



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Refusal of a change to the marketing authorisation for Emgality (galcanezumab)

The European Medicines Agency has recommended the refusal of a change to the marketing authorisation for Emgality. The change concerned an extension of indication to add prevention of attacks in adults who suffer from episodic cluster headache. For this use, Emgality was to be available as a pre-filled syringe containing 100 mg of the medicine.

The Agency issued this opinion on 27 February 2020.

The company that applied for the change to the authorisation, Eli Lilly Nederland B.V, may ask for re-examination of the opinion within 15 days of receiving the opinion.

What is Emgality and what is it used for?

Emgality is a medicine used to prevent migraine in adults who have migraines at least 4 days a month. It has been authorised in the EU since November 2018.

Emgality contains the active substance galcanezumab and is available for injection under the skin using a pre-filled syringe or pen containing 120 mg.

Further information on Emgality's uses can be found on the Agency's website:
ema.europa.eu/en/medicines/human/EPAR/emgality.

What change had the company applied for?

The company applied for an extension of indication of Emgality to add the prevention of attacks throughout a cluster period in adults with episodic cluster headache.

Cluster headaches cause severe pain typically on one side of the head and around an eye. The attacks occur during 'cluster periods' which can last weeks to months.

How does Emgality work?

A substance called CGRP is involved in the development of migraine. It widens blood vessels in the brain. The active substance of Emgality, galcanezumab, is a monoclonal antibody (a type of protein)



designed to attach to and block CGRP, thereby helping blood vessels to return to their normal size. This will stop the symptoms of migraine.

In episodic cluster headaches, the company considered that Emgality is expected to work in the same way as it does in its existing use.

What did the company present to support its application?

A main study involving 106 patients with episodic cluster headache compared Emgality with placebo (a dummy treatment). The main measure of effectiveness was a reduction, over a 3-week period, in the frequency of headache attacks each week.

What were the main reasons for refusing the change to the marketing authorisation?

The results from the single study in patients with episodic cluster headache did not show clearly that Emgality is effective for preventing attacks. Therefore, the Agency's opinion was that the benefits of Emgality in the prevention of attacks in patients with episodic cluster headache did not outweigh its risks. Hence, the Agency recommended refusing the change to the marketing authorisation.

Does this refusal affect patients in clinical trials?

The company informed the Agency that patients with cluster headache who are receiving Emgality in clinical trials can continue their treatment until the next visit when the clinical trial doctor will discuss the treatment plan with the patient.

If you are in a clinical trial and need more information about your treatment, speak with your clinical trial doctor.

What is happening with Emgality for in other uses?

There are no consequences for Emgality for the prevention of migraine in adults.