Patient Leaflet in Accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a physician's prescription only

EMGALITY 120 MG

Solution for injection in a pre-filled pen

Active ingredient and its quantity:
Each pre-filled pen contains:
120 mg galcanezumab in 1 ml solution.

Inactive ingredients and allergens in the preparation: see chapter 2 section "Important information about some of the ingredients of this medicine" and chapter 6 "Additional Information".

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information regarding this medicine. If you have any further questions, contact your doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Emgality is indicated for the prophylaxis of migraine in adults who have at least 4 migraine days per month.

Therapeutic group: analgesics, calcitonin gene-related peptide (CGRP) antagonists.

Emgality contains an active substance called galcanezumab, a medicine that stops the activity of a naturally occurring substance in the body called calcitonin gene-related peptide (CGRP). People with migraine may have increased levels of CGRP. Emgality can reduce the frequency of migraine headache and improve your quality of life. It starts working in about a week.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- you are sensitive (allergic) to the active ingredient or any of the other ingredients of this medicine (listed in section 6).

Special warnings regarding the use of this medicine
Talk to your doctor, pharmacist or nurse before or during treatment with Emgality if:

- you have a serious cardiovascular disease. Emgality has not been studied in patients with serious cardiovascular diseases.

Look out for allergic reactions
Emgality can potentially cause serious allergic reactions. Serious allergic reactions happen mainly within 1 day after using Emgality, but some reactions can be delayed (happen more than 1 day to 4 weeks after having taken Emgality). Some allergic reactions can be prolonged in duration. You must look out for signs of these

reactions while you are using Emgality. Stop using Emgality and tell your doctor or seek medical help immediately if you notice any signs of a serious allergic reaction. Such signs are listed under “Serious side effects” in section 4.

Children and adolescents
This medicine should not be given to children and adolescents under 18 years of age because it has not been studied in this age group.

Drug interactions
Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including non-prescription medications and nutritional supplements.

Pregnancy, breastfeeding and fertility
If you are a woman of childbearing age, you are advised to avoid becoming pregnant while using Emgality.

If you are pregnant, think you may be pregnant or are planning to become pregnant, 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.

If you are breastfeeding or are planning to breastfeed, talk to your doctor before using this medicine.
You and your doctor should decide if you should use Emgality while breastfeeding.

Driving and using machines
Galcanezumab could have a minor effect on your ability to drive and use machines. Some patients have had vertigo (a feeling of dizziness or “spinning”) whilst using Emgality.

Important information about some of the ingredients of this medicine
This medicine contains less than 1 mmol sodium (23 mg) per 120 mg dose, that is to say it is essentially “sodium-free”.

3. HOW TO USE THIS MEDICINE?

Always use this medicine exactly as your doctor has told you. Check with your doctor, pharmacist or nurse if you are not sure about the dosage and manner of treatment with this medicine.
The dosage and manner of treatment will be determined by the doctor only. The usual dose is:
Emgality pre-filled pen is for single use only and contains one dose of Emgality (120 mg).

- The first time you receive Emgality your doctor or nurse will inject two pens (total 240 mg).
- After the first dose, you will use one pen (120 mg) every month.

Do not exceed the recommended dose.

Duration of treatment
Your doctor will decide for how long you should use Emgality.

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

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

The pen must not be shaken.

Read the “Instructions for Use” for the pen carefully before using Emgality.

If you accidentally take a higher dose
If you have injected more Emgality than you should, e.g. if after the first dose of 240 mg, you have injected it twice in a single month, or if anyone else has accidentally used Emgality, contact your doctor immediately.

If you forgot to take the medicine
Do not take a double dose to make up for a forgotten injection.

If you have forgotten to inject a dose of Emgality, inject the missed dose as soon as possible and then inject the next dose after a month from that date.

Treatment should be continued as recommended by the doctor.

If you stop taking the medicine
You should not stop using Emgality without speaking to your doctor first.

Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take a medicine. Wear glasses if you need them.

If you have any further questions on the use of this medicine, consult the doctor or pharmacist.

4. <u>SIDE EFFECTS</u>

As with any medicine, the use of Emgality may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

Serious side effects
Allergic reactions with Emgality are usually mild to moderate (such as rash or itching). Serious allergic reactions may occur rarely (may affect up to 1 in 1,000 users) and the signs may include:

- difficulty breathing or swallowing.
- low blood pressure, which can cause dizziness or light-headedness.
- Swelling of the neck, face, mouth, lips, tongue or throat which may develop rapidly.
- severe itching of the skin, with a red rash or raised bumps.

Tell your doctor or get emergency medical help straight away if you notice any of those signs.

Additional side effects that have been reported

Very common side effects (may affect more than 1 in 10 users):

- Injection site pain
- Injection site reactions (e.g. red skin, itching, bruising, swelling)

Common side effects (may affect up to 1 in 10 users):
- Vertigo (a feeling of dizziness or “spinning”)
- Constipation
- Itching
- Rash

Uncommon side effects (may affect up to 1 in 100 users):
- Hives (raised itchy areas of skin)

If a side effect occurs, if one of the side effects worsens or if you have a side effect not mentioned in the leaflet, consult your doctor.

Reporting of side effects
Side effects can be reported to the Ministry of Health by clicking on the link “Reporting Side Effects due to Drug Treatment” that can be found on the Home Page of the Ministry of Health’s website (www.health.gov.il), which refers to the online form for reporting side effects, or via the following link:
https://sideeffects.health.gov.il

5. HOW TO STORE THIS MEDICINE?

Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

Do not use this medicine after the expiry date (exp. date) which is stated on the label and on the carton. The expiry date refers to the last day of that month.

Storage conditions

Store in the refrigerator (2°C - 8°C). Do not freeze. Do not shake.

Store in the original package in order to protect from light.
Emgality 120 mg may be stored unrefrigerated for up to 7 days when stored at temperatures up to 30°C. Once the device has been stored at room temperature, do not return to the refrigerator and discard if unused within this 7-day period.
Do not use this medicine if you notice that the pen is damaged, or the medicine is cloudy or has particles in it.

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. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

In addition to the active ingredient, the medicine also contains:
Sodium chloride, L-histidine hydrochloride monohydrate, L-histidine, polysorbate 80 and water for injection.

What does the medicine look like and contents of the pack
Emgality is a solution for injection in a clear glass syringe. Its color may vary from colorless to slightly yellow or to slightly brown.

The syringe is encased in a disposable, single-dose pen. Pack sizes of 1, 2 pre-filled pens.

Not all pack sizes may be marketed.

Registration holder name and address: Eli Lilly Israel Ltd., 4 HaSheizaf Street, P.O.Box 4246, Ra'anana 4366411.

Manufacturer name and address: Eli Lilly & Company, Indianapolis, Indiana 46285, USA.

Revised in August 2022 according to MOHs guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 162-90-35852-00

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