EMA/107467/2019
EMEA/H/C/004833

# Ajovy (*fremanezumab*)

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

## What is Ajovy and what is it used for?

Ajovy is a medicine used to prevent migraine in adults who have migraines at least 4 days a month. The active substance contained in Ajovy is fremanezumab.

## How is Ajovy used?

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

The recommended dose is either 225 mg every month or 675 mg every three months. For the 675 mg dose, three injections of 225 mg have to be injected one after another, each in a different place.

Ajovy can only be obtained with a prescription and treatment should be started by a doctor experienced in the diagnosis and treatment of migraine.

For more information about using Ajovy, see the package leaflet or contact your doctor or pharmacist.

## How does Ajovy work?

A chemical messenger called CGRP contributes to the development of migraine. Ajovy is a monoclonal antibody (a type of protein) designed to attach to CGRP and prevent it from binding to its target on the body's cells thereby helping to prevent migraines from occurring.

## What benefits of Ajovy have been shown in studies?

Ajovy was shown to reduce the number of days patients have moderate to severe headaches and migraines in 2 main studies.

In a study of 1,130 patients who had moderate to severe headaches 13 days a month on average, those treated with Ajovy had between 4 and 5 fewer days with moderate to severe headaches per month compared with 2 to 3 fewer days for patients on placebo (a dummy treatment), during the 12 week-study.

**Official address** Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
**Address for visits and deliveries** Refer to www.ema.europa.eu/how-to-find-us
**Send us a question** Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

In a study with 875 patients who had migraines 9 days a month on average, those treated with Ajovy had between 3 and 4 fewer days with migraines per month compared with around 2 fewer days for patients on placebo, during the 12 week-study.

## What are the risks associated with Ajovy?

The most common side effects with Ajovy (which may affect more than 1 in 10 people) are reactions at the site of injection: pain, hardening (induration) and reddening of the skin (erythema).

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

## Why is Ajovy authorised in the EU?

Ajovy can reduce the number of days patients have moderate to severe headaches and migraines. As most of the side effects are manageable and mild or moderate in severity, the European Medicines Agency decided that Ajovy'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 Ajovy?

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

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

## Other information about Ajovy

Ajovy received a marketing authorisation valid throughout the EU on 28/03/2019.

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

This overview was last updated in 02-2019.