swissmedic

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Vyepti® (active substance: eptinezumab)

Authorisation in Switzerland: 11.10.2021

Medicinal product (infusion) for preventive treatment of migraines

About the medicinal product

Vyepti is a medicinal product which is used for the preventive treatment of migraines and contains the active substance eptinezumab. It is administered as an infusion into a vein.

Vyepti is used in adults to reduce migraine attacks. Treatment with Vyepti is initiated and monitored by a doctor experienced in migraine treatment.

Mode of action

Migraines are a headache disorder with repeated, severe headaches and other symptoms that occur as sudden attacks. Women are far more frequently affected by this disorder than men. Depending on the frequency of attacks, migraines are classified as episodic (up to 14 days of headaches per month) or chronic (15 or more days of headaches per month). There are medications for acute treatment and for prevention (prophylaxis) of migraines.

Vyepti reduces the number of attacks or days of migraines and is therefore a preventive treatment. The exact mechanism of action is unknown. However, there is growing evidence that specific proteins known as calcitonin gene-related peptides (CGRPs) play an important role in migraine attacks. The active substance eptinezumab is a monoclonal antibody (immunologically active protein) and blocks the action of these CGRPs in the body.

Use

Vyepti is a prescription-only medicine. 100 mg of the active substance eptinezumab are administered per infusion. If necessary, the dose can also be increased to 300 mg eptinezumab per infusion.

Infusions are given every 12 weeks. The treatment is prescribed and monitored by a doctor experienced in migraine treatment.

Efficacy

The efficacy of Vyepti has been demonstrated in two studies in migraine patients. Both studies assessed the two doses of eptinezumab (100 mg and 300 mg) against placebo (dummy drug).

Study 006 was performed in patients with episodic migraines and study 011 in patients with chronic migraines.

Vyepti at both doses (100 mg and 300 mg) reduced the number of monthly migraine days in both studies. Study 006 (episodic migraines): decrease of 3.9 and 4.3 days versus 3.2 days in the placebo group; study 011 (chronic migraines): decrease of 7.7 and 8.2 days versus 5.6 days in the placebo group.

Precautions, undesirable effects & risks

Vyepti must not be used in those who are hypersensitive to the active substance or any of the excipients.

Like all medicines, Vyepti can produce side effects, although not necessarily in everyone.

Frequent side effects (affecting more than 1 in 100 but fewer than 1 in 10 users) include nasopharyngitis (combined inflammation of the nose and throat) as well as hypersensitivity reactions, which mostly occur during the infusion.

All precautions, risks and other possible undesirable effects are listed in the Information for healthcare professionals.

Why the medicinal product has been authorised

The frequency of migraine days in both episodic and chronic migraine was reduced through intravenous administration of Vyepti.

Based on all the available data, the benefits of Vyepti outweigh the risks. The medicinal product Vyepti with the active substance eptinezumab has been authorised in Switzerland for the treatment of adult patients with episodic or chronic migraines.

Further information on the medicinal product

At the time of publication of the Public Summary SwissPAR for Vyepti, the Information for healthcare professionals and the Patient information (package leaflet) were not yet available. As soon as the medicine becomes available in Switzerland, the Information for healthcare professionals and the Patient information will be made available on the following website: www.swissmedicinfo.ch
Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

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