EMA/658658/2018
EMEA/H/C/004648

Emgality (*galcanezumab*)

An overview of Emgality and why it is authorised in the EU

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 contains the active substance galcanezumab.

How is Emgality used?

Emgality is injected under the skin using a pre-filled syringe or pen. Patients can inject the medicine themselves after being trained.

Treatment should be started with the injection of the content of 2 syringes (or pens), followed a month later by single injections given every month. Doctors should review treatment after 3 months and only continue it if patients benefit from it.

Emgality can only be obtained with a prescription and treatment should be started by a doctor experienced in the treatment of migraine. For more information about using Emgality, see the package leaflet or contact your doctor or pharmacist.

How does Emgality work?

A substance called CGRP has been shown to be involved in the development of migraine by widening 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.

What benefits of Emgality have been shown in studies?

Emgality was shown to be effective at reducing the number of days patients suffer migraines in 3 main studies. Overall, Emgality led to 2 fewer days with migraines per month compared with placebo (a dummy treatment).

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In two studies involving 1,784 patients who had migraines between 4 and 14 days a month, those treated with Emgality had 4 or 5 fewer days with migraines per month, compared with 2 to 3 fewer days for patients on a placebo injection.

In a third study of 1,117 patients who had migraines for more than 15 days a month on average (chronic migraine), those treated with Emgality had on average around 5 fewer days with migraines per month compared with around 3 fewer days for patients on placebo.

What are the risks associated with Emgality?

The most common side effects with Emgality (which may affect more than 1 in 10 people) are reactions at the site of injection such as pain, redness, itching, bruising or swelling.

For the full list of side effects and restrictions of Emgality, see the package leaflet.

Why is Emgality authorised in the EU?

Emgality was shown to be more effective than placebo at reducing the number of days of migraine, although the size of the effect is limited particularly for patients with chronic migraine.

The side effects seen with Emgality are considered manageable with most being mild or moderate in severity.

The European Medicines Agency therefore decided that Emgality's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Emgality?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Emgality have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Emgality are continuously monitored. Side effects reported with Emgality are carefully evaluated and any necessary action taken to protect patients.

Other information about Emgality

Emgality received a marketing authorisation valid throughout the EU on 14 November 2018.

Further information on Emgality can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports.

This overview was last updated in 12-2018.