EMGALITY- galcanezumab-gnlm injection, solution
Eli Lilly and Company

Close All Sections

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use EMGALITY safely and effectively. See full prescribing information for EMGALITY.
EMGALITY (galcanezumab-gnlm) injection, for subcutaneous use
Initial U.S. Approval: 2018

RECENT MAJOR CHANGES

Indications and Usage, Episodic Cluster Headache (1.2)	06/2019
Dosage and Administration, Recommended Dosing for Episodic Cluster Headache (2.2)	06/2019
Warnings and Precautions, Hypersensitivity Reactions (5.1)	12/2019

INDICATIONS AND USAGE

EMGALITY® is a calcitonin-gene related peptide antagonist indicated in adults for the:

- preventive treatment of migraine. (1.1)
- treatment of episodic cluster headache. (1.2)

DOSAGE AND ADMINISTRATION

- For subcutaneous use only. (2.1, 2.2, 2.3)
- Migraine recommended dosage: 240 mg loading dose (administered as two consecutive injections of 120 mg each), followed by monthly doses of 120 mg. (2.1)
- Episodic cluster headache recommended dosage: 300 mg (administered as three consecutive injections of 100 mg each) at the onset of the cluster period, and then monthly until the end of the cluster period. (2.2)
- Administer in the abdomen, thigh, back of the upper arm, or buttocks subcutaneously. (2.3)

DOSAGE FORMS AND STRENGTHS

- Injection: 120 mg/mL solution in a single-dose prefilled pen (3)
- Injection: 120 mg/mL solution in a single-dose prefilled syringe (3)
- Injection: 100 mg/mL solution in a single-dose prefilled syringe (3)

CONTRAINDICATIONS

EMGALITY is contraindicated in patients with serious hypersensitivity to galcanezumab-gnlm or to any of the excipients. (4)

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions: If a serious hypersensitivity reaction occurs, discontinue administration of EMGALITY and initiate appropriate therapy. Hypersensitivity reactions can occur days after administration, and may be prolonged. (5.1)

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥2% and at least 2% greater than placebo) in EMGALITY clinical studies were injection site reactions. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Eli Lilly and Company at 1-800-LillyRx (1-800-545-5979) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 12/2019

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1 INDICATIONS AND USAGE

1.1 Migraine

EMGALITY is indicated for the preventive treatment of migraine in adults.

1.2 Episodic Cluster Headache

EMGALITY is indicated for the treatment of episodic cluster headache in adults.

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2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosing for Migraine

The recommended dosage of EMGALITY is 240 mg (two consecutive subcutaneous injections of 120 mg each) once as a loading dose, followed by monthly doses of 120 mg injected subcutaneously.

If a dose of EMGALITY is missed, administer as soon as possible. Thereafter, EMGALITY can be scheduled monthly from the date of the last dose.

2.2 Recommended Dosing for Episodic Cluster Headache

The recommended dosage of EMGALITY is 300 mg (three consecutive subcutaneous injections of 100 mg each) at the onset of the cluster period, and then monthly until the end of the cluster period.

If a dose of EMGALITY is missed during a cluster period, administer as soon as possible. Thereafter, EMGALITY can be scheduled monthly from the date of the last dose until the end of the cluster period.

2.3 Important Administration Instructions

EMGALITY is for subcutaneous use only.

EMGALITY is intended for patient self-administration. Prior to use, provide proper training to patients and/or caregivers on how to prepare and administer EMGALITY using the single-dose prefilled pen or single-dose prefilled syringe, including aseptic technique *[see How Supplied/Storage and Handling (16.2) and Instructions for Use]*:

- Protect EMGALITY from direct sunlight.
- Prior to subcutaneous administration, allow EMGALITY to sit at room temperature for 30 minutes. Do not warm by using a heat source such as hot water or a microwave.
- Do not shake the product.
- Inspect EMGALITY visually for particulate matter and discoloration prior to administration, whenever solution and container permit *[see Dosage Forms and Strengths (3) and How Supplied/Storage and Handling (16.1)]*. Do not use EMGALITY if it is cloudy or there are visible particles.
- Administer EMGALITY in the abdomen, thigh, back of the upper arm, or buttocks subcutaneously. Do not inject into areas where the skin is tender, bruised, red, or hard.
- Both the prefilled pen and prefilled syringe are single-dose and deliver the entire contents.

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– 3 DOSAGE FORMS AND STRENGTHS

EMGALITY is a sterile clear to opalescent, colorless to slightly yellow to slightly brown solution available as follows:

- Injection: 120 mg/mL in a single-dose prefilled pen
- Injection: 120 mg/mL in a single-dose prefilled syringe
- Injection: 100 mg/mL in a single-dose prefilled syringe

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– 4 CONTRAINDICATIONS

EMGALITY is contraindicated in patients with serious hypersensitivity to galcanezumab-gnlm or to any of the excipients *[see Warnings and Precautions (5.1)]*.

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– 5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity Reactions

Hypersensitivity reactions, including dyspnea, urticaria, and rash, have occurred with EMGALITY in clinical studies and the postmarketing setting. Cases of anaphylaxis and angioedema have also been reported in the postmarketing setting. If a serious or severe hypersensitivity reaction occurs, discontinue administration of EMGALITY and initiate appropriate therapy *[see Contraindications (4), Adverse Reactions (6.1), and Patient Counseling Information (17)]*. Hypersensitivity reactions can occur days after administration and may be prolonged.

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6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Hypersensitivity Reactions *[see Contraindications (4) and Warnings and Precautions (5.1)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared with rates in clinical trials of another drug and may not reflect the rates observed in clinical practice.

Migraine

The safety of EMGALITY has been evaluated in 2586 patients with migraine who received at least one dose of EMGALITY, representing 1487 patient-years of exposure. Of these, 1920 patients were exposed to EMGALITY once monthly for at least 6 months, and 526 patients were exposed for 12 months.

In placebo-controlled clinical studies (Studies 1, 2, and 3), 705 patients received at least one dose of EMGALITY 120 mg once monthly, and 1451 patients received placebo, during 3 months or 6 months of double-blind treatment *[see Clinical Studies (14.1)]*. Of the EMGALITY-treated patients, approximately 85% were female, 77% were white, and the mean age was 41 years at study entry.

The most common adverse reaction was injection site reactions. In Studies 1, 2, and 3, 1.8% of patients discontinued double-blind treatment because of adverse events. Table 1 summarizes the adverse reactions that occurred within up to 6 months of treatment in the migraine studies.

Table 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 Studies 1, 2, and 3

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.

Episodic Cluster Headache

EMGALITY was studied for up to 2 months in a placebo-controlled trial in patients with episodic cluster headache (Study 4) *[see Clinical Studies (14.2)]*. A total of 106 patients were studied (49 on EMGALITY and 57 on placebo). Of the EMGALITY-treated patients, approximately 84% were male, 88% were white, and the mean age was 47 years at study entry. Two EMGALITY-treated patients discontinued double-blind treatment because of adverse events.

Overall, the safety profile observed in patients with episodic cluster headache treated with EMGALITY 300 mg monthly is consistent with the safety profile in migraine patients.

6.2 Immunogenicity

As with all therapeutic proteins, there is potential for immunogenicity. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease.

For these reasons, comparison of the incidence of antibodies to galcanezumab-gnlm in the studies described below with the incidence of antibodies in other studies or to other products may be misleading.

The immunogenicity of EMGALITY has been evaluated using an in vitro immunoassay for the detection of binding anti-galcanezumab-gnlm antibodies. For patients whose sera tested positive in the screening immunoassay, an in vitro ligand-binding immunoassay was performed to detect neutralizing antibodies.

In controlled studies with EMGALITY up to 6 months (Study 1, Study 2, and Study 3), the incidence of anti-galcanezumab-gnlm antibody development was 4.8% (33/688) in patients receiving EMGALITY once monthly (32 out of 33 of whom had *in vitro* neutralizing activity). 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.

6.3 Postmarketing Experience

The following adverse reactions have been identified during post-approval use of EMGALITY. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to EMGALITY exposure.

Immune System Disorders — Anaphylaxis, angioedema *[see Contraindications (4) and Warnings and Precautions (5.1)]*.

Skin and Subcutaneous Tissue Disorders — Rash.

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– 8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no adequate data on the developmental risk associated with the use of EMGALITY in pregnant women. Administration of galcanezumab-gnlm to rats and rabbits during the period of organogenesis or to rats throughout pregnancy and lactation at plasma exposures greater than that expected clinically did not result in adverse effects on development *(see Animal Data)*.

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% - 4% and 15% - 20%, respectively. The estimated rate of major birth defects (2.2% - 2.9%) and miscarriage (17%) among deliveries to women with migraine are similar to rates reported in women without migraine.

Clinical Considerations

Disease-Associated Maternal and/or Embryo/Fetal Risk

Published data have suggested that women with migraine may be at increased risk of preeclampsia during pregnancy.

Data

Animal Data

When galcanezumab-gnlm was administered to female rats by subcutaneous injection in two studies (0, 30, or 100 mg/kg; 0 or 250 mg/kg) prior to and during mating and continuing throughout organogenesis, no adverse effects on embryofetal development were observed. The highest dose tested (250 mg/kg) was associated with a plasma exposure ($C_{ave, ss}$) 38 or 18 times that in humans at the recommended human dose (RHD) for migraine (120 mg) or episodic cluster headache (300 mg), respectively. Administration of galcanezumab-gnlm (0, 30, or 100 mg/kg) by subcutaneous injection to pregnant rabbits throughout the period of organogenesis produced no adverse effects on embryofetal development. The higher dose tested was associated with a plasma $C_{ave, ss}$ 64 or 29 times that in humans at 120 mg or 300 mg, respectively.

Administration of galcanezumab-gnlm (0, 30, or 250 mg/kg) by subcutaneous injection to rats throughout pregnancy and lactation produced no adverse effects on pre- and postnatal development. The higher dose tested was associated with a plasma $C_{ave, ss}$ 34 or 16 times that in humans at 120 mg or 300 mg, respectively.

8.2 Lactation

Risk Summary

There are no data on the presence of galcanezumab-gnlm in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for EMGALITY and any potential adverse effects on the breastfed infant from EMGALITY or from the underlying maternal condition.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

8.5 Geriatric Use

Clinical studies of EMGALITY did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger patients.

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11 DESCRIPTION

Galcanezumab-gnlm is a humanized IgG4 monoclonal antibody specific for calcitonin-gene related peptide (CGRP) ligand. Galcanezumab-gnlm is produced in Chinese Hamster Ovary (CHO) cells by recombinant DNA technology. Galcanezumab-gnlm is composed of two identical immunoglobulin kappa light chains and two identical immunoglobulin gamma heavy chains and has an overall molecular weight of approximately 147 kDa.

EMGALITY (galcanezumab-gnlm) injection is a sterile, preservative-free, clear to opalescent and colorless to slightly yellow to slightly brown solution, for subcutaneous use. EMGALITY is supplied in a 1 mL single-dose prefilled pen to deliver 120 mg of galcanezumab-gnlm or a 1 m single-dose prefilled syringe to deliver 100 mg or 120 mg of galcanezumab-gnlm. Each mL of

solution contains 100 mg or 120 mg of galcanezumab-gnlm; L-histidine (0.5 mg); L-histidine hydrochloride monohydrate (1.5 mg); Polysorbate 80 (0.5 mg); Sodium Chloride (8.8 mg); Water for Injection, USP. The pH range is 5.3 - 6.3.

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12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Galcanezumab-gnlm is a humanized monoclonal antibody that binds to calcitonin gene-related peptide (CGRP) ligand and blocks its binding to the receptor.

12.2 Pharmacodynamics

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

12.3 Pharmacokinetics

Galcanezumab-gnlm exhibits linear pharmacokinetics and exposure increases proportionally with doses between 1 and 600 mg.

A loading dose of 240 mg achieved the serum galcanezumab-gnlm steady-state concentration after the first dose. A dose of 300 mg monthly would achieve steady-state concentration after the fourth dose. The time to maximum concentration is 5 days, and the elimination half-life is 27 days.

There was no difference in pharmacokinetic parameters between healthy volunteers, patients with episodic or chronic migraine, and patients with episodic cluster headache.

Absorption

Following a subcutaneous dose of galcanezumab-gnlm, the time to maximum concentration was about 5 days.

Injection site location did not significantly influence the absorption of galcanezumab-gnlm.

Distribution

The apparent volume of distribution (V/F) of galcanezumab-gnlm was 7.3 L (34% Inter Individual Variability [IIV]).

Metabolism and Elimination

Galcanezumab-gnlm is expected to be degraded into small peptides and amino acids via catabolic pathways in the same manner as endogenous IgG.

The apparent clearance (CL/F) of galcanezumab-gnlm was 0.008 L/h and the elimination half-life of galcanezumab was approximately 27 days.

Specific Populations

Age, Sex, Weight, Race, Ethnicity

The pharmacokinetics of galcanezumab-gnlm were not affected by age, sex, race, subtypes of migraine spectrum (episodic or chronic migraine), or headache diagnosis (migraine vs. episodic cluster headache) based on a population pharmacokinetics analysis. Body weight has no clinically relevant effect on the pharmacokinetics of galcanezumab-gnlm.

Patients with Renal or Hepatic Impairment

Renal and hepatic impairment are not expected to affect the pharmacokinetics of galcanezumab-gnlm. Population pharmacokinetic analysis of integrated data from the galcanezumab-gnlm clinical studies revealed that creatinine clearance did not affect the pharmacokinetics of galcanezumab-gnlm in patients with mild or moderate renal impairment. Patients with severe renal impairment (creatinine clearance <30 mL/min) have not been studied. Based on a population PK analysis, bilirubin concentration did not significantly influence the CL/F of galcanezumab-gnlm.

No dedicated clinical studies were conducted to evaluate the effect of hepatic impairment or renal impairment on the pharmacokinetics of galcanezumab-gnlm.

Drug Interaction Studies

P450 Enzymes

Galcanezumab-gnlm is not metabolized by cytochrome P450 enzymes; therefore, interactions with concomitant medications that are substrates, inducers, or inhibitors of cytochrome P450 enzymes are unlikely.

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– 13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

The carcinogenic potential of galcanezumab-gnlm has not been assessed.

Mutagenesis

Genetic toxicology studies of galcanezumab-gnlm have not been conducted.

Impairment of Fertility

When galcanezumab-gnlm (0, 30, or 250 mg/kg) was administered to male rats by subcutaneous injection prior to and during mating, no adverse effects on fertility was observed. The higher dose tested was associated with a plasma exposure ($C_{ave, ss}$) 8 or 4 times that in humans at the recommended human dose (RHD) for migraine (120 mg) or episodic cluster headache (300 mg), respectively. When galcanezumab-gnlm was administered to female rats by subcutaneous injection in two studies (0, 30, or 100 mg/kg; 0 or 250 mg/kg) prior to and during mating and continuing throughout organogenesis, no adverse effects on fertility were observed. The highest dose tested (250 mg/kg) was associated with a plasma $C_{ave, ss}$ 38 or 18 times that in humans at 120 mg or 300 mg, respectively.

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– 14 CLINICAL STUDIES

14.1 Migraine

The efficacy of EMGALITY was evaluated as a preventive treatment of episodic or chronic migraine in three multicenter, randomized, double-blind, placebo-controlled studies: two 6-month studies in patients with episodic migraine (Studies 1 and 2) and one 3-month study in patients with chronic migraine (Study 3).

Episodic Migraine

Study 1 (NCT02614183) and Study 2 (NCT02614196) included adults with a history of episodic migraine (4 to 14 migraine days per month). All patients were randomized in a 1:1:2 ratio to receive once-monthly subcutaneous injections of EMGALITY 120 mg, EMGALITY 240 mg, or placebo. All patients in the 120 mg EMGALITY group received an initial 240 mg loading dose. Patients were allowed to use acute headache treatments, including migraine-specific medications (i.e., triptans, ergotamine derivatives), NSAIDs, and acetaminophen during the study.

The studies excluded patients on any other migraine preventive treatment, patients with medication overuse headache, 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.

The primary efficacy endpoint for Studies 1 and 2 was the mean change from baseline in the number of monthly migraine headache days over the 6-month treatment period. Key secondary endpoints included response rates (the mean percentages of patients reaching at least 50%, 75%, and 100% reduction from baseline in the number of monthly migraine headache days over the 6-month treatment period), the mean change from baseline in the number of monthly migraine headache days with use of any acute headache medication during the 6-month treatment period, and the impact of migraine on daily activities, as assessed by the mean change from baseline in the average Migraine-Specific Quality of Life Questionnaire version 2.1 (MSQ v2.1) Role Function-Restrictive domain score during the last 3 months of treatment (Months 4 to 6). Scores are scaled from 0 to 100, with higher scores indicating less impact of migraine on daily activities.

In Study 1, a total of 858 patients (718 females, 140 males) ranging in age from 18 to 65 years, were randomized. A total of 703 patients completed the 6-month double-blind phase. In Study 2, a total of 915 patients (781 female, 134 male) ranging in age from 18 to 65 years, were randomized. A total of 785 patients completed the 6-month double-blind phase. In Study 1 and Study 2, the mean migraine frequency at baseline was approximately 9 migraine days per month, and was similar across treatment groups.

EMGALITY 120 mg demonstrated statistically significant improvements for efficacy endpoints compared to placebo over the 6-month period, as summarized in Table 2. EMGALITY treatment with the 240 mg once-monthly dose showed no additional benefit over the EMGALITY 120 mg once-monthly dose.

Table 2: Efficacy Endpoints in Studies 1 and 2

	Study 1		Study 2	
	EMGALITY 120 mg N = 210	**Placebo N = 425**	**EMGALITY 120 mg N = 226**	**Placebo N = 450**
Monthly Migraine Headache Days (over Months 1 to 6)				
Baseline migraine headache days	9.2	9.1	9.1	9.2
Mean change from baseline	-4.7	-2.8	-4.3	-2.3
Difference from placebo[a]	-1.9		-2.0	
≥50% Migraine Headache Days Responders (over Months 1 to 6)				

[a] p<0.001

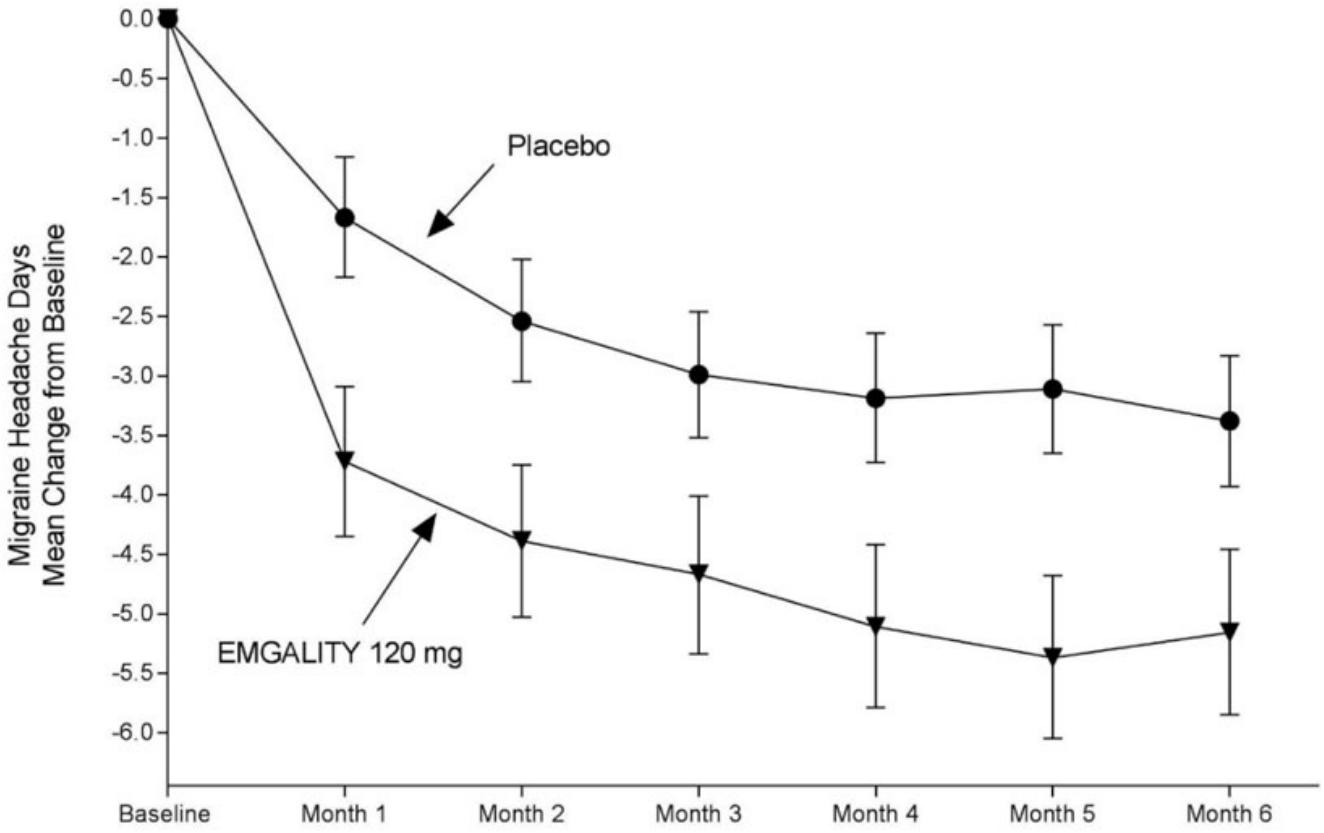
[b] N = 189 for EMGALITY 120 mg and N = 377 for placebo in Study 1; N = 213 for EMGALITY 120 mg a N = 396 for placebo in Study 2.

% Responders[a]	62%	39%	59%	36%
≥75% Migraine Headache Days Responders (over Months 1 to 6)				
% Responders[a]	39%	19%	34%	18%
100% Migraine Headache Days Responders (over Months 1 to 6)				
% Responders[a]	16%	6%	12%	6%
Monthly Migraine Headache Days that Acute Medication was Taken (over Months 1 to 6)				
Mean change from baseline (days)[a]	-4.0	-2.2	-3.7	-1.9
MSQ Role Function-Restrictive Domain Score (over Months 4 to 6)				
Baseline	51.4	52.9	52.5	51.4
Mean change from baseline[b]	32.4	24.7	28.5	19.7
Difference from placebo[a]	7.7		8.8	

[a] p<0.001

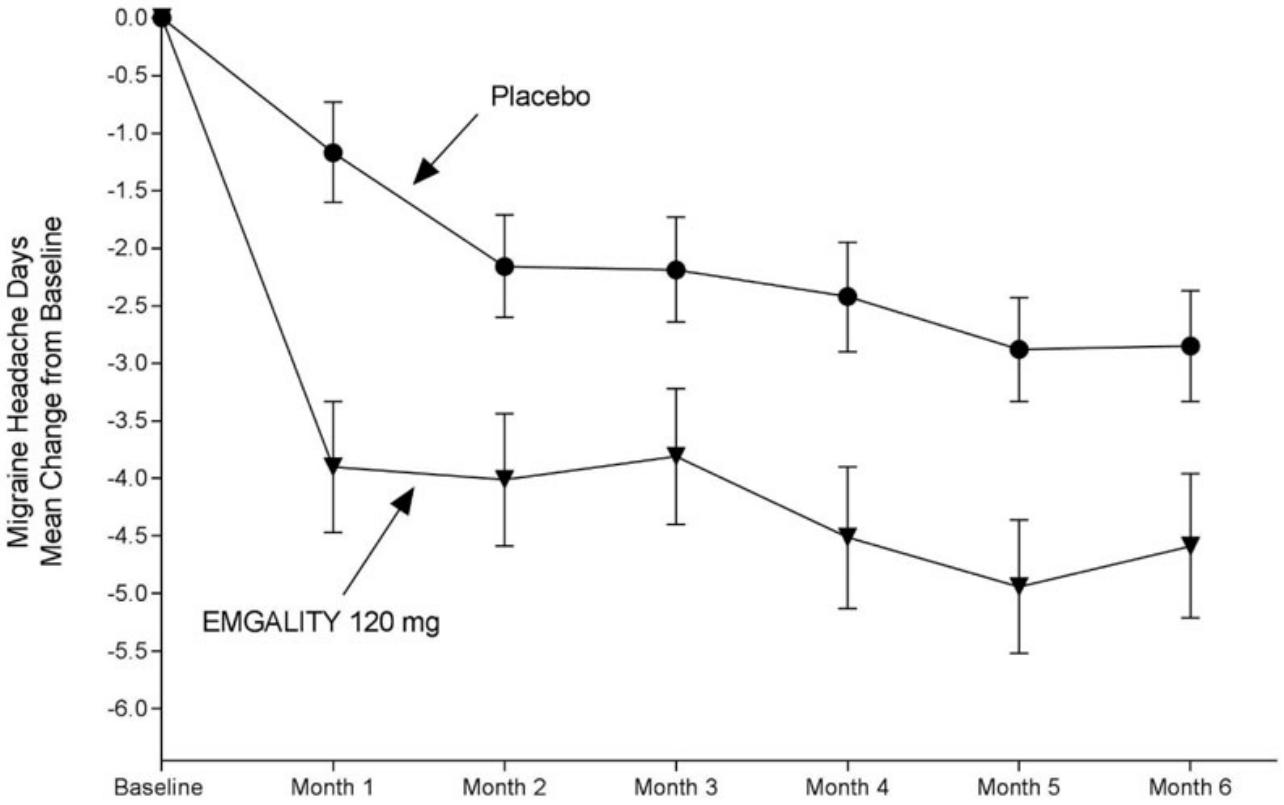
[b] N = 189 for EMGALITY 120 mg and N = 377 for placebo in Study 1; N = 213 for EMGALITY 120 mg and N = 396 for placebo in Study 2.

Figure 1: Change from Baseline in Monthly Migraine Headache Days in Study 1[a]



[a] Least-square means and 95% confidence intervals are presented.

Figure 2: Change from Baseline in Monthly Migraine Headache Days in Study 2[a]



[a] Least-square means and 95% confidence intervals are presented.

Figure 3 shows the distribution of change from baseline in the mean number of monthly migraine headache days in bins of 2 days, by treatment group, in Study 1. A treatment benefit over placebo for EMGALITY is seen across a range of changes from baseline in monthly migraine headache days.

Figure 3: Distribution of Change from Baseline in Mean Monthly Migraine Headache Days over Months 1 to 6 by Treatment Group in Study 1

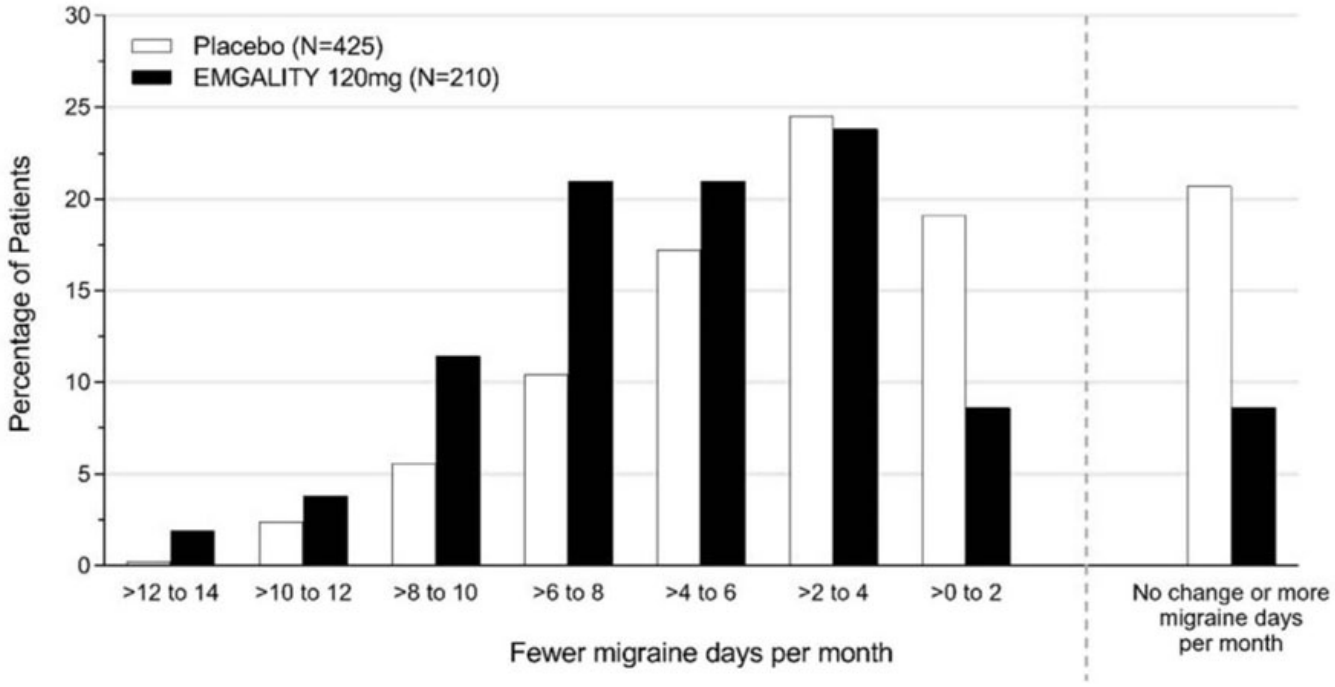
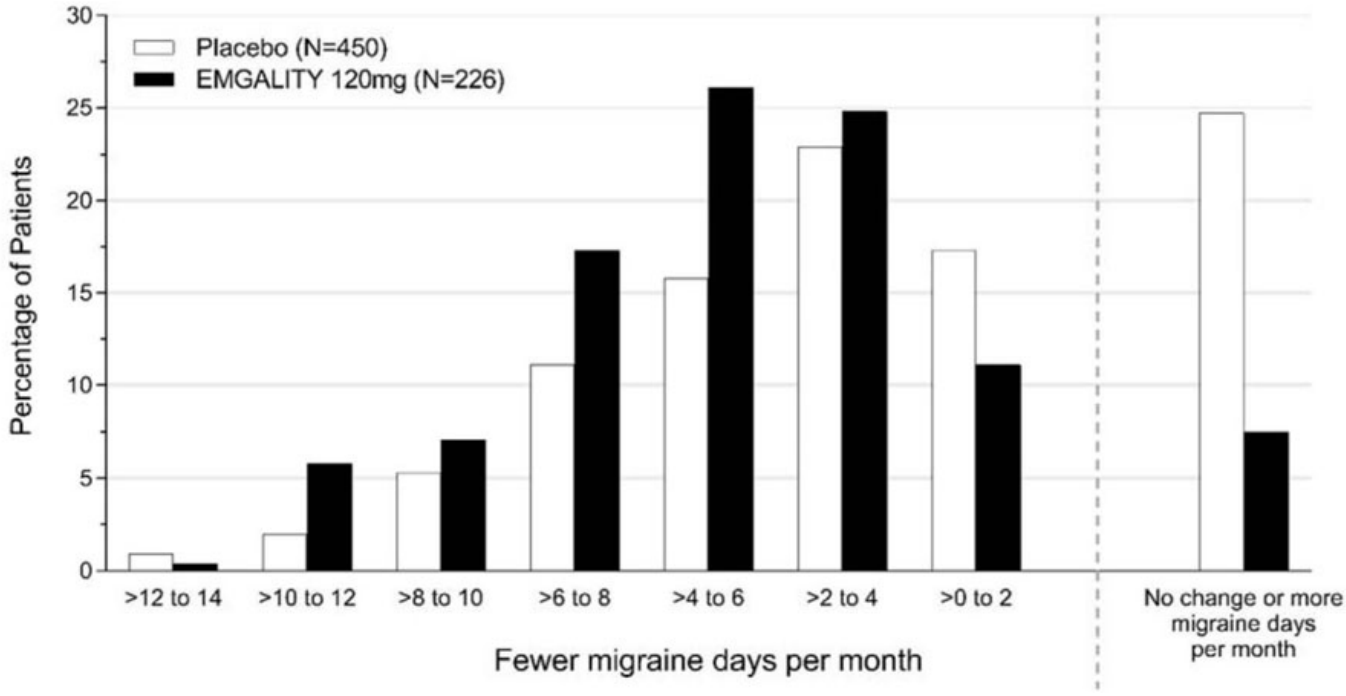


Figure 4 shows the distribution of change from baseline in the mean number of monthly migraine headache days in bins of 2 days, by treatment group, in Study 2. A treatment benefit over placebo for EMGALITY is seen across a range of changes from baseline in monthly migraine headache days.

Figure 4: Distribution of Change from Baseline in Mean Monthly Migraine Headache Days over Months 1 to 6 by Treatment Group in Study 2



Chronic Migraine

Study 3 (NCT02614261) included adults with a history of chronic migraine (≥15 headache days per month with ≥8 migraine days per month). All patients were randomized in a 1:1:2 ratio to receive once-monthly subcutaneous injections of EMGALITY 120 mg, EMGALITY 240 mg, or placebo over a 3-month treatment period. All patients in the 120 mg EMGALITY group received an initial 240 mg loading dose.

Patients were allowed to use acute headache treatments including migraine-specific medications (i.e., triptans, ergotamine derivatives), NSAIDs, and acetaminophen. A subset of patients (15%) was allowed to use one concomitant migraine preventive medication. Patients with medication overuse headache were allowed to enroll.

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.

The primary endpoint was the mean change from baseline in the number of monthly migraine headache days over the 3-month treatment period. The secondary endpoints were response rates (the mean percentages of patients reaching at least 50%, 75% and 100% reduction from baseline in the number of monthly migraine headache days over the 3-month treatment period), the mean change from baseline in the number of monthly migraine headache days with use of any acute headache medication during the 3-month treatment period, and the impact of migraine on daily activities as assessed by the mean change from baseline in the MSQ v2.1 Role Function-Restrictive domain score at Month 3. Scores are scaled from 0 to 100, with higher scores indicating less impact of migraine on daily activities.

In Study 3, a total of 1113 patients (946 female, 167 male) ranging in age from 18 to 65 years, were randomized. A total of 1037 patients completed the 3-month double-blind phase. The mean number of monthly migraine headache days at baseline was approximately 19.

EMGALITY 120 mg demonstrated statistically significant improvement for the mean change from baseline in the number of monthly migraine headache days over the 3-month treatment period, and in the mean percentage of patients reaching at least 50% reduction from baseline in the number of monthly migraine headache days over the 3-month treatment period, as summarized in Table 3. EMGALITY treatment with the 240 mg once-monthly dose showed no additional benefit over the EMGALITY 120 mg once-monthly dose.

Table 3: Efficacy Endpoints in Study 3

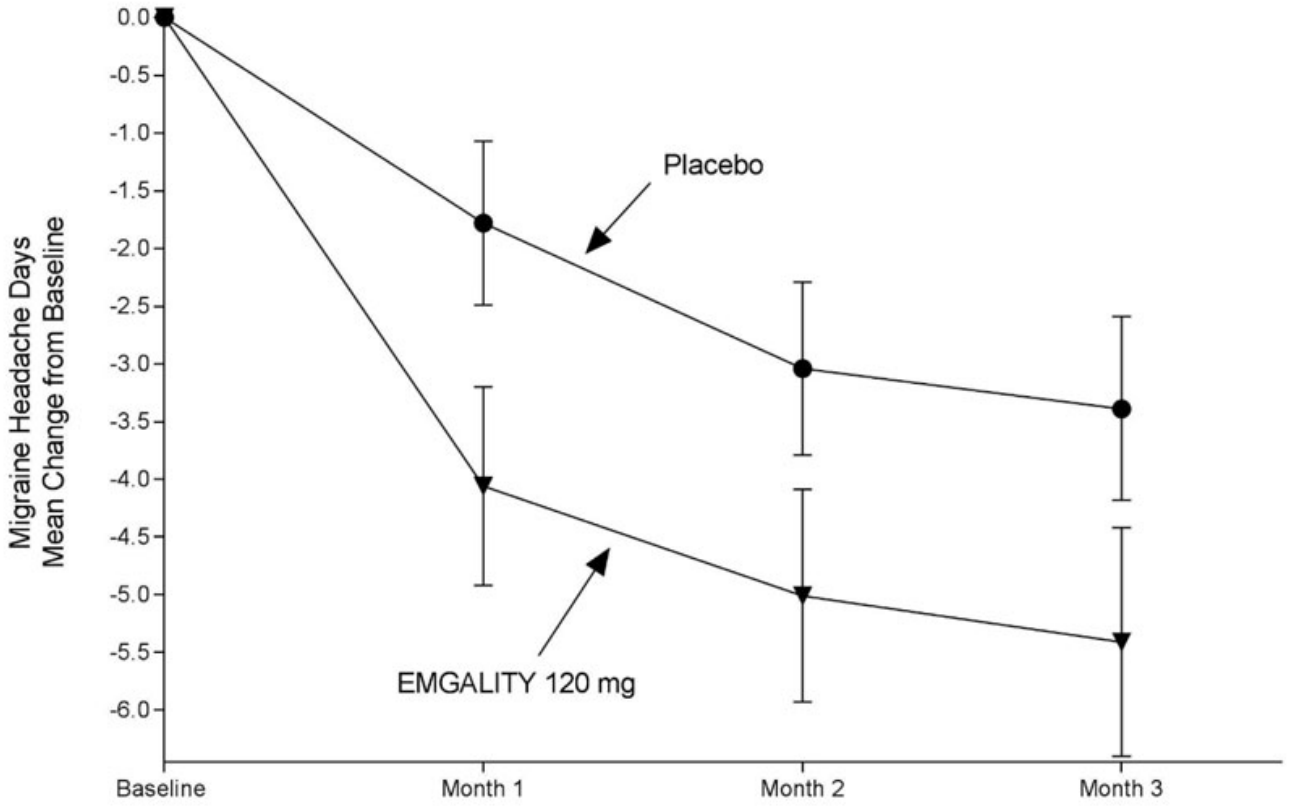
	EMGALITY 120 mg N = 273	**Placebo N =538**
Monthly Migraine Headache Days (over Months 1 to 3)		
Baseline migraine headache days	19.4	19.6
Mean change from baseline	-4.8	-2.7
Difference from placebo[a]	-2.1	
≥50% Migraine Headache Days Responders (over Months 1 to 3)		
% Responders[a]	28%	15%

[a] p<0.001

Study 3 utilized a sequential testing procedure to control the Type-I error rate for the multiple secondary endpoints. Once a secondary endpoint failed to reach the required level for statisti

significance, formal hypothesis testing was terminated for subsequent endpoints, and p-values were considered nominal only. In Study 3, EMGALITY 120 mg was not significantly better than placebo for the proportion of patients with ≥75% or 100% reduction in migraine headache days. Patients treated with EMGALITY 120 mg showed a nominally greater reduction in the number of monthly migraine headache days that acute medication was taken (-4.7 for EMGALITY 120 mg vs. -2.2 for placebo; nominal p-value <0.001), and the mean change from baseline in the MSQ Role Function-Restrictive Domain score at Month 3 was nominally greater in patients treated with EMGALITY 120 mg than in patients on placebo (21.8 for EMGALITY 120 mg vs. 16.8 for placebo; nominal p-value <0.001).

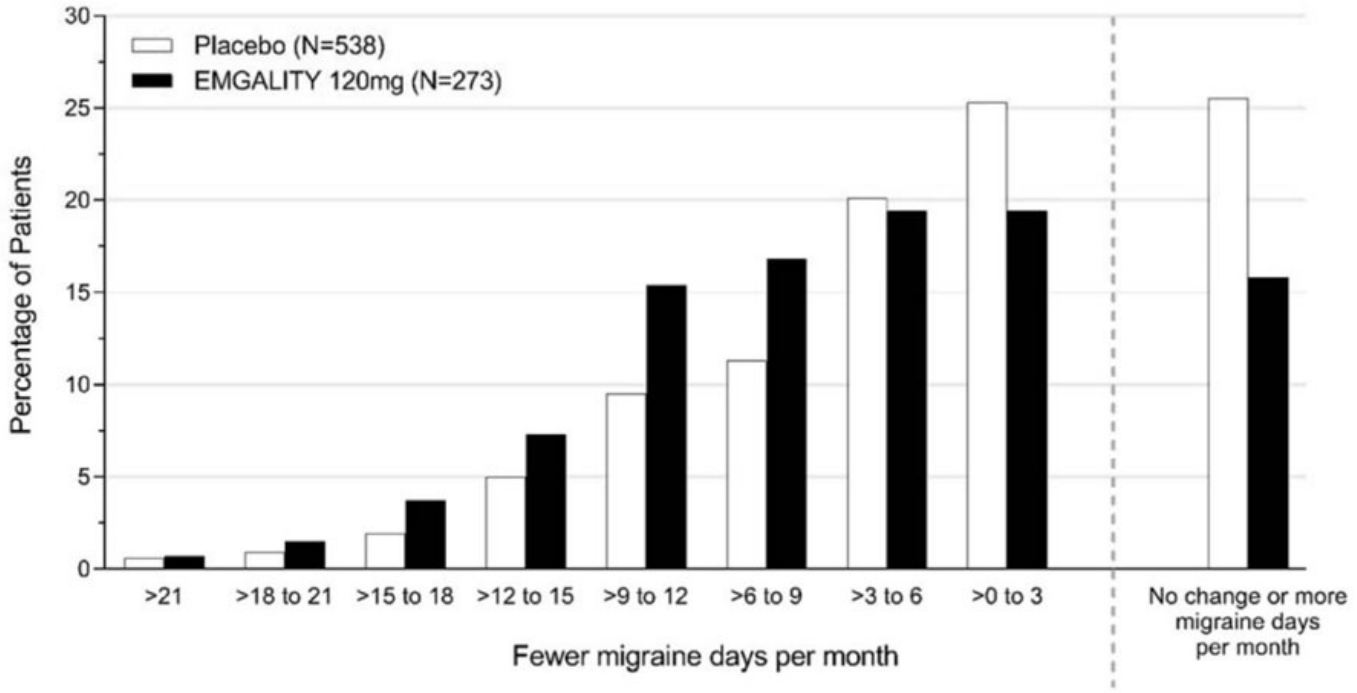
Figure 5: Change from Baseline in Monthly Migraine Headache Days in Study 3[a]



[a] Least-square means and 95% confidence intervals are presented.

Figure 6 shows the distribution of change from baseline in the mean number of monthly migraine headache days for the 3-month study period in bins of 3 days by treatment group. A treatment benefit over placebo for EMGALITY is seen across a range of changes from baseline in monthly migraine headache days.

Figure 6: Distribution of Change from Baseline in Mean Monthly Migraine Headache Days over Months 1 to 3 by Treatment Group in Study 3



14.2 Episodic Cluster Headache

The efficacy of EMGALITY was evaluated for the treatment of episodic cluster headache in a randomized, 8-week, double-blind, placebo-controlled study (Study 4).

Study 4 (NCT02397473) included adults who met the International Classification of Headache Disorders 3rd edition (beta version) diagnostic criteria for episodic cluster headache and had a maximum of 8 attacks per day, a minimum of one attack every other day, and at least 4 attacks during the prospective 7-day baseline period. All patients were randomized in a 1:1 ratio to receive once-monthly subcutaneous injections of EMGALITY 300 mg or placebo. Patients were allowed to use certain specified acute/abortive cluster headache treatments, including triptans, oxygen, acetaminophen, and NSAIDs during the study.

The study excluded patients on other treatments intended to reduce the frequency of cluster headache attacks; patients with medication overuse headache; patients with ECG abnormalities compatible with an acute cardiovascular event or conduction delay; and patients with a history of myocardial infarction, unstable angina, percutaneous coronary intervention, coronary artery bypass grafting, deep vein thrombosis, or pulmonary embolism within 6 months of screening. In addition, patients with any history of stroke, intracranial or carotid aneurysm, intracranial hemorrhage, or vasospastic angina; clinical evidence of peripheral vascular disease; or diagnosis of Raynaud's disease were excluded.

The primary efficacy endpoint for Study 4 was the mean change from baseline in weekly cluster headache attack frequency across Weeks 1 to 3. A secondary endpoint was the percentage of patients who achieved a response (defined as a reduction from baseline of 50% or greater in the weekly cluster headache attack frequency) at Week 3.

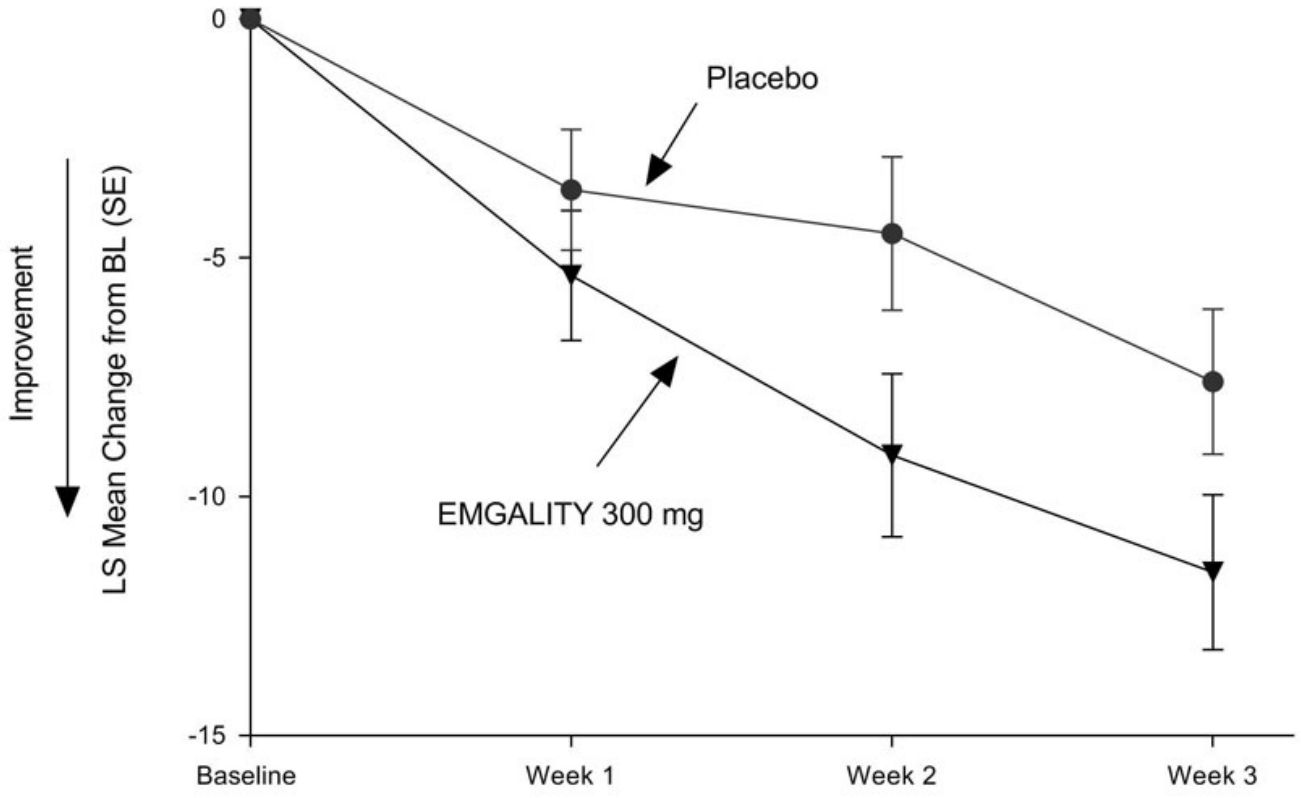
In Study 4, a total of 106 patients (88 males, 18 females) ranging in age from 19 to 65 years were randomized and treated. A total of 90 patients completed the 8-week double-blind phase. In the prospective baseline phase, the mean number of weekly cluster headache attacks was 17.5, and was similar across treatment groups.

EMGALITY 300 mg demonstrated statistically significant improvements for efficacy endpoints compared to placebo, as summarized in Table 4.

Table 4: Efficacy Endpoints in Study 4

	EMGALITY 300 mg N = 49	Placebo N = 57
Mean Reduction in Weekly Cluster Headache Attack Frequency (over Weeks 1 to 3)		
Prospective Baseline Cluster Headache Attack Frequency	17.8	17.3
Mean change from baseline	-8.7	-5.2
Difference from placebo	-3.5	
p-value	0.036	
≥50% Weekly Cluster Headache Attack Frequency Responders (at Week 3)		
% Responders	71.4%	52.6%
Difference from placebo	18.8%	
p-value	0.046	

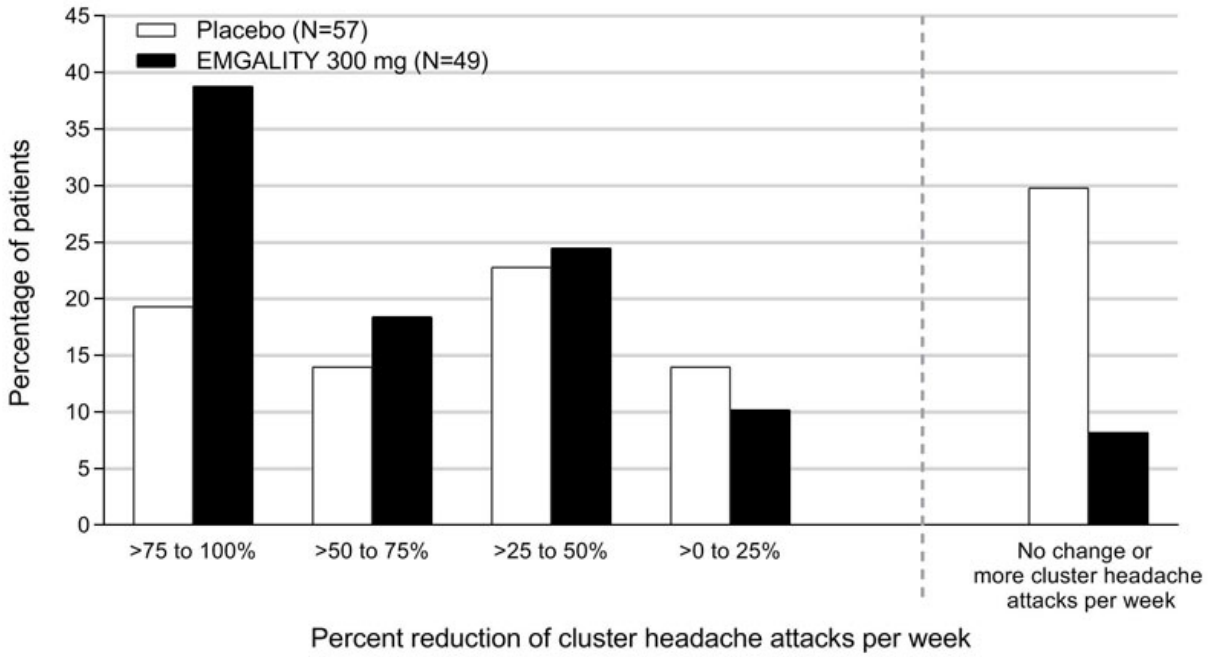
Figure 7: Mean Change in Weekly Cluster Headache Attack Frequency over Weeks 1 to 3 in Study 4[a]



[a] Abbreviations: BL = baseline; LS = least square; SE = standard error.

Figure 8 shows the distribution of the average percent change from baseline in weekly cluster headache attack frequency across Weeks 1 to 3 in bins of 25%, by treatment group, in Study 4.

Figure 8: Distribution of the Average Percent Change from Baseline in Weekly Cluster Headac Attack Frequency over Weeks 1 to 3 in Study 4[a]



[a] N = number of intent to treat patients with non-missing average percentage change from baseline in weekly cluster headache attack frequency over weeks 1 to 3.

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– 16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

EMGALITY (galcanezumab-gnlm) injection is a sterile, preservative-free, clear to opalescent, colorless to slightly yellow to slightly brown solution for subcutaneous administration.

EMGALITY is not made with natural rubber latex.

EMGALITY is supplied as follows:

	Pack Size	NDC
Prefilled pen		
120 mg/mL single-dose	Carton of 1	0002-1436-11
120 mg/mL single-dose	Carton of 2	0002-1436-27
Prefilled syringe		
100 mg/mL single-dose	Carton of 3	0002-3115-09
120 mg/mL single-dose	Carton of 1	0002-2377-11
120 mg/mL single-dose	Carton of 2	0002-2377-27

16.2 Storage and Handling

- Store refrigerated at 2°C to 8°C (36°F to 46°F) in the original carton to protect EMGALITY from light until use.
- Do not freeze.

- Do not shake.
- EMGALITY may be stored out of refrigeration in the original carton at temperatures up to 30°C (86°F) for up to 7 days. Once stored out of refrigeration, do not place back in the refrigerator.
- If these conditions are exceeded, EMGALITY must be discarded.
- Discard the EMGALITY single-dose prefilled pen or syringe after use in a puncture-resistant container.

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– 17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information and Instructions for Use).

Instructions on Self-Administration: Provide guidance to patients and/or caregivers on proper subcutaneous injection technique, including aseptic technique, and how to use the prefilled pen or prefilled syringe correctly *[see Instructions for Use]*. Instruct patients and/or caregivers to read and follow the Instructions for Use each time they use EMGALITY.

Hypersensitivity Reactions: Advise patients to seek immediate medical attention if they experience any symptoms of serious or severe hypersensitivity reactions *[see Warnings and Precautions (5.1)]*.

For more information go to www.emgality.com or call 1-833-EMGALITY (1-833-364-2548).

Literature revised: 12/2019

Eli Lilly and Company, Indianapolis, IN 46285, USA

US License Number 1891

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EMG-0005-USPI-20191205

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– PATIENT PACKAGE INSERT

PATIENT INFORMATION **EMGALITY® (em-GAL-it-ē)** **(galcanezumab-gnlm)** **injection, for subcutaneous use**
What is EMGALITY? EMGALITY is a prescription medicine used in adults for the: • preventive treatment of migraine. • treatment of episodic cluster headache. It is not known if EMGALITY is safe and effective in children.
Who should not use EMGALITY? Do not use EMGALITY if you are allergic to galcanezumab-gnlm or any of the ingredients in EMGALITY. See the end of this Patient Information for a complete list of ingredients in EMGALITY.

This Patient Information has been approved by the U.S. Food and Drug Administration Revised: 06/2019

Before you use EMGALITY, tell your healthcare provider if you:

- are pregnant or plan to become pregnant. It is not known if EMGALITY will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if EMGALITY passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby while using EMGALITY.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of your medicines with you to show your healthcare provider and pharmacist when you get a new medicine.

How should I use EMGALITY?

- See the Instructions for Use that come with EMGALITY prefilled pen or prefilled syringe about how to use EMGALITY the right way.
- Use EMGALITY exactly as your healthcare provider tells you to.
- EMGALITY is given by injection under the skin (subcutaneous injection).
- Inject EMGALITY in your stomach area (abdomen), thigh, back of the upper arm, or buttocks.
- Your healthcare provider should show you or a caregiver how to prepare and inject EMGALITY the right way before you start to use it.
- EMGALITY comes in 2 different types of devices:
  - a single-dose (1 time) prefilled pen
  - a single-dose (1 time) prefilled syringe

  Your healthcare provider will prescribe the type that is best for you.
- If you have questions about injecting the medicine, talk to your pharmacist or healthcare provider.
- If you are using the EMGALITY 120 mg prefilled pen or prefilled syringe for migraine:
  - Inject EMGALITY 1 time each month.
  - For the first dose (loading dose), you will get 2 separate injections one time, right after each other. You will need 2 prefilled pens or 2 prefilled syringes for your first dose (1-time loading dose).
  - For your regular monthly dose, you will get 1 injection. You will need 1 prefilled pen or 1 prefilled syringe for your regular monthly dose.
  - If you miss a dose of EMGALITY, inject the missed dose as soon as possible. Then inject EMGALITY 1 month from the date of your last dose to get back on a monthly dosing schedule. If you have questions about your schedule, ask your healthcare provider.
- If you are using the EMGALITY 100 mg prefilled syringe for episodic cluster headache:
  - You will get 3 separate injections, right after each other, using 3 prefilled syringes for each of your doses.
  - Use EMGALITY at the start of a cluster period and then every month until the end of the cluster period.
- If you miss a dose of EMGALITY, inject the missed dose as soon as possible. Then, if the cluster headache period has not yet ended, inject EMGALITY 1 month after your last dose to get back on a monthly dosing schedule. If you have questions about when you should use EMGALITY, ask your healthcare provider.

What are the possible side effects of EMGALITY?
EMGALITY may cause serious side effects, including:

- **Allergic reactions.** Allergic reactions, including itching, rash, hives, and trouble breathing, can happen after receiving EMGALITY. This can happen days after using EMGALITY. Call your healthcare provider or get emergency medical help right away if you have any of the following symptoms, which may be part of an allergic reaction:
  - swelling of the face, mouth, tongue, or throat
  - trouble breathing

The most common side effects of EMGALITY include:

- injection site reactions

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.
These are not all of the possible side effects of EMGALITY. For more information, ask your healthcare provider or pharmacist.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store EMGALITY?

- Store EMGALITY in the refrigerator between 36°F to 46°F (2°C to 8°C).
- EMGALITY may be stored out of the refrigerator in the original carton at temperatures up to 86°F (30°C) for up to 7 days. After storing out of the refrigerator, **do not** place EMGALITY back in the refrigerator.
- **Do not** freeze EMGALITY.
- Keep EMGALITY in the carton it comes in to protect it from light until time of use.
- **Do not** shake EMGALITY.
- Throw away EMGALITY if any of the above conditions are not followed.

Keep EMGALITY and all medicines out of the reach of children.

General information about the safe and effective use of EMGALITY.
Medicines are sometimes prescribed for purposes other than those listed in the Patient Information. Do not use EMGALITY for a condition for which it was not prescribed. Do not give EMGALITY to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about EMGALITY that is written for health professionals.

What are the ingredients in EMGALITY?
Active ingredient: galcanezumab-gnlm
Inactive ingredients: L-histidine, L-histidine hydrochloride monohydrate, Polysorbate 80, Sodium Chloride, and Water for Injection, USP.

EMGALITY prefilled pen and prefilled syringes are not made with natural rubber latex.

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US License Number 1891
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EMG-0004-PPI-20190604
For more information, call 1-833-EMGALITY (1-833-364-2548) or go to www.emgality.com.

This Patient Information has been approved by the U.S. Food and Drug Administration Revised: 06/2

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– INSTRUCTIONS FOR USE

INSTRUCTIONS FOR USE

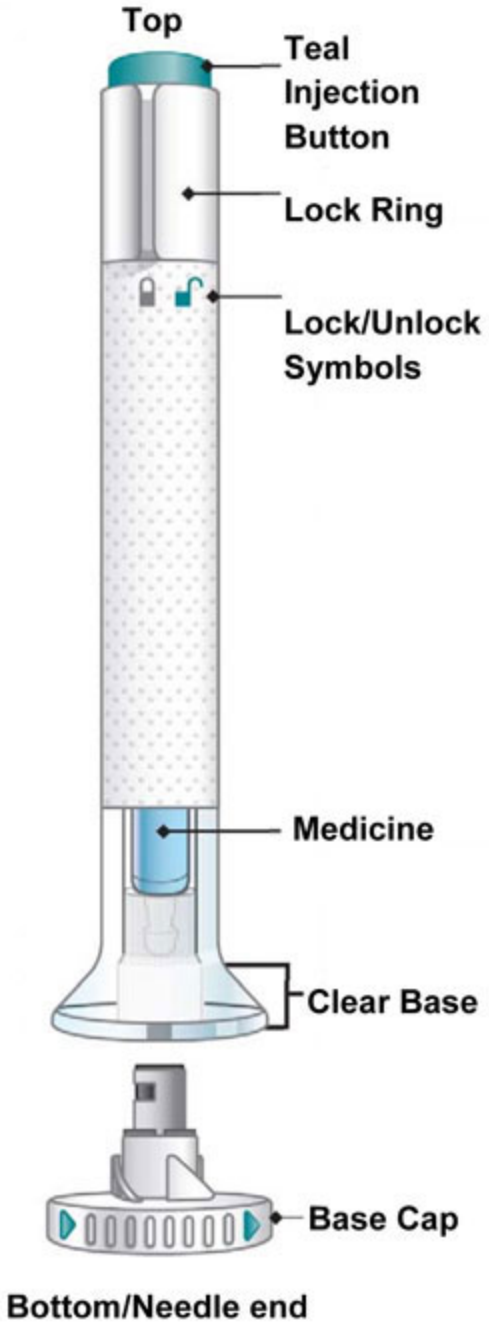
EMGALITY® (em-GAL-it-ē)
(galcanezumab-gnlm)
injection, for subcutaneous use
Prefilled Pen

This Instructions for Use is for patients with migraine.
For subcutaneous injection only.
Before you use the EMGALITY prefilled pen (Pen), read and carefully follow all the step-by-step instructions.
Important Information

- Your healthcare provider or nurse should show you how to prepare and inject EMGALITY using the Pen. Do not inject yourself or someone else until you have been shown how to inject EMGALITY.
- Keep this Instructions for Use and refer to it as needed.
- Each EMGALITY Pen is for **one-time use only. Do not** share or reuse your EMGALITY Pen. You may give or get an infection.
- The Pen contains glass parts. Handle it carefully. If you drop it on a hard surface, do not use it. Use a new Pen for your injection.
- Your healthcare provider may help you decide where on your body to inject your dose. You can also read the "**Choose your injection site**" section of these instructions to help you choose which area can work best for you.
- If you have vision or hearing problems, **do not** use EMGALITY Pen without help from a caregiver.
- See "**Storage and Handling Information**" for important storage information.

INSTRUCTIONS FOR USE

Before you use the EMGALITY Pen, read and carefully follow all the step-by-step instructions.
Parts of the EMGALITY Pen



Before You Get Started

Take the Pen from the refrigerator

Check your prescription.

- EMGALITY comes as a single-dose prefilled Pen.
- You will need 2 Pens for your first dose (**1-time loading dose**). You will need 1 Pen for your monthly dose.

Put the original package with any unused Pens back in the refrigerator.

Leave the base cap on until you are ready to inject.

Leave the Pen at room temperature for 30 minutes before injecting.

Do not microwave the Pen, run hot water over it, or leave it in direct sunlight.

Do not shake.

Gather Supplies

For each injection you will need:

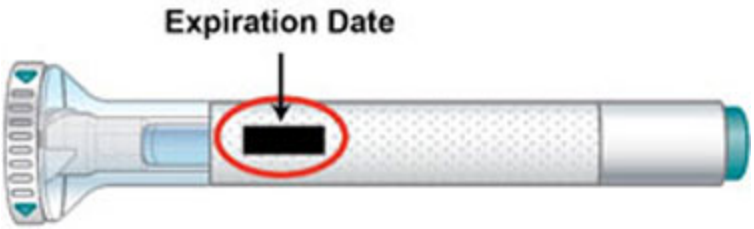
- 1 alcohol wipe
- 1 cotton ball or piece of gauze
- 1 sharps disposal container. See "After You Inject Your Medicine."

Inspect the Pen and the medicine

Make sure you have the right medicine. The medicine inside should be clear. Its color may be colorless to slightly yellow to slightly brown.

Do not use the Pen, and throw away (dispose of) as directed by your healthcare provider or pharmacist if:

- it looks damaged
- the medicine is cloudy, is discolored, or has small particles
- the Expiration Date (Exp.) printed on the label has passed
- the medicine is frozen

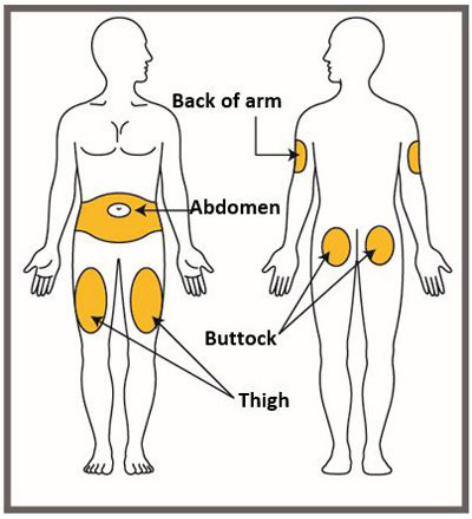


Prepare for injection

Wash your hands with soap and water before you inject your EMGALITY. Make sure a sharps disposal container is close by.

Choose your injection site

Your healthcare provider can help you choose the injection site that is best for you.

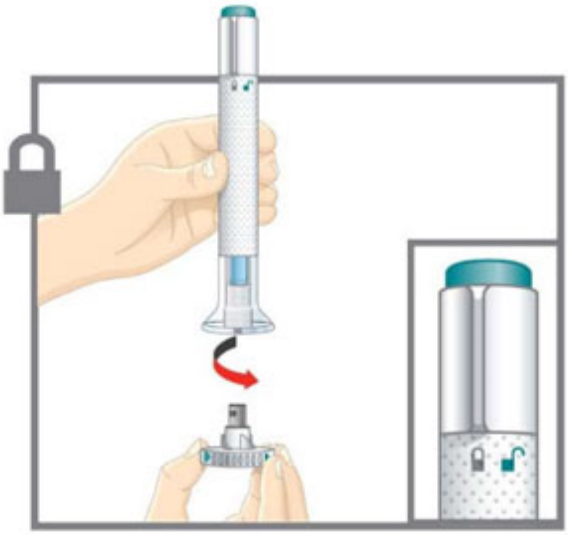


- **You** may inject the medicine into your stomach area (abdomen). Do not inject within 2 inches of the belly button (navel).
- You may inject the medicine into the front of your thighs. This area should be at least 2 inches above the knee and 2 inches below the groin.
- **Another person** may give you the injection in the back of your upper arm, or buttocks.
- **Do not** inject in the exact same spot. For example, if you are giving 2 injections for your **first dose (1-time loading dose)** and want to use the same body site for the two separate injections, choose a different injection spot. If your first injection was in your abdomen, your next injection could be in another area of your abdomen.

- **Do not** inject into areas where the skin is tender, bruised, red, or hard.
- **Clean your injection site with an alcohol wipe. Let the injection site dry before you inject.**

1 Uncap the Pen

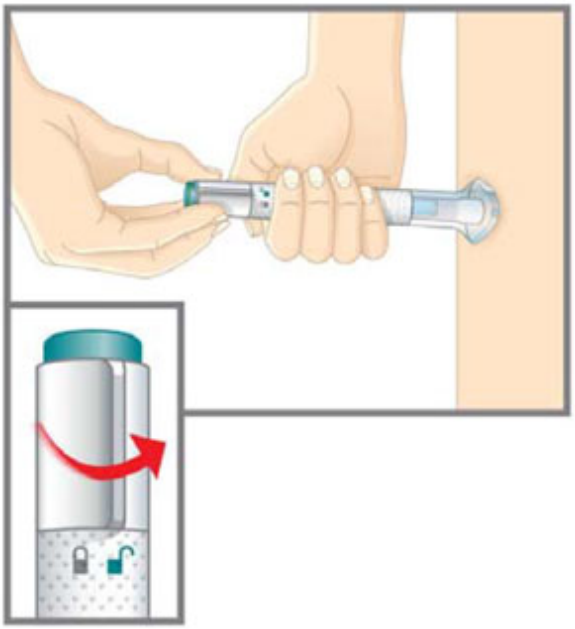
Make sure the Pen is locked. Leave the base cap on until you are ready to inject.



- Twist off the base cap and throw it away in your household trash.
- **Do not** put the base cap back on – this could damage the needle.
- **Do not** touch the needle.

2 Place and Unlock

- Place and hold the clear base flat and firmly against your skin.

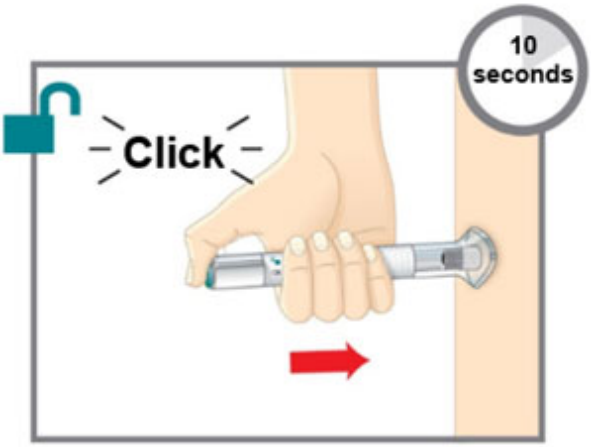


Turn the lock ring to the **unlock** position.

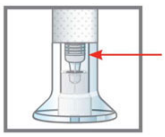
3 Press and Hold for 10 Seconds

- Press and hold the teal injection button; you will hear a loud click.
- **Keep holding the clear base firmly against**

your skin. You will hear a second click in about 10 seconds after the first one. This second click tells you that your injection is complete.



- Remove the Pen from your skin.



You will know your injection is complete when the gray plunger is visible.

- If you have bleeding at the injection site, press a cotton ball or gauze over the injection site. **Do not** rub the injection site.

After You Inject Your Medicine

Throw away the used Pen

- Put the used EMGALITY Pen in an FDA-cleared sharps disposal container right away after use. **Do not** throw away (dispose of) the EMGALITY Pen in your household trash.

- If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:

– made of a heavy-duty plastic,
– can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
– upright and stable during use,
– leak-resistant, and
– properly labeled to warn of hazardous waste inside the container.

- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state you live in, go to the FDA's website at: http://www.fda.gov/safesharpsdisposal.

- **Do not** recycle your used sharps disposal container.

Commonly Asked Questions

Q. What if I see bubbles in the Pen?

A. It is normal to have air bubbles in the Pen. EMGALITY is injected under your skin (subcutaneous injection), so these air bubbles will not harm you.

Q. What if there is a drop of liquid on the tip of the needle when I remove the base cap?

A. It is okay to see a drop of liquid on the tip of the needle.

Q. What if I unlocked the Pen and pressed the teal injection button before I twisted off the base cap?

A. Do not remove the base cap. Dispose of the Pen and get a new one.

Q. Do I need to hold the injection button down until the injection is complete?

A. This is not necessary, but it may help you keep the Pen steady and firm against your skin.

Q. What if the needle did not retract after my injection?

A. Do not touch the needle or replace the base cap. Store in a safe place to avoid an accidental needlestick and contact 1-833-364-2548 for instructions on how to return the Pen.

Q. What if there is a drop of liquid or blood on my skin after my injection?

A. This is normal. Press a cotton ball or gauze over the injection site. Do not rub the injection site.

Q. What if I heard more than 2 clicks during my injection – 2 loud clicks and a soft one. Did I get my complete injection?

A. Some patients may hear a soft click right before the second loud click. That is the normal operation of the Pen. Do not remove the Pen from your skin until you hear the second loud click.

Q. How can I tell if my injection is complete?

A. After you press the teal injection button, you will hear 2 loud clicks. The second click tells you that your injection is complete. You will also see the gray plunger at the top of the clear base.

If you have more questions about how to use the EMGALITY Pen:

- Call your healthcare provider
- Call 1-833-EMGALITY (1-833-364-2548)
- Visit www.emgality.com

Storage and Handling Information

- Store your Pen in the refrigerator between 36ºF to 46ºF (2ºC to 8ºC).
- Your Pen may be stored out of the refrigerator in the original carton at temperatures up to 86°F (30°C) for up to 7 days. After storing out of the refrigerator, **do not** place EMGALITY back in the refrigerator.
- **Do not** freeze your Pen.
- Keep your Pen in the carton it comes in to protect it from light until time of use.
- **Do not** shake your Pen.

- Throw away your Pen if any of the above conditions are not followed.
- **Keep your Pen and all medicines out of the reach of children.**

Read the full Prescribing Information and Patient Information for EMGALITY inside this box to learn more about your medicine.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.
Eli Lilly and Company
Indianapolis, IN 46285, USA
US License Number 1891

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Revised: 11/2019

The Pen meets the current dose accuracy and functional requirements of ISO 11608-1 and 11608-5.

EMG-0005-AI-120MG-IFU-20191127

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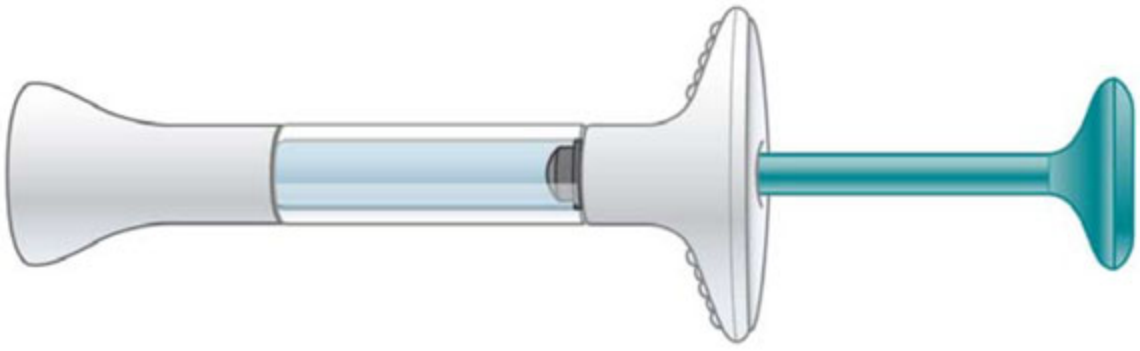
− INSTRUCTIONS FOR USE

INSTRUCTIONS FOR USE
EMGALITY® (em-GAL-it-ē)
(galcanezumab-gnlm)
injection, for subcutaneous use
Prefilled Syringe



This Instructions for Use is for patients with migraine.

- **If you are using EMGALITY for episodic cluster headache, there is a different Instructions for Use because the dose and number of syringes needed is different.**

For subcutaneous injection only.

Before you use the EMGALITY prefilled syringe, read and carefully follow all the step-by-step instructions.

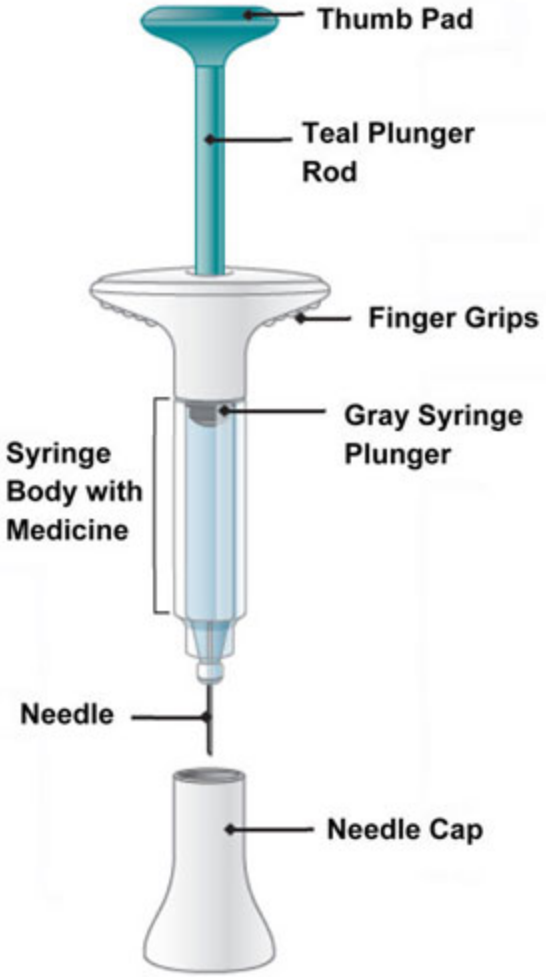
Important Information

- Your healthcare provider or nurse should show you how to prepare and inject EMGALITY using the prefilled syringe. **Do not** inject yourself or someone else until you have been shown how to inject EMGALITY.
- Keep this Instructions for Use and refer to it as needed.
- Each EMGALITY prefilled syringe is for **one-time use only. Do not** share or reuse your EMGALITY prefilled syringe. You may give or get an infection.
- Your healthcare provider may help you decide where on your body to inject your dose. You can also read the "**Choose your injection site**" section of these instructions to help you choose which area can work best for you.
- If you have vision problems, **do not** use EMGALITY prefilled syringe without help from a caregiver.
- See "**Storage and Handling Information**" for important storage information.

INSTRUCTIONS FOR USE

Before you use the EMGALITY prefilled syringe, read and carefully follow all the step-by-step instructions.

Parts of the EMGALITY Prefilled Syringe



Before You Get Started

Take the Prefilled Syringe from the refrigerator

Check your prescription.

- EMGALITY comes as a single-dose prefilled syringe.
- You will need 2 prefilled syringes for your first dose (**1-time loading dose**). You will need 1 prefilled syringe for your monthly dose.

Put the original package with any unused syringes back in the refrigerator.

Leave the needle cap on until you are ready to inject.

Leave the prefilled syringe at room temperature for 30 minutes before injecting.

Do not microwave the prefilled syringe, run hot water over it, or leave it in direct sunlight.

Do not shake.

Gather Supplies

For each injection you will need:

- 1 alcohol wipe
- 1 cotton ball or piece of gauze
- 1 sharps disposal container. See "After You Inject Your Medicine."

Inspect the Prefilled Syringe

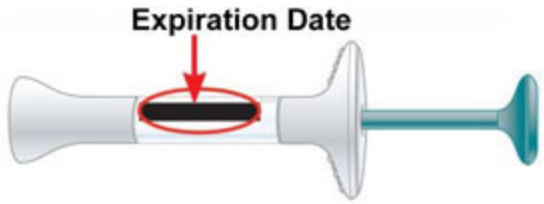
Make sure you have the right medicine. The medicine insi

and the medicine

should be clear. Its color may be colorless to slightly yellow to slightly brown.

Do not use the prefilled syringe, and throw away (dispose of) as directed by your healthcare provider or pharmacist if:

- it looks damaged
- the medicine is cloudy, is discolored, or has small particles
- the Expiration Date (Exp.) printed on the label has passed
- the medicine is frozen

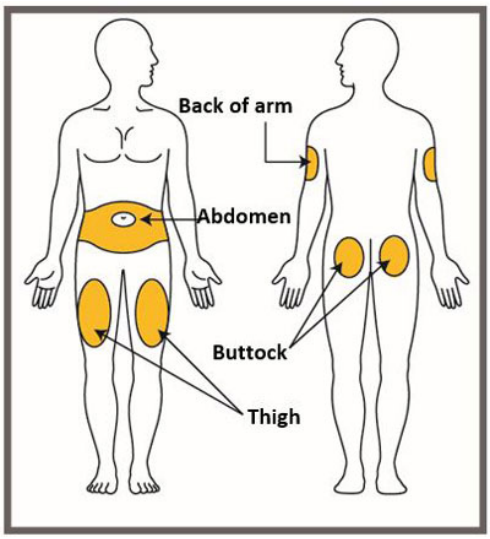


Prepare for injection

Wash your hands with soap and water before you inject your EMGALITY. Make sure a sharps disposal container is close by.

Choose your injection site

Your healthcare provider can help you choose the injection site that is best for you.

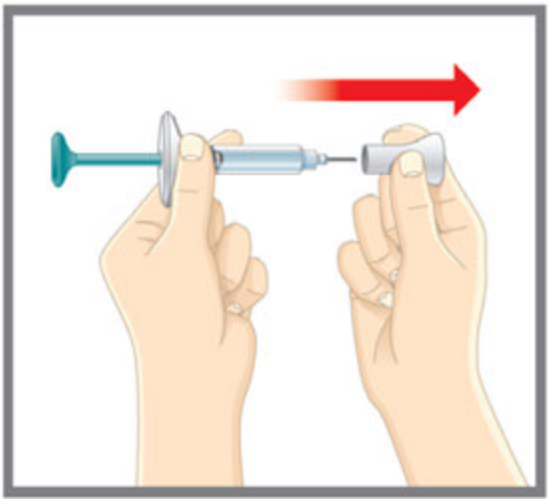


- **You** may inject the medicine into your stomach area (abdomen). **Do not** inject within 2 inches of the belly button (navel).
- You may inject the medicine into the front of your thighs. This area should be at least 2 inches above the knee and 2 inches below the groin.
- **Another person** may give you the injection in the back of your upper arm, or buttocks.
- **Do not** inject in the exact same spot. For example, if you are giving 2 injections for your **first dose (1-time loading dose)** and want to use the same body site for the two separate injections, choose a different injection spot. If your first injection was in your abdomen, your next injection could be in another area of your abdomen.
- Do not inject into areas where the skin is tender, bruised, red, or hard.
- **Clean your injection site with an alcohol wipe. Let the injection site dry before you inject.**

1 Uncap

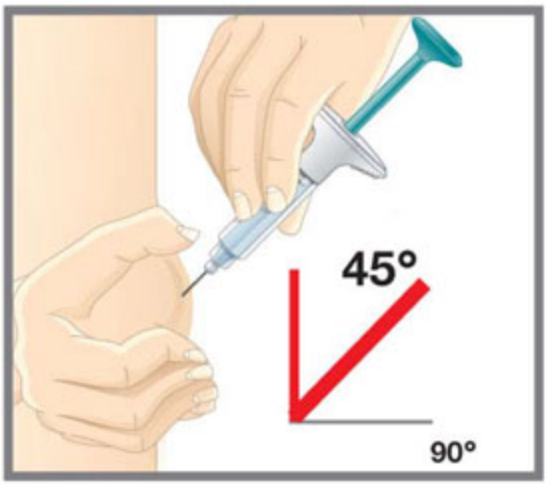
- **Leave the needle cap on until you are ready to inject.**

- Pull the needle cap off and throw it away in your household trash.
- **Do not** put the needle cap back on. You could damage the needle or stick yourself by accident.
- **Do not** touch the needle.



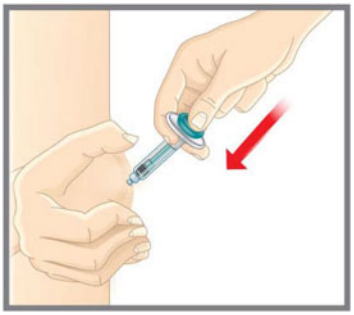
2 Insert

- Gently pinch and hold a fold of skin where you will inject.
- Insert the needle at a 45-degree angle.

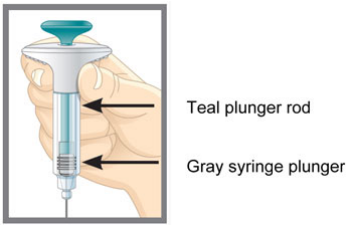


3 Inject

- Slowly push on the thumb pad to push the plunger all the way in until all the medicine is injected.
- The gray syringe plunger should be pushed all the way to the needle end of the syringe.



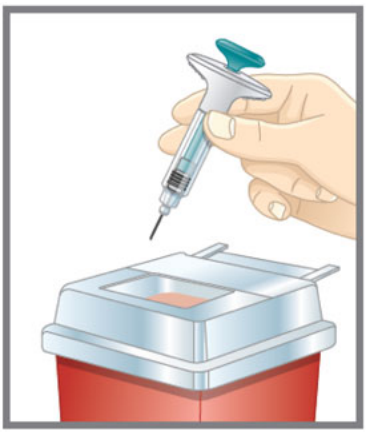
- You should see the teal plunger rod show through the syringe body when the injection is complete as shown.
- Remove the needle from your skin and gently let go of your skin.
- If you have bleeding at the injection site, press a cotton ball or gauze over the injection site. **Do not** rub the injection site.
- **Do not** put the needle cap back on the prefilled syringe.



After You Inject Your Medicine

Throw away the used prefilled syringe

- Put the used EMGALITY prefilled syringe in an FDA-cleared sharps disposal container right away after use. **Do not** throw away (dispose of) the EMGALITY prefilled syringe in your household trash.



- If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:

  – made of a heavy-duty plastic,
  – can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
  – upright and stable during use,
  – leak-resistant, and
  – properly labeled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state you live in, go to the FDA's website at: http://www.fda.gov/safesharpsdisposal.

- **Do not** recycle your used sharps disposal container.

Commonly Asked Questions

Q. What if I see air bubbles in my EMGALITY prefilled syringe?
A. It is normal to have air bubbles in the prefilled syringe. EMGALITY is injected under your skin (subcutaneous injection), so these air bubbles will not harm you.
Q. What if there is a drop of liquid on the tip of the needle when I remove the needle cap?
A. It is okay to see a drop of liquid on the tip of the needle.
Q. What if I cannot push in the plunger?
A. If the plunger is stuck or damaged:

- **Do not** continue to use the syringe
- Remove the needle from your skin
- Dispose of the syringe and get a new one

Q. What if there is a drop of liquid or blood on my skin after my injection?
A. This is normal. Press a cotton ball or gauze over the injection site. **Do not** rub the injection site.
Q. How can I tell if my injection is complete?

A. When your injection is complete:

- The teal plunger rod should show through the body of the syringe.
- The gray syringe plunger should be pushed all the way to the needle end of the syringe.

If you have more questions about how to use the EMGALITY prefilled syringe:

- Call your healthcare provider
- Call 1-833-EMGALITY (1-833-364-2548)
- Visit www.emgality.com

Storage and Handling Information

- Store your prefilled syringe in the refrigerator between 36ºF to 46ºF (2ºC to 8ºC).
- Your prefilled syringe may be stored out of the refrigerator in the original carton at temperatures up to 86°F (30°C) for up to 7 days. After storing out of the refrigerator, **do not** place EMGALITY back in the refrigerator.
- **Do not** freeze your prefilled syringe.
- Keep your prefilled syringe in the carton it comes in to protect it from light until time of use.
- **Do not** shake your prefilled syringe.
- Throw away your prefilled syringe if any of the above conditions are not followed.
- **Keep your prefilled syringe and all medicines out of the reach of children.**

Read the full Prescribing Information and Patient Information for EMGALITY inside this box to learn more about your medicine.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.
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Indianapolis, IN 46285, USA
US License Number 1891

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EMG-0004-PFS-120MG-IFU-20190604

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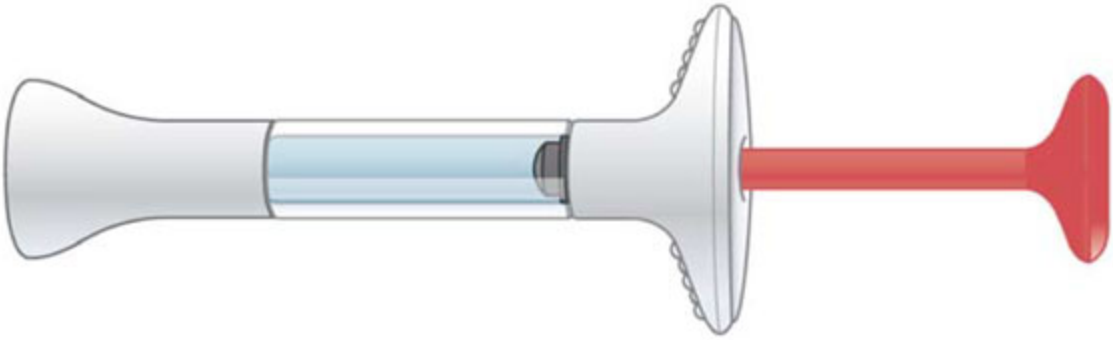
– INSTRUCTIONS FOR USE

INSTRUCTIONS FOR USE
EMGALITY® (em-GAL-it-ē)
(galcanezumab-gnlm)
injection, for subcutaneous use
Prefilled Syringe



This Instructions for Use is for patients with episodic cluster headache.

- **If you are using EMGALITY for preventive treatment of migraine, there is a different Instructions for Use because the dose and number of syringes needed is different.**

For subcutaneous injection only.

Before you use the EMGALITY prefilled syringe, read and carefully follow all the step-by-step instructions.

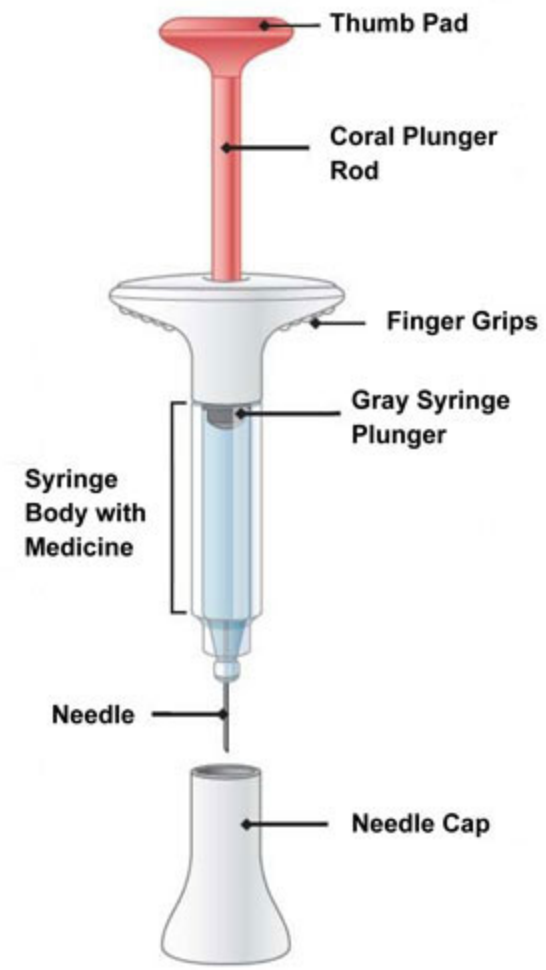
Important Information

- Your healthcare provider or nurse should show you how to prepare and inject EMGALITY using the prefilled syringe. **Do not** inject yourself or someone else until you have been shown how to inject EMGALITY.
- Keep this Instructions for Use and refer to it as needed.
- Each EMGALITY prefilled syringe is for **one-time use only. Do not** share or reuse your EMGALITY prefilled syringe. You may give or get an infection.
- Your healthcare provider may help you decide where on your body to inject your dose. You can also read the "**Choose your injection site**" section of these instructions to help you choose which area can work best for you.
- If you have vision problems, **do not** use EMGALITY prefilled syringe without help from a caregiver.
- See "**Storage and Handling Information**" for important storage information.

INSTRUCTIONS FOR USE

Before you use the EMGALITY prefilled syringe, read and carefully follow all the step-by-step instructions.

Parts of the EMGALITY Prefilled Syringe



Before You Get Started

Take the Prefilled Syringes from the refrigerator

Take 3 EMGALITY prefilled syringes from the refrigerator.

Check your prescription.

- EMGALITY comes as a single-dose prefilled syringe.
- You will need 3 prefilled syringes for each dose.

Leave the needle caps on until you are ready to inject.

Leave the prefilled syringes at room temperature for 30 minutes before injecting.

Do not microwave the prefilled syringes, run hot water over them, or leave them in direct sunlight.

Do not shake.

Gather Supplies

For each injection you will need:

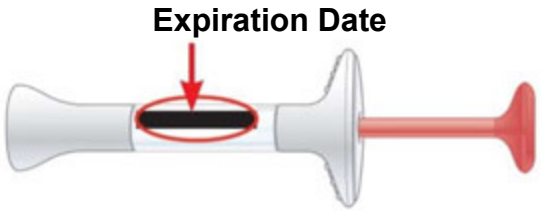
- 1 alcohol wipe
- 1 cotton ball or piece of gauze
- 1 sharps disposal container. See "After You Inject Your Medicine."

Inspect the Prefilled Syringe and the medicine

Make sure you have the right medicine. The medicine inside should be clear. Its color may be colorless to slightly yellow to slightly brown.

Do not use the prefilled syringe, and throw away (dispose of) as directed by your healthcare provider or pharmacist if:

- it looks damaged
- the medicine is cloudy, is discolored, or has small particles
- the Expiration Date (Exp.) printed on the label has passed
- the medicine is frozen

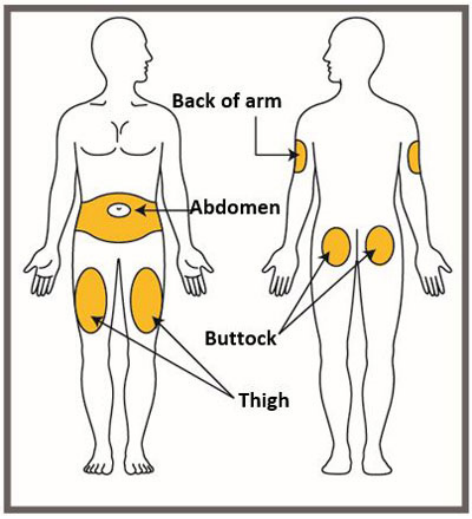


Prepare for injection

Wash your hands with soap and water before you inject your EMGALITY. Make sure a sharps disposal container is close by.

Choose your injection site

Your healthcare provider can help you choose the injection site that is best for you.

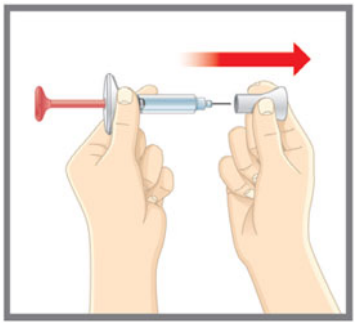


- **You** may inject the medicine into your stomach area (abdomen). **Do not** inject within 2 inches of the belly button (navel).
- You may inject the medicine into the front of your thighs. This area should be at least 2 inches above the knee and 2 inches below the groin.
- **Another person** may give you the injection in the back of your upper arm or buttocks.
- **Do not** inject in the exact same spot. For example, if your first injection was in your abdomen, your next injection could be in another area of your abdomen.
- Do not inject into areas where the skin is tender, bruised, red, or hard.
- **Clean your injection site with an alcohol wipe. Let the injection site dry before you inject.**

1 Uncap

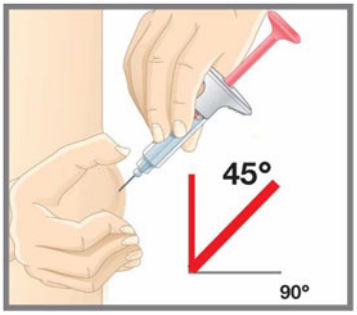
- **Leave the needle cap on until you are ready to inject.**
- Pull the needle cap off and throw it away in your household trash.

- **Do not** put the needle cap back on. You could damage the needle or stick yourself by accident.
- **Do not** touch the needle.



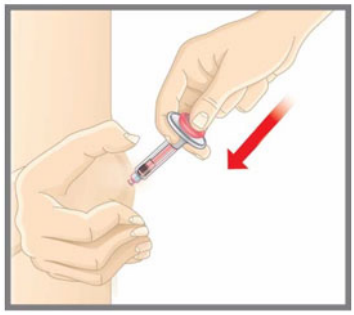
2 Insert

- Gently pinch and hold a fold of skin where you will inject.
- Insert the needle at a 45-degree angle.

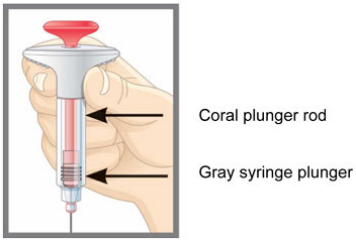


3 Inject

- Slowly push on the thumb pad to push the plunger all the way in until all the medicine is injected.
- The gray syringe plunger should be pushed all the way to the needle end of the syringe.



- You should see the coral plunger rod show through the syringe body when the injection is complete as shown.
- Remove the needle from your skin and gently let go of your skin.
- If you have bleeding at the injection site, press a cotton ball or gauze over the injection site. Do not rub the injection site.
- **Do not** put the needle cap back on the prefilled syringe.



After You Inject Your Medicine

Throw away the used prefilled syringe

- Put the used EMGALITY prefilled syringe in an FDA-cleared sharps disposal container right away after use. **Do not** throw away (dispose of) the EMGALITY prefilled syringe in your household trash.

- If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:
  - made of a heavy-duty plastic,
  - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
  - upright and stable during use,
  - leak-resistant, and
  - properly labeled to warn of hazardous waste inside the container.
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- **Do not** recycle your used sharps disposal container.

For each of the 3 injections, repeat all instructions with a new prefilled syringe.

Commonly Asked Questions

Q. What if I see air bubbles in my EMGALITY prefilled syringe?

A. It is normal to have air bubbles in the prefilled syringe. EMGALITY is injected under your [illegible] (subcutaneous injection), so these air bubbles will not harm you.

Q. What if there is a drop of liquid on the tip of the needle when I remove the needle cap?

A. It is okay to see a drop of liquid on the tip of the needle.

Q. What if I cannot push in the plunger?

A. If the plunger is stuck or damaged:

- **Do not** continue to use the syringe
- Remove the needle from your skin
- Dispose of the syringe and get a new one

Q. What if there is a drop of liquid or blood on my skin after my injection?

A. This is normal. Press a cotton ball or gauze over the injection site. **Do not** rub the injection site.

Q. How can I tell if my injection is complete?

A. When your injection is complete:

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- **Do not** freeze your prefilled syringes.
- Keep your prefilled syringes in the carton they come in to protect them from light until time of use.
- **Do not** shake your prefilled syringes.
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