EMA/475404/2018
EMEA/H/C/004454

Veyvondi (*vonicog alfa*)

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

What is Veyvondi and what is it used for?

Veyvondi is a medicine used to control bleeding in patients with von Willebrand disease (an inherited bleeding disorder), who cannot be treated with another medicine called desmopressin or when desmopressin is ineffective.

It is used 'on demand' to treat bleeding episodes and is also used to prevent and treat bleeding during surgery.

Veyvondi contains the active substance vonicog alfa.

How is Veyvondi used?

Veyvondi can only be obtained with a prescription and treatment should be supervised by a doctor experienced in treating patients with bleeding disorders.

Veyvondi is available as a powder and solvent that are mixed together to make a solution for injection into a vein. The dose and frequency of treatment depend on the type and seriousness of the bleeding episode or extent of the surgery, and the patient's condition and body weight.

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

How does Veyvondi work?

Patients with von Willebrand disease lack von Willebrand factor, a protein needed for normal clotting of the blood, and as a result, they bleed readily. The active substance in Veyvondi, vonicog alfa, works in the body in the same way as natural von Willebrand factor. It replaces the missing protein, thereby helping the blood to clot and giving temporary control of the bleeding disorder.

What benefits of Veyvondi have been shown in studies?

The benefits of Veyvondi in controlling bleeding have been shown in two main studies involving 52 patients with von Willebrand disease.

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The first study involved 37 patients who were given Veyvondi for the treatment of bleeding episodes. The main measure of effectiveness was based on an assessment of how well the treatment worked. Treatment with Veyvondi was successful in 95% of patients (20 out of 22). A total of 193 bleeding episodes were recorded, and Veyvondi was rated 'excellent' or 'good' at treating around 98% of bleedings.

The second study involved 15 patients who were given Veyvondi to prevent bleeding during surgery, including major surgery such as knee replacement. In the 15 major and minor surgeries that occurred during the study, Veyvondi was rated as excellent or good at preventing bleeding episodes for all 15 surgeries.

What are the risks associated with Veyvondi?

The following side effects may occur during treatment with Veyvondi: hypersensitivity (allergic) reactions, thromboembolic events (problems due to the formation of blood clots in the blood vessels), development of inhibitors (antibodies) against von Willebrand factor, causing the medicine to stop working and resulting in a loss of bleeding control. The most common side effects with Veyvondi (which may affect up to 1 in 10 patients) are dizziness, vertigo (a spinning sensation), dysgeusia (taste disturbances), tremor, rapid heartbeat, deep venous thrombosis (blood clot in a deep vein, usually in the leg), hypertension (high blood pressure), hot flush, vomiting, nausea (feeling sick), pruritus (itching), chest discomfort, sensations like numbness, tingling, pins and needles at the site of infusion, and an abnormal reading on the electrocardiogram (ECG).

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

Veyvondi must not be used in patients who have had allergic reactions to mouse or hamster proteins.

Why is Veyvondi authorised in the EU?

The European Medicines Agency decided that Veyvondi's benefits are greater than its risks and it can be authorised for use in the EU. Veyvondi was shown to be effective in treating bleeding episodes in patients with von Willebrand disease. Veyvondi was also effective for preventing and treating bleeding related to surgery. However EMA decided that, as for similar medicines, Veyvondi should be used only when desmopressin (the main treatment for von Willebrand disease) cannot be used or is not working well enough.

The side effects with Veyvondi were considered typical for this type of medicine.

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

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

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

Other information about Veyvondi

Veyvondi received a marketing authorisation valid throughout the EU on 31 August 2018.

Further information on Veyvondi can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports.

This overview was last updated in 08-2018.