EMA/621260/2022
EMEA/H/C/005332

Rayvow (*lasmiditan*)

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

What is Rayvow and what is it used for?

Rayvow is a medicine used to treat migraine with or without aura (unusual visual or other sensory experiences) in adults.

Rayvow contains the active substance lasmiditan.

How is Rayvow used?

Rayvow is available as a tablet and is taken by mouth. The recommended starting dose is 100 mg. The dose may be adjusted depending on the patient's response to treatment.

If the migraine resolves after a first dose of 50 mg or 100 mg and then comes back within 24 hours, a second dose of the same strength may be taken at least two hours after the first dose. No more than 200 mg should be taken in any 24-hour period.

If the migraine does not resolve after the first dose, a second dose for the same attack is unlikely to be effective.

The medicine can only be obtained with a prescription.

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

How does Rayvow work?

Migraine symptoms can be reduced through the action of a chemical messenger called serotonin (5-hydroxytriptamine, 5-HT) at specific receptors (target sites) in the brain, including the 5-HT1F receptor. The active substance in Rayvow, lasmiditan, is a 5-HT1F receptor agonist, meaning that it activates one such serotonin receptor. The exact way in which the medicine works is not fully understood, but by binding to these receptors, lasmiditan is thought to both lower the amount of other chemical messengers in the brain known to play role in migraine and suppress pain pathways.

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

What benefits of Rayvow have been shown in studies?

Three main studies involving a total of around 7,000 adults showed that Rayvow is more effective than placebo (a dummy treatment) at treating migraine. Patients with a migraine attack causing moderate to severe headache recorded the level of pain 2 hours after treatment using a 4-point scale.

In the first study, 28% (142 out of 503) of patients who took 100 mg Rayvow and 32% (167 out of 518) of those who took 200 mg reported no pain 2 hours after treatment, compared with 15% of those who took placebo (80 out of 524).

In the second study, 31% of patients who took 100 mg (167 out of 532) and 39% of those who took 200 mg (205 out of 528) reported no pain after 2 hours, compared with 21% of those who took placebo (115 out of 540). Another group of patients received 50 mg Rayvow, and the medicine was effective in 29% of these patients (159 out of 556).

In the last study, 26% of patients who took 100 mg Rayvow (108 out of 419) and 29% of those who took 200 mg (127 out of 434) reported no pain after 2 hours, compared with 8%, of those who took placebo (37 out of 443). This study also showed that Rayvow remained effective across multiple attacks. Of patients taking 100 mg or 200 mg Rayvow, 14% (49 out of 340) and 24% (82 out of 336), respectively, reported no pain after two hours in at least two out of three attacks, compared with 4% of those treated with placebo (16 out of 373).

What are the risks associated with Rayvow?

The most common side effect with Rayvow (which may affect more than 1 in 10 people) is dizziness. Other side effects (which may affect up to 1 in 10 people) are somnolence (sleepiness), tiredness, paraesthesia (abnormal sensations like pins and needles), nausea, vertigo (feeling dizzy), hypoaesthesia (reduced sense of touch) and muscle weakness.

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

Why is Rayvow authorised in the EU?

Three main studies have shown that Rayvow is effective at treating headache in patients suffering from migraines. The side effects are considered manageable. The European Medicines Agency therefore decided that Rayvow'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 Rayvow?

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

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

Other information about Rayvow

Rayvow received a marketing authorisation valid throughout the EU on 17 August 2022.

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

This overview was last updated in 08-2022.