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Vyepti (*eptinezumab*)

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

What is Vyepti and what is it used for?

Vyepti is a medicine used to prevent migraine in adults who have migraines at least 4 days a month.

Vyepti contains the active substance eptinezumab.

How is Vyepti used?

The medicine can only be obtained with a prescription. Treatment should be started and monitored by healthcare professionals experienced in the diagnosis and treatment of migraine.

Vyepti is given by infusion (drip) into a vein over 30 minutes once every 12 weeks. The recommended dose is 100 mg. This dose may be increased to 300 mg, depending on how the patient responds.

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

How does Vyepti work?

A substance in the body called calcitonin gene-related peptide (CGRP) contributes to the development of migraine. The active substance in Vyepti, eptinezumab, 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 Vyepti have been shown in studies?

Two main studies showed that Vyepti is effective at reducing the number of days patients suffer from migraines.

The first was a 48-week study involving 898 adults who had at least 4 migraine days a month and between 4 to 14 headache days a month. Those treated with 100 mg or 300 mg Vyepti had around 4 fewer days with migraines per month during the first 12 weeks of treatment, compared with 3 fewer days for patients on placebo (dummy treatment).

The second was a 24-week study involving 1,121 adults who had migraines for at least 8 days a month and between 15 and 26 headache days a month. Those treated with 100 mg or 300 mg Vyepti had on

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average 8 fewer days with migraines per month during the first 12 weeks of treatment compared with around 6 fewer days for patients on placebo.

What are the risks associated with Vyepti?

The most common side effects with Vyepti (which may affect up to 1 in 10 people) are nasopharyngitis (inflammation of the nose and throat), hypersensitivity (allergic) reactions and tiredness.

For the full list of side effects of Vyepti, see the package leaflet.

Why is Vyepti authorised in the EU?

The European Medicines Agency decided that Vyepti's benefits are greater than its risks and it can be authorised for use in the EU. Two main studies have shown that Vyepti is effective at reducing the number of days patients suffer from migraines. The side effects are considered manageable.

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

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

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

Other information about Vyepti

Vyepti received a marketing authorisation valid throughout the EU on 24 January 2022.

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

This overview was last updated in 12-2021.