



EUROPEAN MEDICINES AGENCY
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EPAR summary for the public

Idelvion

albutrepenonacog alfa

This is a summary of the European public assessment report (EPAR) for Idelvion. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Idelvion.

For practical information about using Idelvion, patients should read the package leaflet or contact their doctor or pharmacist.

What is Idelvion and what is it used for?

Idelvion is a medicine used to prevent and treat bleeding in patients with haemophilia B, an inherited bleeding disorder caused by lack of a clotting protein called factor IX. It can be used in patients of all ages.

Because the number of patients with haemophilia B is low, the disease is considered 'rare', and Idelvion was designated an 'orphan medicine' (a medicine used in rare diseases) on 4 February 2010.

Idelvion contains the active substance albutrepenonacog alfa.

How is Idelvion used?

Idelvion can only be obtained with a prescription, and treatment should be supervised by a doctor with experience in treating haemophilia.

Idelvion is available as powder and solvent that are mixed together to make a solution for injection into a vein. The dose and the frequency of the injections depend on the patient's bodyweight and whether Idelvion is used to treat or prevent bleeding, as well as the severity of the patient's factor IX deficiency, the extent and location of the bleeding and the patient's age and health. For further information on how to use this medicine, see the summary of product characteristics (also part of the EPAR).



How does Idelvion work?

Patients with haemophilia B lack factor IX, a protein needed for normal clotting of the blood, and as a result, they bleed readily. The active substance in Idelvion, albutrepenonacog alfa, works in the body in the same way as human factor IX. It replaces the missing factor IX, thereby helping the blood to clot and giving temporary control of bleeding.

What benefits of Idelvion have been shown in studies?

In a study in 80 adults and adolescents and another study in 27 children aged less than 12 years, Idelvion was effective at preventing bleeding, with most patients experiencing no bleeding while on preventive treatment. Furthermore, Idelvion was effective in treating bleeding episodes when they did occur; around 93% of the bleeding episodes resolved with one Idelvion injection.

What are the risks associated with Idelvion?

Hypersensitivity (allergic) reactions can occur rarely with Idelvion and include: swelling, burning and stinging at the injection site, chills, flushing, itchy rash, headache, hives, low blood pressure, lethargy, nausea and vomiting, restlessness, a fast heartbeat, tightness of the chest and wheezing. In some cases these reactions can become severe.

Some patients taking factor IX medicines may develop inhibitors (antibodies) against factor IX, causing the medicine to stop working and resulting in a loss of bleeding control. Factor IX medicines can also potentially cause problems due to the formation of blood clots in the blood vessels. For the full list of side effects reported with Idelvion, see the package leaflet.

Idelvion must not be used in patients who are hypersensitive (allergic) to the active substance or other ingredients of the medicine. It must also not be used in patients allergic to hamster proteins.

Why is Idelvion approved?

Studies show that Idelvion is effective at preventing and treating bleeding episodes in patients with haemophilia B, and its safety is comparable to that of other factor IX products. The Agency's Committee for Medicinal Products for Human Use (CHMP) therefore decided that Idelvion's benefits are greater than its risks and recommended that it be approved for use in the EU.

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

A risk management plan has been developed to ensure that Idelvion is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Idelvion, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Idelvion

The European Commission granted a marketing authorisation valid throughout the European Union for Idelvion on 11 May 2016.

The full EPAR for Idelvion can be found on the Agency's website: ema.europa.eu/Find_medicine/Human_medicines/European_public_assessment_reports. For more information about treatment with Idelvion, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The summary of the opinion of the Committee for Orphan Medicinal Products for Idelvion can be found on the Agency's website: [ema.europa.eu/Find medicine/Human medicines/Rare disease designation](http://ema.europa.eu/Find%20medicine/Human%20medicines/Rare%20disease%20designation).

This summary was last updated in 05-2016.