

- ▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

EMGALITY®

Prefilled Pen (Autoinjector) and Prefilled Syringe

Galcanezumab

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about EMGALITY. It does not contain all the available information. It should not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking EMGALITY against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What EMGALITY is used for

EMGALITY is used to prevent migraine in adult patients.

Migraine is a disease affecting the nervous system where patients suffer with repeated headaches, often only affecting one side of the head. The headaches are commonly associated with feeling nauseous, or actually vomiting, and patients can also be very sensitive to light and sound.

The active ingredient in EMGALITY is galcanezumab. Galcanezumab belongs to a group of preventative medicines that stop the activity of a naturally occurring substance in the body called calcitonin-gene-related peptide (CGRP). Increased levels of CGRP have been associated with migraine.

EMGALITY has been shown to improve quality of life by significantly reducing the frequency of migraine headache, with an onset of effect as early as one week after starting treatment.

Ask your doctor if you have any questions about why EMGALITY has been prescribed for you.

Your doctor may have prescribed it for another reason.

EMGALITY is available only with a doctor's prescription.

.EMGALITY could have a minor effect on your ability to drive and use machines. Some patients have had vertigo whilst using EMGALITY.

EMGALITY has not been studied in patients under 18 years of age.

Before you take EMGALITY

When you must not take it

Do not take EMGALITY if you have an allergy to:

- Galcanezumab
- Any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not give this medicine to children and adolescents under 18 years of age.

EMGALITY is not recommended for children and adolescents under 18 years of age because it has not been studied in this age group.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. It is preferable to avoid the use of EMGALITY in pregnancy, as the effects of this medicine in pregnant women are not known.

Your doctor will advise the most appropriate contraceptive method for you to take while using EMGALITY.

If you are breast-feeding or are planning to breast-feed, talk to your doctor before using this medicine. You and your doctor should decide if you should breast-feed and use EMGALITY.

If you have not told your doctor about any of the above, tell him/her before you start taking EMGALITY.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and EMGALITY may interfere with each other.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take EMGALITY

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

EMGALITY is given by injection under your skin (subcutaneous injection). You and your doctor or nurse should decide if you should inject EMGALITY yourself.

It is important not to try to inject yourself until you have been trained by your doctor, pharmacist or nurse. A caregiver may also give you your EMGALITY injection after proper training.

Comprehensive instructions for administration are given in the Instructions For Use in the package insert.

How much to take

Each pen and syringe contains one dose of EMGALITY (120 mg). Each pen or syringe delivers only one dose.

- The first dose is 240 mg (two 120 mg injections) by subcutaneous injection.
- After the first dose, you will use a 120 mg dose (one injection) every month.

How to take it

The pen and syringe must not be shaken.

Read the "Instructions for Use" for the pen or syringe carefully before using EMGALITY.

When to take it

Take your medicine at about the same time each month.

Taking it at the same time each month will have the best effect. It will also help you remember when to take it.

How long to take it

Your doctor will decide how long you should use EMGALITY.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

Do not take a double dose to make up for the forgotten injection when you next inject.

If you have forgotten to inject a dose of EMGALITY, inject the missed dose as soon as possible and then resume monthly dosing.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

If, after the initial dose of 240 mg, you have injected twice in a single monthly period, then you should inform your doctor.

While you are using EMGALITY

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking EMGALITY.

If you become pregnant while taking this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not take EMGALITY to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine, or change the dosage, without checking with your doctor.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking EMGALITY.

This medicine helps most people with migraine, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Injection site reactions e.g. red skin, pain.
- Vertigo (a feeling of dizziness or 'spinning').
- Constipation.
- Itching.
- Rash

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor as soon as possible if you notice:

- Sudden signs of allergy such as rash, itching, hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing
- swelling of the face, lips, mouth, tongue or throat which may be rapid and may cause difficulty in swallowing or breathing.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

Although the allergic reactions usually seen with EMGALITY are mild to moderate (such as rash or itching), it is possible that more serious reactions could occur, so it is important for you to stop using EMGALITY and tell your doctor if you think that you have had an allergic reaction.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After taking EMGALITY

Storage

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and on the carton after 'EXP'.

The expiry date refers to the last day of that month.

Store in a refrigerator (2°C to 8°C). Do not freeze.

Store in original packaging in order to protect from light.

EMGALITY can be left out of the fridge for up to 7 days at a temperature not above 30°C. If these conditions are exceeded, then EMGALITY must be thrown away. Once EMGALITY has been stored out of refrigeration, do not place it back in the refrigerator.

Do not use this medicine if you notice that the pen or syringe is damaged, or that the medicine is cloudy or has particles in it.

This medicine is for single use only.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Do not throw away any medicines via wastewater or household waste. Ask your doctor, nurse or pharmacist how to throw away medicines you no longer use. This will help protect the environment.

Product Description

What it looks like

Prefilled Pen:

EMGALITY is a solution in a clear glass syringe. Its colour may vary from colourless to slightly yellow. The syringe is encased in a disposable, single-dose pen.

Prefilled pens may be available in pack sizes of 1, 2, or 3.

Prefilled Syringe:

EMGALITY is a solution in a clear glass syringe. Its colour may vary from colourless to slightly yellow.

Prefilled syringes may be available in pack sizes of 1, 2 or 3.

Note: all presentations or pack sizes may not be available.

Ingredients

EMGALITY contains 120 mg of galcanezumab as the active ingredient.

- Histidine
- Histidine hydrochloride monohydrate
- Polysorbate 80
- Sodium chloride
- Water for injections

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dye.

Supplier

EMGALITY is supplied in Australia by:

Eli Lilly Australia Pty Limited

112 Wharf Road

West Ryde, NSW 2114

AUSTRALIA

®= Registered Trademark

If you have any questions about EMGALITY, contact Eli Lilly at 1800 454 559 (Australia) or your healthcare professional for assistance.

Australian Registration Numbers

EMGALITY 120 mg/mL prefilled pen – AUST R 302146

EMGALITY 120 mg/mL prefilled syringe – AUST R 302145

Further Information

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