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Jivi (*damoctocog alfa pegol*)

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

What is Jivi and what is it used for?

Jivi is a medicine used to treat and prevent bleeding in patients with haemophilia A, an inherited bleeding disorder caused by lack of a clotting protein called factor VIII. Jivi can be used in adults and children from 7 years of age who have been treated previously.

Jivi contains the active substance damoctocog alfa pegol.

How is Jivi used?

Jivi can only be obtained with a prescription, and treatment should be under the supervision of a doctor who has experience in the treatment of haemophilia.

Jivi is given by injection into a vein. The dose and frequency of treatment depend on whether it is used to treat or prevent bleeding, as well as on the severity of the haemophilia, the extent and location of the bleeding and the patient's condition and weight. Patients or their carers may be able to inject Jivi themselves at home once they have been trained appropriately.

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

How does Jivi work?

Patients with haemophilia A lack factor VIII, a protein needed for blood to clot and, as a result, they bleed readily. The active substance in Jivi, damoctocog alfa pegol, is a man-made version of factor VIII and works in the same way as the body's factor VIII. It replaces the missing factor VIII, thereby helping the blood to clot and giving temporary control of the bleeding disorder.

In Jivi, the factor VIII is attached to a substance called polyethylene glycol (PEG), which helps the medicine remain in the body for longer, thereby prolonging its action and allowing it to be given less often.

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What benefits of Jivi have been shown in studies?

Jivi has been shown to be effective at reducing the number of bleeding episodes in patients with severe haemophilia A and stopping bleeding when it occurs. Jivi was not compared with another treatment or placebo (a dummy treatment) in these studies.In a study involving 134 patients from 12 years of age, 114 patients given Jivi as a preventive treatment had around 2 bleeding episodes per year. The 20 patients who were given Jivi for treating bleeding when it occurred had around 23 bleeding episodes a year. In a second part of the study, 17 patients received Jivi to control bleeding during 20 major surgeries. Jivi was rated good or excellent at stopping bleeding in all surgeries.

In a second study involving 61 children aged below 12 years, Jivi given as preventive treatment reduced the number of bleeding episodes to around 3 episodes a year.

In a third study involving 35 previously treated children aged 7 to 11 years, 32 children given Jivi as a preventive treatment had an average of 1 bleeding episode per year. Jivi was rated good or excellent at stopping bleeding in 71% of cases.

What are the risks associated with Jivi?

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

The most common side effect with Jivi (which may affect more than 1 in 10 people) is headache. Hypersensitivity (allergic) reactions are common with Jivi (affecting up to 1 in 10 people) and may include swelling, burning and stinging at the injection site, chills, flushing, tingling, itchy rash, headache, hives, low blood pressure, lethargy, nausea and vomiting, restlessness, a rapid heartbeat, tightness of the chest and wheezing. In some cases, these reactions can become severe.

Following treatment with factor VIII products, including Jivi, some patients may develop inhibitors (antibodies) against factor VIII, preventing the medicine from working effectively and resulting in a loss of bleeding control. In such cases, a specialised haemophilia centre should be contacted.

Jivi must not be used in patients with allergy to mouse or hamster proteins.

Why is Jivi authorised in the EU?

The European Medicines Agency decided that Jivi's benefits are greater than its risks and it can be authorised for use in the EU.

Studies show that Jivi is effective at preventing and treating bleeding episodes in patients with haemophilia A and its safety is comparable to that of other factor VIII products.

At the time of authorisation, laboratory studies showed that PEG, which is part of the active substance in Jivi, may accumulate in the body, including in a structure in the brain called choroid plexus, following long-term treatment. Since this could potentially cause problems especially in children below 12 years of age, Jivi was initially only approved for use in adults and children from 12 years of age. The company has since provided data showing that the safety profile in patients aged 7 to 11 years is comparable to that in patients aged 12 years and older.

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

The company that markets Jivi is conducting a study to investigate the potential effects of PEG accumulation in the choroid plexus of the brain and other organs.

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

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

Other information about Jivi

Jivi received a marketing authorisation valid throughout the EU on 22 November 2018.

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

This overview was last updated in 06-2025.