -4.0 mean MHDs per month with Emgality vs -2.2 mean MHDs per month with placebo
- EVOLVE-2: -3.7 mean MHDs per month with Emgality vs -1.9 mean MHDs per month with placebo

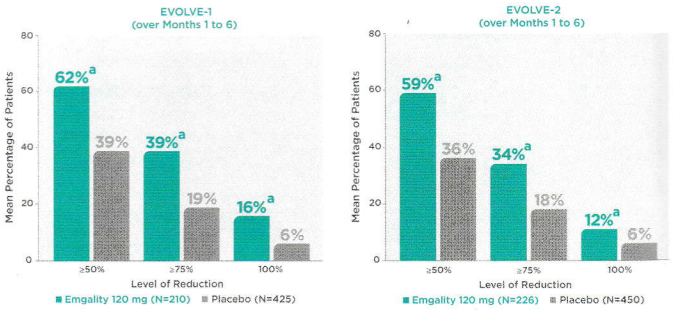
Emgality® (galcanezumab-gnlm) 120 mg injection

For your patients with 4-14 MHDs per month,

Emgality makes it possible for some patients to be totally migraine headache-free for a month[1]

Emgality **demonstrated ≥50%, ≥75%, and 100% reductions** in monthly MHDs from baseline for a significantly greater mean percentage of patients vs placebo ($p<0.001$)[1]

Mean Percentage of Patients Meeting Defined Levels of Reduction in Monthly MHDs[1]



[a]$p<0.001$ vs placebo.

Up to 62% of patients had a **≥50% reduction** in monthly MHDs from baseline ($p<0.001$)[1]

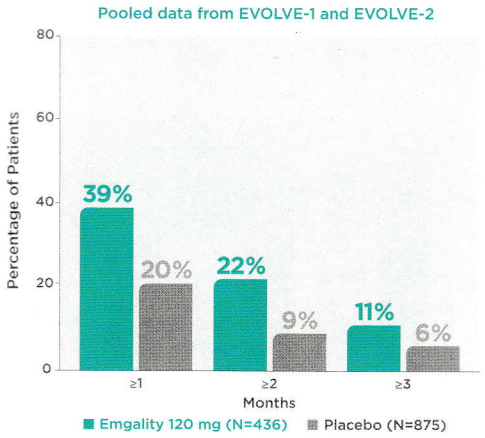
Up to 39% of patients achieved a **≥75% reduction** in monthly MHDs from baseline ($p<0.001$)[1]

Up to 16% of patients had a **100% reduction** in monthly MHDs from baseline ($p<0.001$)[1]

Please see study design for EVOLVE-1 and EVOLVE-2 on page 7.

100% reduction of monthly MHDs in at least 1, 2, or 3 months[15]

Percentage of Patients Experiencing 100% Reduction in Monthly MHDs in at Least 1, 2, or 3 Months in the 6-Month Treatment Period[15]



Post-hoc analyses of EVOLVE-1 and EVOLVE-2 pooled data. Results reported are simple calculations of percentages. As these analyses are post hoc, no conclusions of statistical or clinical significance can be drawn.

SELECT IMPORTANT SAFETY INFORMATION

Hypersensitivity Reactions

Hypersensitivity reactions (e.g., rash, urticaria, and dyspnea) have been reported with Emgality in clinical studies. If a serious or severe hypersensitivity reaction occurs, discontinue administration of Emgality and initiate appropriate therapy. Hypersensitivity reactions can occur days after administration and may be prolonged.

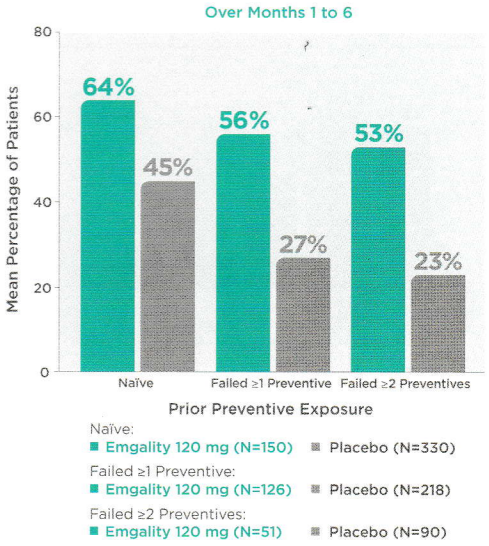
Please see Important Safety Information on back cover and accompanying Full Prescribing Information. See Instructions for Use included with the device.

Emgality® (galcanezumab-gnlm) 120 mg injection

For your patients with 4-14 MHDs per month,

≥50% reduction of monthly MHDs in preventive naïve patients and patients who failed ≥1 or ≥2 preventives[1,16-18]

Subgroup Analysis of ≥50% Responders in Reduction of Monthly MHDs in Preventive Naïve and Prior Preventive Treatment Exposed[16-18]

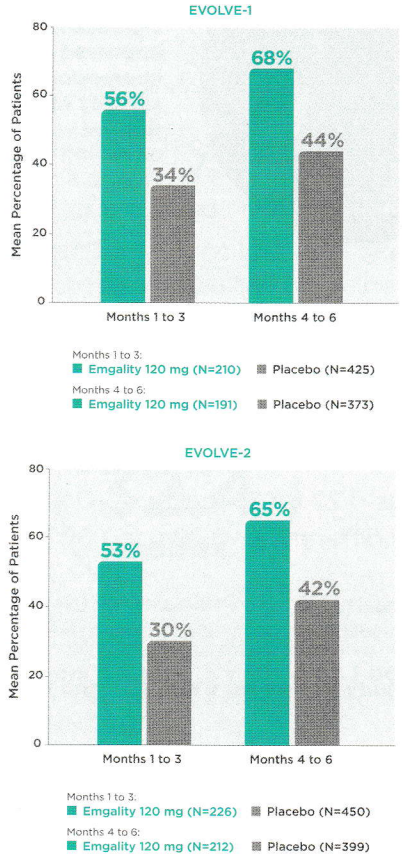


Post-hoc analysis of EVOLVE-1 and EVOLVE-2 pooled data. The studies were not adequately powered nor error-controlled for subgroup analyses. Treatment differences observed in these subgroups cannot be regarded as statistically significant. Patients were excluded from the study if they had failed to respond to 3 or more adequately dosed migraine preventive treatments from different **classes** (that is, maximum tolerated dose for at least 2 months). Failure to respond due to tolerability issues was not considered an exclusion criterion. Migraine preventive treatments are defined as Level A and Level B of the American Academy of Neurology's Evidence-based Guideline Update: Pharmacologic Treatment for Episodic Migraine Prevention in Adults as well as botulinum toxin A or B. Assignment to the subgroup of patients who were naïve, failed ≥1, and failed ≥2 **individual** preventive medications was based on patient report of previous discontinuation of a migraine preventive due to lack of efficacy, suboptimal efficacy, or intolerability.[19]

Please see study design for EVOLVE-1 and EVOLVE-2 on page 7.

≥50% reduction of mean monthly MHDs for Months 1 to 3 and Months 4 to 6[20]

≥50% Reduction of Monthly MHDs[20]



Post-hoc analysis of EVOLVE-1 and EVOLVE-2. No conclusions of statistical or clinical significance can be drawn. The mean monthly percentage of patients meeting response criteria during Months 1 to 3 and Months 4 to 6 of the double-blind treatment phase was estimated using generalized linear repeated measures models.

SELECT IMPORTANT SAFETY INFORMATION

Adverse Reactions

The most common adverse reactions (incidence ≥2% and at least 2% greater than placebo) in Emgality clinical studies were injection site reactions.

Please see Important Safety Information on back cover and accompanying Full Prescribing Information. See Instructions for Use included with the device.

Emgality® (galcanezumab-gnlm) 120 mg injection

For your patients with 4-14 MHDs per month,

Patients reported a significantly greater reduction in the severity of their disease with Emgality[1,12]

Emgality **significantly improved patients' impression of the severity of their disease** vs placebo, on average, over Months 4 to 6[12]

- EVOLVE-1: Mean change from baseline in PGI-S score was -1.59 for Emgality vs -1.27 for placebo. LS mean difference: -0.32 (p=0.002)[a]
- EVOLVE-2: Mean change from baseline in PGI-S score was -1.22 for Emgality vs -0.94 for placebo. LS mean difference: -0.29 (p=0.002)[a]

[a]EVOLVE-1: Emgality 120 mg (N=189), placebo (N=377); EVOLVE-2: Emgality 120 mg (N=213), placebo (N=396).

Please see study design for EVOLVE-1 and EVOLVE-2 on page 7.

Emgality significantly reduced the impact of migraine on daily activities[1]

Patients completed the RF-R domain of the MSQ v2.1, a **functional impact tool**[1,13]

MSQ v2.1 is a self-administered tool developed to assess the impact of migraine on patients' health-related quality of life[1,13]

- Areas measured included: relationships with family and friends, leisure time, productivity, concentration, energy, and tiredness
- Scores are scaled from 0 to 100, with higher scores indicating less impact of migraine on daily activities

32.4 points

- In EVOLVE-1, Emgality demonstrated a mean improvement of **32.4 points from baseline** (N=189) vs **24.7 points** with placebo (N=377) over Months 4 to 6 (baseline: **51.4 points** vs **52.9 points**) (p<0.001)[1]

28.5 points

- In EVOLVE-2, Emgality demonstrated a mean improvement of **28.5 points from baseline** (N=213) vs **19.7 points** with placebo (N=396) over Months 4 to 6 (baseline: **52.5 points** vs **51.4 points**) (p<0.001)[1]

SELECT IMPORTANT SAFETY INFORMATION

Contraindications

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Safety evaluated across three Phase 3 trials[1,14]

The safety of Emgality was assessed in a large clinical trial program in migraine prevention[1]

Adverse Reactions Occurring in Adults With Migraine With an Incidence of at Least 2% for Emgality and at Least 2% Greater Than Placebo (Up to 6 Months of Treatment) in EVOLVE-1, EVOLVE-2, and REGAIN[1]

Adverse Reaction	Emgality 120 mg Monthly (N=705)	Placebo Monthly (N=1451)
Injection site reactions[a]	18%	13%

[a]Injection site reactions include multiple related adverse event terms, such as injection site pain, injection site reaction, injection site erythema, and injection site pruritus.

- Across 3 studies, **2 patients on Emgality discontinued** due to injection site reactions[21]

due to treatment-related adverse events during double-blind treatment with both Emgality and placebo[1,22]

Immunogenicity[1]

As with all therapeutic proteins, there is the potential for immunogenicity. Comparison of the incidence of antibodies to galcanezumab-gnlm with the incidence of antibodies in other studies or to other products may be misleading.

In controlled studies of Emgality up to 6 months (EVOLVE-1, EVOLVE-2, and REGAIN), the incidence of anti-galcanezumab-gnlm antibody development was 4.8% (33/688) in patients receiving Emgality once monthly.

With 12 months of treatment in an open-label study, up to 12.5% (16/128) of Emgality-treated patients developed anti-galcanezumab-gnlm antibodies, most of whom tested positive for neutralizing antibodies.

Although anti-galcanezumab-gnlm antibody development was not found to affect the pharmacokinetics, safety, or efficacy of Emgality in these patients, the available data are too limited to make definitive conclusions.

Please see Important Safety Information on back cover and accompanying Full Prescribing Information. See Instructions for Use included with the device.

Emgality® (galcanezumab-gnlm) 120 mg injection

Emgality offers a once-monthly, self-administered, subcutaneous injection[1]

Recommended dosing with no titration required[1a]

- **Month 1:** Initial loading dose of two 120 mg injections
- **Subsequent months:** One 120 mg injection per month

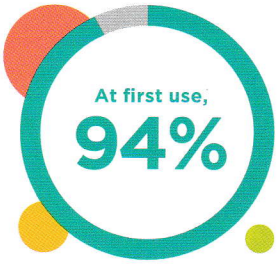
A loading dose of 240 mg resulted in steady-state Emgality concentrations **after the first dose.**[1]

Month 1[1]
2 injections

Subsequent Months[1]
1 injection per month

With the Emgality loading dose, 15% of patients' first-year therapy is administered on Day 1.[1b]

Emgality comes in an **easy-to-use, latex-free pen** for self-administration.[1,23]



of patients in a study agreed that the **Emgality Pen** was **"easy to use"** and **96% agreed** that they were **confident in their ability to use it**[23]

Patient- and caregiver-rated experiences with the pen were assessed in an open-label, 12-month study. A total of 84 patients who received once-monthly injections of Emgality 120 mg completed a questionnaire that included ratings of the medication delivery device's overall ease of use and the respondents' confidence in their ability to use the device.[24]

[a]The Emgality Pen needle is 27 gauge x 1/2 inch.[25]
[b]Calculation: 240 mg loading dose + 120 mg/month x 11 months=1560 mg; 240 mg/1560 mg=0.1538 (15%).[1]

Emgality administration[26]

Preparation[26]

- Check the pen to be sure it is not expired, damaged, cloudy, discolored, or has particles in it
- Choose an area for injection (abdomen or thigh if self-injecting, and buttocks or back of upper arm if another person is injecting), being sure to choose a different site (even within an area) each month
- Clean the site with an alcohol wipe and let it dry before injecting

A simple approach: The 3 key administration steps[26]

Please review the full Instructions for Use with your patients to ensure they understand how to properly administer Emgality

1. Uncap the pen

2. Place and unlock

3. Press and hold

Telephonic injection training and an **injection how-to video** are available to help guide your patients through self-administration.

Questions? Call 1-833-EMGALITY (1-833-364-2548) Mon-Fri, 9 AM to 8 PM ET.

SELECT IMPORTANT SAFETY INFORMATION

Hypersensitivity Reactions

Hypersensitivity reactions (e.g., rash, urticaria, and dyspnea) have been reported with Emgality in clinical studies. If a serious or severe hypersensitivity reaction occurs, discontinue administration of Emgality and initiate appropriate therapy. Hypersensitivity reactions can occur days after administration and may be prolonged.

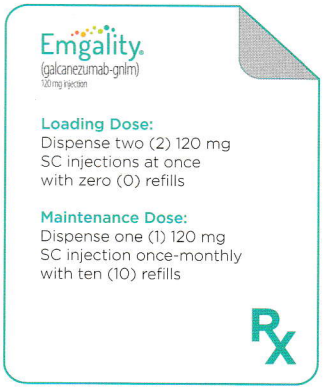
Please see Important Safety Information on back cover and accompanying Full Prescribing Information. See Instructions for Use included with the device.

Emgality® (galcanezumab-gnlm) 120 mg injection

How to write a prescription for Emgality

If a patient begins treatment with a Loading Dose Kit (sample)[a] in the office:

If a patient does NOT begin treatment with a Loading Dose Kit (sample) in the office:



NDC: 0002-1436-11

[a]Loading Dose Kits (samples) are intended to establish safety and efficacy for a patient in the office.
SC=subcutaneous.

SELECT IMPORTANT SAFETY INFORMATION

Adverse Reactions

The most common adverse reactions (incidence ≥2% and at least 2% greater than placebo) in Emgality clinical studies were injection site reactions.

Please see Important Safety Information on back cover and accompanying Full Prescribing Information. See Instructions for Use included with the device.

For your eligible, commercially insured patients,

Get your patients started with the Emgality savings card[b]

Patients can get Emgality **FREE for up to 12 months**

Help patients save with just a couple of steps:

[b]**Terms and Conditions:** Offer good for up to 12 months until 12/31/2020 if healthcare provider submits a prior authorization form or coverage exception request, when required, to the patient's insurance provider. $0 monthly offer for commercially insured with insurance provider coverage, subject to wholesale acquisition cost plus usual and customary pharmacy charges and a separate $4900 maximum annual cap. $0 monthly offer for commercially insured without insurance provider coverage, subject to monthly and separate annual cap of wholesale acquisition cost plus usual and customary pharmacy charges. **This offer is not available for patients without commercial drug insurance or those whose prescription claims are eligible to be reimbursed, in whole or in part, by Medicare Part D, Medicaid, TRICARE, or any other state or federal program.** Offer void where prohibited by law and subject to change or discontinue without notice. Card activation is required. Subject to additional terms and conditions, which can be found at **Emgality.com/savings.**

Emgality
(galcanezumab-gnlm)
120 mg injection

The efficacy and safety of Emgality were evaluated in chronic migraine in a Phase 3 trial[1,27]

REGAIN was a 3-month, randomized, multicenter, double-blind, placebo-controlled study conducted in the US and 11 other countries[1,27]

Patients with ≥15 headache days per month (N=1113)[1]

- Of which at least 8 had the features of migraine
- Participants were randomized to receive once-monthly placebo, Emgality 120 mg after an initial loading dose of 240 mg, or Emgality 240 mg. 240 mg is an unapproved dose
- The study excluded patients with ECG abnormalities compatible with an acute cardiovascular event, and patients with a history of stroke, myocardial infarction, unstable angina, percutaneous coronary intervention, coronary artery bypass grafting, deep vein thrombosis, or pulmonary embolism within 6 months of screening

3-month treatment period[1]

- Acute headache treatments including migraine-specific medications (ie, triptans, ergotamine derivatives), NSAIDs, and acetaminophen were allowed
- 15% of patients continued 1 concomitant preventive treatment
- Patients with medication overuse headache were allowed to enroll

Primary endpoint[1]

- Mean change from baseline in the number of monthly MHDs over the 3-month treatment period

Key secondary endpoint[1]

- Response rates (the mean percentages of patients reaching at least 50%, 75%, and 100% reduction from baseline in the number of monthly MHDs over the 3-month treatment period)

Additional key secondary endpoints[1]

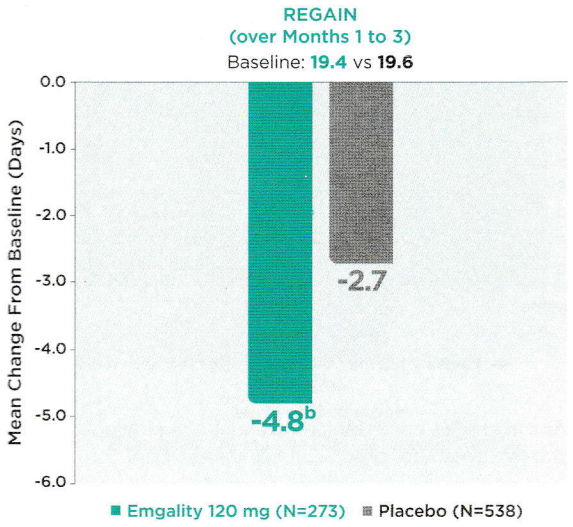
- Mean change from baseline in the number of monthly MHDs with use of any acute headache medication during the 3-month treatment period
- Impact of migraine on daily activities, as assessed by the mean change from baseline in the average MSQ v2.1 RF-R domain score at Month 3[a]

[a]MSQ v2.1 is a self-administered tool developed to assess the impact of migraine on patients' health-related quality of life. Areas measured included: relationships with family and friends, leisure time, productivity, concentration, energy, and tiredness. Scores are scaled from 0 to 100, with higher scores indicating less impact of migraine on daily activities.[1,13]

For your patients with ≥15 headache days per month, Emgality delivered significantly more migraine-free days vs placebo[1]

Emgality demonstrated an average **reduction of 4.8 mean MHDs per month** vs **2.7 mean MHDs per month** with placebo (baseline mean: **19.4** vs **19.6**) ($p<0.001$)[1]

Mean Reduction in Monthly MHDs[1]



[b]$p<0.001$ vs placebo.

SELECT IMPORTANT SAFETY INFORMATION

Contraindications

Emgality is contraindicated in patients with serious hypersensitivity to galcanezumab-gnlm or to any of the excipients.

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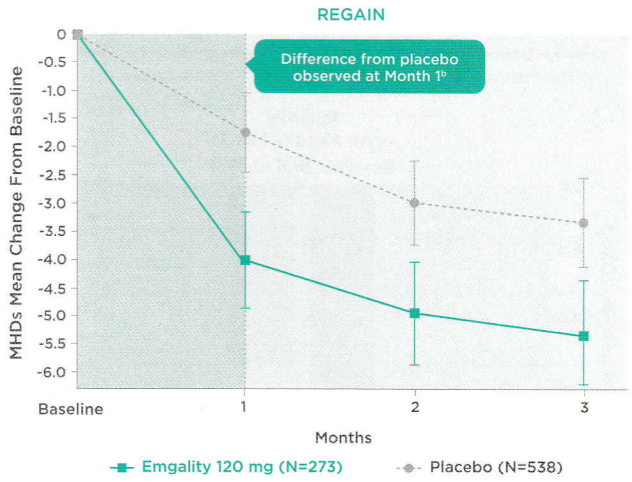
Emgality® (galcanezumab-gnlm) 120 mg injection

For your patients with ≥15 headache days per month,

Emgality reduced mean monthly MHDs at the first month and every following month[1]

Emgality **demonstrated reductions in MHDs in every month** of the 3-month treatment period, on average[1]

Change From Baseline in Monthly MHDs[1,14a]



[a]LS means and 95% confidence intervals are presented.
[b]Earliest post-baseline, prespecified assessment.

REGAIN: **-4.1 mean MHDs** with Emgality in the first month vs **-1.8 mean MHDs** with placebo[14]

Please see study design for REGAIN on page 22.

SELECT IMPORTANT SAFETY INFORMATION

Hypersensitivity Reactions

Hypersensitivity reactions (e.g., rash, urticaria, and dyspnea) have been reported with Emgality in clinical studies. If a serious or severe hypersensitivity reaction occurs, discontinue administration of Emgality and initiate appropriate therapy. Hypersensitivity reactions can occur days after administration and may be prolonged.

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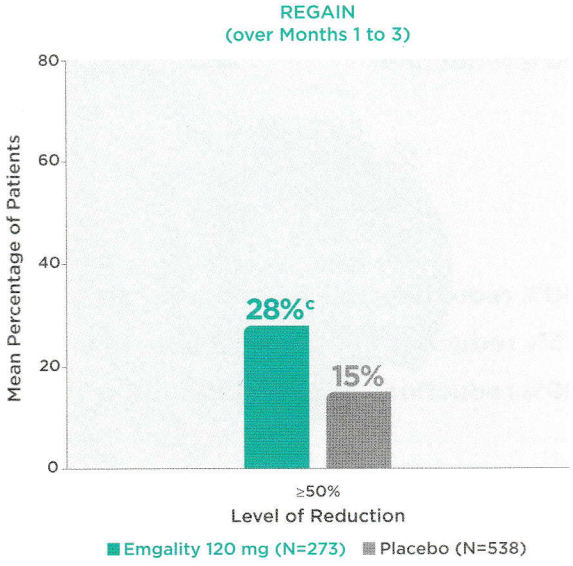
Additional secondary endpoints for REGAIN trial[1]

Emgality **reduced monthly MHDs from baseline by at least half** in a significantly greater mean percentage of patients: 28% of patients ($p<0.001$)[1]

≥50% Reduction of Monthly MHDs[1]



[c]$p<0.001$ vs placebo.

In REGAIN, Emgality 120 mg was not significantly better than placebo for the mean percentage of patients with ≥75% or 100% reduction from baseline in the number of monthly MHDs over the 3-month treatment period. Statistical significance vs placebo was not observed after controlling for multiple comparisons for mean change in MSQ v2.1 RF-R or for reduction in mean MHDs with acute medication use.[1]

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More is possible with Emgality

Mean percentage of patients meeting defined levels of reduction in monthly MHDs from baseline across three clinical trials[1]

EVOLVE-1
(over Months 1 to 6)

	Emgality 120 mg (N=210)	Placebo (N=425)
≥50% reduction:	**62%[a]**	**39%**
≥75% reduction:	**39%[a]**	**19%**
100% reduction:	**16%[a]**	**6%**

EVOLVE-2
(over Months 1 to 6)

	Emgality 120 mg (N=226)	Placebo (N=450)
≥50% reduction:	**59%[a]**	**36%**
≥75% reduction:	**34%[a]**	**18%**
100% reduction:	**12%[a]**	**6%**

REGAIN
(over Months 1 to 3)

	Emgality 120 mg (N=273)	Placebo (N=538)
≥50% reduction:	**28%[a]**	**15%**
≥75% reduction:	Not significant	
100% reduction:	Not significant	

[a]$p<0.001$ vs placebo.

Please see study design for EVOLVE-1 and EVOLVE-2 on page 7 and for REGAIN on page 22.

SELECT IMPORTANT SAFETY INFORMATION

Adverse Reactions

The most common adverse reactions (incidence ≥2% and at least 2% greater than placebo) in Emgality clinical studies were injection site reactions.

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For your patients with 4-14 MHDs per month (EVOLVE-1/ EVOLVE-2) or ≥15 headache days per month (REGAIN)

Emgality **prevented significantly more mean MHDs** per month vs placebo ($p<0.001$)[1]

EVOLVE-1: 4.7 vs **2.8** (baseline mean: **9.2** vs **9.1**)

EVOLVE-2: 4.3 vs **2.3** (baseline mean: **9.1** vs **9.2**)

REGAIN: 4.8 vs **2.7** (baseline mean: **19.4** vs **19.6**)

Comes in a once-monthly, latex-free pen

Saving on Emgality[b]

YOU: Prescribe Emgality and submit a prior authorization using iAssist® or CoverMyMeds®

YOUR PATIENT: Activates the Emgality savings card and picks up Rx at their local pharmacy

[b]Governmental beneficiaries excluded. See full Terms and Conditions on page 21.

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