EMA/851078/2018
EMEA/H/C/004459

Vihuma (*simoctocog alfa*)

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

What is Vihuma and what is it used for?

Vihuma is a medicine used for the treatment and prevention of bleeding in patients of all ages with haemophilia A (an inherited bleeding disorder caused by lack of factor VIII). It contains the active substance simoctocog alfa (human coagulation factor VIII).

This medicine is the same as Nuwiq, which is already authorised in the EU. The company that makes Nuwiq has agreed that its scientific data can be used for Vihuma ('informed consent').

How is Vihuma used?

Vihuma can only be obtained with a prescription, and treatment should be supervised by a doctor experienced in the treatment of haemophilia.

Vihuma is available as a powder and solvent to mix together to make a solution that is injected into a vein. The dose and duration of treatment depend on whether Vihuma is used to treat or prevent bleeding, or during surgery, as well as on the patient's factor VIII levels, the seriousness of the haemophilia, the extent and location of the bleeding and the patient's condition and weight. Vihuma can be used for short-term or long-term treatment.

Patients or their carers may be able to inject Vihuma themselves at home once they have been trained.

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

How does Vihuma work?

The active substance in Vihuma, simoctocog alfa (human coagulation factor VIII), is a substance that helps the blood to clot. Patients with haemophilia A lack factor VIII, and this causes blood clotting problems leading to events such as bleeding in the joints, muscles or internal organs. Vihuma corrects the factor VIII deficiency by replacing the missing factor VIII, giving temporary control of the bleeding disorder.

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What benefits of Vihuma have been shown in studies?

Vihuma was effective at preventing and treating bleeding episodes in three main studies involving 113 patients with haemophilia A.

The first study involved 22 patients aged 12 years and above, who were given Vihuma for the treatment of bleeding episodes or to prevent bleeding during surgery. A total of 986 bleeding episodes were recorded, most of which resolved with one injection of Vihuma. The main measure of effectiveness was based on patients' assessment of how well treatment worked. Treatment with Vihuma was rated 'excellent' or 'good' for 94% of bleeding episodes. In the 2 surgeries during the study, Vihuma was rated excellent in preventing bleeding episodes.

The second study involved 32 patients aged 12 years and above who were given Vihuma to prevent and treat bleeding events as well as to prevent bleeding during surgery. When used to prevent bleeding, an average of 0.19 bleeding episode per month was recorded for each patient. When used for treating bleeding episodes, Vihuma was mainly rated 'excellent' or 'good' at treating major bleeding episodes and most bleeding episodes resolved following one or more injections of Vihuma. In the 5 surgeries during the study, Vihuma was rated excellent in preventing bleeding episodes for 4 surgeries and as moderate to prevent bleeding during one surgical intervention.

The third study involved 59 children aged 2 to 12 years. When Vihuma was used to prevent bleeding, an average of 0.34 bleeding episode per month was recorded for each child. When Vihuma was used for treatment, bleeding episodes resolved in 81% of cases following 1 or 2 injections.

What are the risks associated with Vihuma?

Hypersensitivity (allergic) reactions have been reported with factor VIII medicines and they may be severe in some cases.

Some patients treated with factor VIII medicines may develop inhibitors (antibodies) against factor VIII, which may stop the medicine from working and controlling bleeding.

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

Why is Vihuma authorised in the EU?

The European Medicines Agency decided that Vihuma's benefits are greater than its risks and it can be authorised for use in the EU. The Agency concluded that Vihuma was effective at treating and preventing bleeding in patients with haemophilia A and it has an acceptable safety profile.

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

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

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

Other information about Vihuma

Vihuma received a marketing authorisation valid throughout the EU on 13 February 2017.

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

This overview was last updated in 12-2018.