

EMA/231460/2022  
EMA/H/C/005725

## Vydura (*rimegepant*)

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

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

Vydura is a medicine used to treat migraine with or without aura (unusual visual or other sensory experiences) in adults. It is also used to prevent migraine in adults who have at least 4 migraines attacks a month.

Vydura contains the active substance rimegepant.

### How is Vydura used?

Vydura is available as a freeze-dried wafer to be placed on or under the tongue, where it will dissolve.

Vydura is taken once a day for the treatment of migraine, and once every other day for prevention of migraine.

The medicine can only be obtained with a prescription.

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

### How does Vydura work?

A chemical messenger called calcitonin gene-related peptide (CGRP) contributes to the development of migraine. The active substance in Vydura, rimegepant, attaches to the receptor (target) for CGRP. By attaching to this receptor, the medicine prevents CGRP from binding to it. This helps treat migraine and also prevents migraines from occurring.

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

Vydura was shown to be more effective than placebo (a dummy treatment) at treating migraine in three main studies involving a total of around 3,500 adults. Patients with a migraine attack causing moderate to severe headache recorded the level of pain two hours after treatment using a 4-point Likert scale (0 = no pain, 1 = mild pain, 2 = moderate pain, 3 = severe pain).

On average across the three studies, 20% of patients taking Vydura were headache pain-free after two hours, compared with 12% on average for those taking placebo. Vydura was also effective at treating



other migraine symptoms such as photophobia (abnormal sensitivity of the eyes to light), phonophobia (abnormal sensitivity to sounds) or nausea (feeling sick): on average, around 36% of patients taking Vydura were free from one of the above symptoms two hours after treatment, compared with around 27% of those taking placebo.

Another study showed that Vydura is effective at reducing the number of days patients suffer from migraines. The study involved 747 adults who had between 4 to 18 migraine attacks a month; patients took Vydura or placebo every other day for up to 12 weeks. Those treated with Vydura had on average 4.3 fewer days with migraines during the last 4 weeks of the study, compared with 3.5 fewer days for patients on placebo.

## **What are the risks associated with Vydura?**

The most common side effect with Vydura (which may affect up to 1 in 10 people) is nausea. Hypersensitivity (allergic reaction) including dyspnoea (difficulty breathing) and severe rash may affect up to 1 in 100 people.

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

## **Why is Vydura authorised in the EU?**

Vydura was shown to be more effective than placebo at reducing headaches and other migraine symptoms and at reducing the number of days patients experienced migraine, although the size of the effect is considered modest. The safety profile of Vydura is considered favourable.

The European Medicines Agency therefore decided that Vydura'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 Vydura?**

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

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

## **Other information about Vydura**

Vydura received a marketing authorisation valid throughout the EU on 25 April 2022.

Further information on Vydura can be found on the Agency's website:

[ema.europa.eu/medicines/human/EPAR/vydura](https://ema.europa.eu/medicines/human/EPAR/vydura)

This overview was last updated in 04-2022.