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EPAR summary for the public

Iblias

octocog alfa

This is a summary of the European public assessment report (EPAR) for Iblias. 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 Iblias.

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

What is Iblias and what is it used for?

Iblias is a medicine used for the treatment and prevention of bleeding in patients with haemophilia A (an inherited bleeding disorder caused by lack of a clotting protein called factor VIII). It contains the active substance octocog alfa, which is the same as human factor VIII.

How is Iblias used?

Iblias is available as a powder and solvent used to make a solution for injection. The injection is given into a vein over several minutes. The dose and frequency of the injections depend on whether Iblias is used to treat or prevent bleeding, the severity of the patient's factor VIII deficiency, the extent and location of the bleeding and the patient's condition and bodyweight.

Iblias 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. For further information, see the summary of product characteristics (also part of the EPAR).

How does Iblias work?

Patients with haemophilia A lack factor VIII, a protein needed for normal clotting of the blood, and as a result, they bleed readily and may have problems such as bleeding into the joints, muscles and

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internal organs. The active substance in Iblias, octocog alfa, works in the body in the same way as human factor VIII. It replaces the missing factor VIII, thereby helping the blood to clot and giving temporary control of bleeding.

What benefits of Iblias have been shown in studies?

The effectiveness of Iblias in preventing and treating bleeding has been shown in a main study involving 62 patients aged 12 years or older with severe haemophilia A who were previously treated with other factor VIII products. The number of bleeds that occurred during Iblias treatment was calculated as 3.8 bleeds per year on average (mostly into joints). This compared with an average of 6.9 bleeds per year before Iblias treatment. Comparable results were seen in patients who continued to take the medicine after completion of the initial study.

About 70% of the bleeding events that occurred were managed with a single injection of Iblias, and about another 15% responded to a second injection; the response was considered good or excellent in around 80% of cases. In 12 patients who required major surgery during the study, control of blood loss was also rated as good or excellent by the patients' doctors.

A second study involved 51 children under 12 years of age previously treated with other factor VIII products, who also had 3.8 bleeds per year on average during treatment with Iblias (mostly related to injuries). Response to treatment was considered good or excellent in about 90% of cases.

Data from a supportive study also confirmed the benefits of preventative treatment with Iblias in reducing the number of bleeds.

What are the risks associated with Iblias?

Hypersensitivity (allergic) reactions are uncommon with Iblias, affecting from 1 patient in 1,000 to less than 1 patient in 100. If they occur they may include: angioedema (swelling of tissues under the skin), burning and stinging at the injection site, chills, flushing, itchy rash over the whole body, headache, hives, hypotension (low blood pressure), lethargy, nausea (feeling sick), restlessness, tachycardia (rapid heartbeat), tightness of the chest, tingling, vomiting and wheezing. In some cases these reactions can become severe.

Patients may develop antibodies to hamster or mouse proteins; the medicine must not be used in patients who are hypersensitive (allergic) to octocog alfa or to hamster or mouse proteins. There is also a risk with factor VIII medicines that some patients will develop inhibitors (antibodies) against factor VIII, causing the medicine to stop working and resulting in a loss of bleeding control.

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

Why is Iblias approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Iblias's benefits are greater than its risks and recommended that it be approved for use in the EU. Iblias has been shown to be effective in both preventing and treating bleeds, including managing blood loss during surgery, and can be used in all age groups. Regarding safety, the reported effects are in line with those expected for a factor VIII product. Further evidence of effectiveness and safety in patients previously untreated with factor VIII medicines, and further data on long-term use in children should be provided by ongoing studies.

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

A risk management plan has been developed to ensure that Iblias 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 Iblias, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

In addition, the company that markets Iblias will complete studies to investigate the safety and efficacy of the medicine in patients who have not previously been treated with other factor VIII products, and to provide further evidence of the safety and efficacy of long-term treatment with Iblias in children.

Other information about Iblias

The European Commission granted a marketing authorisation valid throughout the European Union for Iblias on 18 February 2016.

The full EPAR and risk management plan summary for Iblias 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 Iblias, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 02-2016.