MORE IS POSSIBLE

FOR YOUR PATIENTS LIKE JESSICA[a]

INDICATIONS

Emgality® is a calcitonin gene-related peptide indicated in adults for the preventive treatment of migraine and for the treatment of episodic cluster headache.

MIGRAINE PATIENT PROFILE

AGE
38

MIGRAINE FREQUENCY:
4 or more MHDs
per month

TREATMENT HISTORY:

- Has implemented lifestyle modifications
- Has tried various acute treatment options
- Has tried **2 prior generic preventives**

[a]Hypothetical patient profile.
MHD=migraine headache day.

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 the last page and click to access Full Prescribing Information.
See Instructions for Use included with the device.

Emgality®
(galcanezumab-gnlm)
120 mg injection/300 mg injection

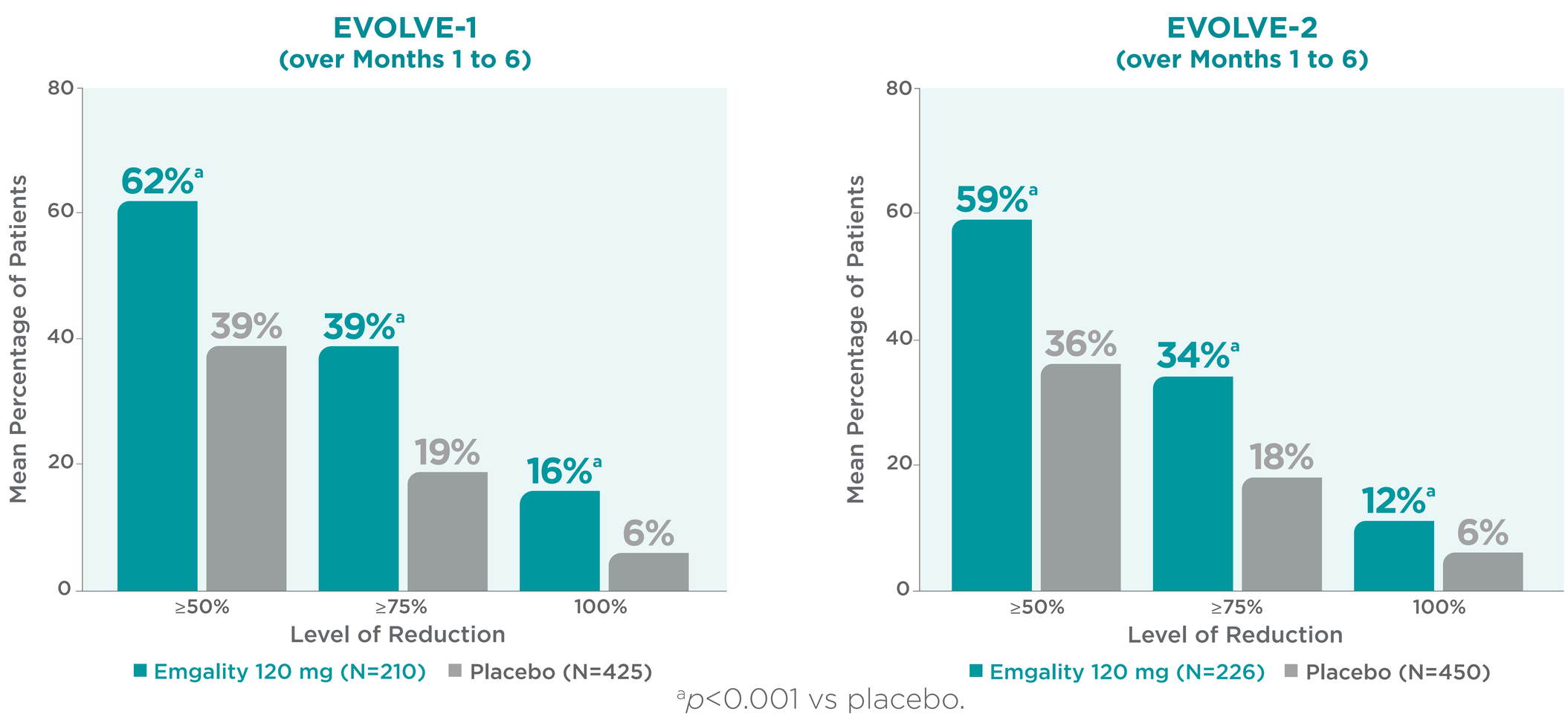
For your patients with episodic migraine (4-14 MHDs per month),

EMGALITY MAKES IT POSSIBLE FOR SOME PATIENTS TO BE **TOTALLY MIGRAINE-FREE FOR A MONTH**[1]

EMGALITY IS THE FIRST AND ONLY CGRP ANTIBODY APPROVED FOR BOTH MIGRAINE AND EPISODIC CLUSTER HEADACHE[1,2]

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.

For your patients with ≥15 headache days per month[1]:

- In **REGAIN**, Emgality 120 mg (N=273) reduced monthly MHDs from baseline by ≥50% in a significantly greater mean percentage of patients: 28% of patients vs 15% of patients with placebo (N=538) over Months 1 to 3 ($p<0.001$)
- Emgality 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

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

For your patients with 4-14 MHDs per month[1]:

- **EVOLVE-1: 4.7** vs **2.8** days over Months 1 to 6 (baseline mean: **9.2** vs **9.1**)[bc]
- **EVOLVE-2: 4.3** vs **2.3** days over Months 1 to 6 (baseline mean: **9.1** vs **9.2**)[bc]

See study designs on last page.

For your patients with ≥15 headache days per month[1]:

- **REGAIN: 4.8** vs **2.7** days over Months 1 to 3 (baseline mean: **19.4** vs **19.6**)[bc]

[b]EVOLVE-1: Emgality 120 mg (N=210), placebo (N=425); EVOLVE-2: Emgality 120 mg (N=226), placebo (N=450); REGAIN: Emgality 120 mg (N=273), placebo (N=538).[1]
[c]Least-square (LS) means are presented.[3]

CGRP=calcitonin gene-related peptide.

SELECT IMPORTANT SAFETY INFORMATION

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. Hypersensitivity reactions can occur days after administration and may be prolonged.

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For your patients with migraine,

EMGALITY COMES IN AN

EASY-TO-USE PEN FOR SELF-ADMINISTRATION[1,4]

At first use,

94% of patients agreed that the Emgality Pen was "easy to use."[4]

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.[5]

Recommended dosing with no titration required[a]

Month 1:
Initial loading dose of 240 mg (two 120 mg injections)

Subsequent months:
One 120 mg injection per month

[a]The Emgality Pen needle is 27 gauge x 1/2 inch.[6]

As of <03/02/2020>,

OVER <90%> OF COMMERCIALLY INSURED PATIENTS

NATIONWIDE HAVE COVERAGE FOR **EMGALITY**[7]

Source: Managed Markets Insight & Technology (MMIT), LLC [or other referenced source] as of <03/2020> and is subject to change without notice. Please contact the plan or state for the most current information. "Coverage" includes all statuses at or equivalent to Preferred, Covered, Specialty, and Generic for prevention of migraine. This information is not a guarantee of coverage or payment (partial or full). Actual benefits are determined by each plan administrator in accordance with its respective policy and procedures. Employers and employer groups may also offer additional benefit designs, which may be different than described.

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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120 mg injection/300 mg injection

ACROSS 4 CLINICAL TRIALS AND 2 DISTINCT DOSES, **EMGALITY** DEMONSTRATED A

CONSISTENT SAFETY PROFILE

IN PATIENTS WITH MIGRAINE AND IN PATIENTS WITH EPISODIC CLUSTER HEADACHE[1]

For patients with migraine,

ADVERSE REACTIONS OCCURRING IN ADULTS WITH MIGRAINE WITH AN INCIDENCE OF AT LEAST 2% FOR EMGALITY AND AT LEAST 2% GREATER THAN PLACEBO[1]

EVOLVE-1, EVOLVE-2, and REGAIN
(up to 6 months of treatment)

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.

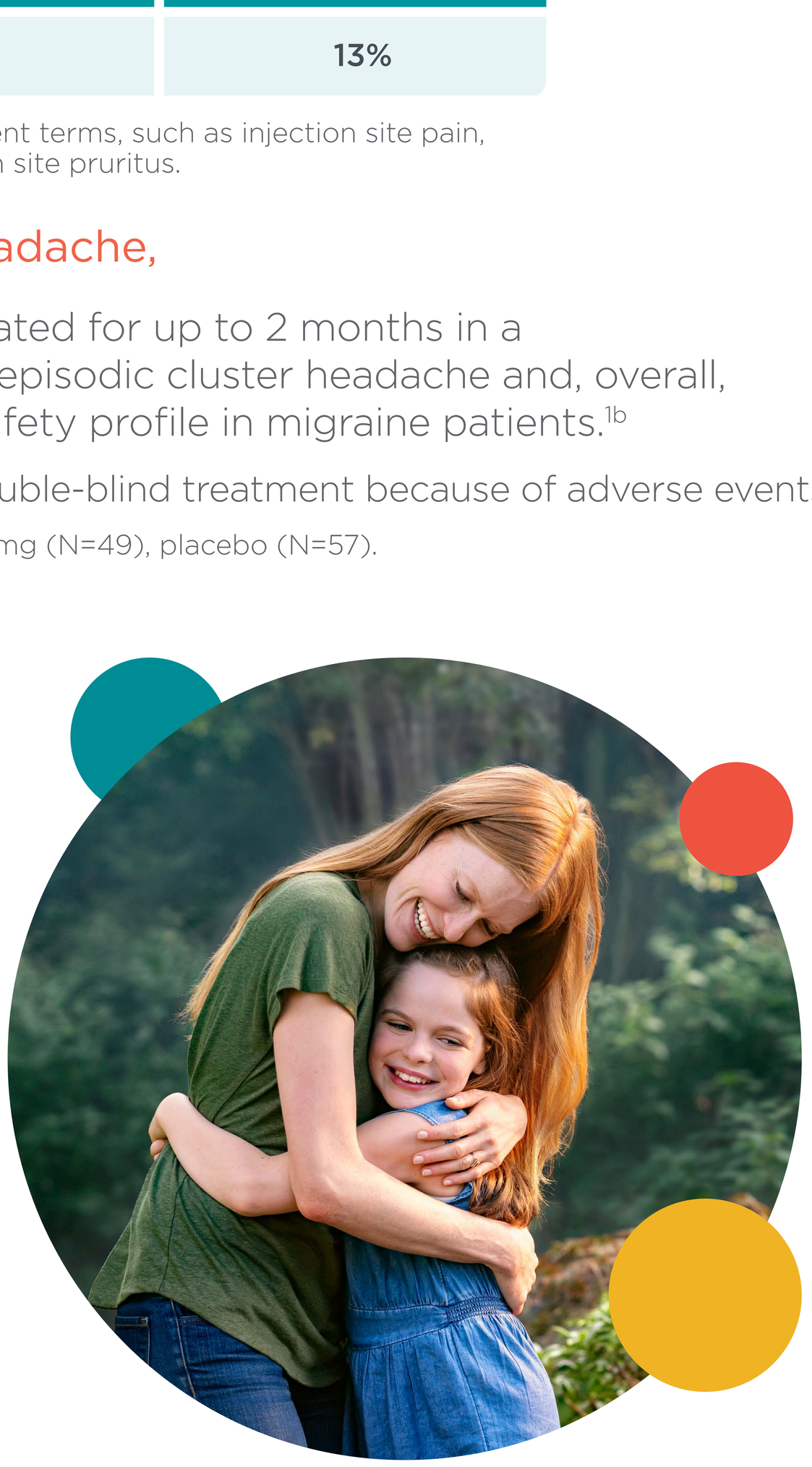
For patients with episodic cluster headache,

The safety of Emgality 300 mg was evaluated for up to 2 months in a placebo-controlled study in patients with episodic cluster headache and, overall, was observed to be consistent with the safety profile in migraine patients.[1b]

- 2 Emgality-treated patients discontinued double-blind treatment because of adverse events

[b]Emgality Episodic Cluster Headache Study: Emgality 300 mg (N=49), placebo (N=57).

CONSIDER EMGALITY FOR YOUR PATIENTS WITH MIGRAINE AND EPISODIC CLUSTER HEADACHE[1]



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Contraindications

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MIGRAINE STUDY DESIGNS[1,3]

EVOLVE-1 and **EVOLVE-2** were 6-month, double-blind, placebo-controlled studies that enrolled adult patients with episodic migraine (defined as 4-14 MHDs per month) (N=1773). **REGAIN** was a 3-month, double-blind, placebo-controlled study that enrolled adult patients with chronic migraine (defined as ≥15 headache days per month with ≥8 migraine days per month) (N=1113). In all 3 studies, patients 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. In **EVOLVE-1** and **EVOLVE-2**, other treatments for migraine prevention were not allowed. In **REGAIN**, a subset of patients (15%) continued 1 concomitant migraine preventive medication. In all 3 studies, patients were allowed to use acute treatments for headache, including migraine-specific medications (ie, triptans, ergotamine derivatives), nonsteroidal anti-inflammatory drugs (NSAIDs), and acetaminophen during the study. For each study, the primary endpoint was the LS mean change from baseline in the number of monthly MHDs over the double-blind treatment period in the intent-to-treat population.

EPISODIC CLUSTER HEADACHE STUDY DESIGN[1,3]

The **Emgality Episodic Cluster Headache Study** was an 8-week, randomized, double-blind, placebo-controlled study that enrolled 106 adults with episodic cluster headache who had a maximum of 8 attacks per day, a minimum of 1 attack every other day, and at least 4 attacks during the prospective 7-day baseline period. Patients were randomized to once-monthly Emgality 300 mg or placebo. The study excluded patients on other treatments intended to reduce the frequency of cluster headache attacks. Patients were allowed to use certain specified acute/abortive cluster headache treatments, including triptans, oxygen, acetaminophen, and NSAIDs during the study. The primary efficacy endpoint was the LS mean change from baseline in weekly cluster headache attack frequency over Weeks 1 to 3.

EXCLUSION CRITERIA ACROSS EMGALITY STUDIES[1]

EVOLVE-1, **EVOLVE-2**, **REGAIN**, and the **Emgality Episodic Cluster Headache Study** excluded 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; in the **Emgality Episodic Cluster Headache Study**, patients with any prior lifetime history of stroke were excluded. **EVOLVE-1**, **EVOLVE-2**, and the **Emgality Episodic Cluster Headache Study** also excluded patients with medication overuse headache. The **Emgality Episodic Cluster Headache Study** also excluded patients with ECG abnormalities compatible with conduction delay; patients with a history of intracranial or carotid aneurysm, intracranial hemorrhage, or vasospastic angina; or patients with clinical evidence of peripheral vascular disease or diagnosis of Raynaud's disease.

INDICATIONS

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IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

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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 click to access Full Prescribing Information. See Instructions for Use included with the device.

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References: 1. Emgality [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC. **2.** Data on File. Lilly USA, LLC. DOF-GZ-US-0085. **3.** Data on File. Lilly USA, LLC. DOF-GZ-US-0120. **4.** Data on File. Lilly USA, LLC. DOF-GZ-US-0013. **5.** Data on File. Lilly USA, LLC. DOF-GZ-US-0020. **6.** Data on File. Lilly USA, LLC. DOF-GZ-US-0060. **7.** Data on File. Lilly USA, LLC. DOF-GZ-US-0111.

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