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EPAR summary for the public

Nuwiq

simoctocog alfa

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

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

What is Nuwiq and what is it used for?

Nuwiq 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).

How is Nuwiq used?

Nuwiq can only be obtained with a prescription and treatment should be started under the supervision of a doctor experienced in the treatment of haemophilia.

Nuwiq is available as a powder and solvent that are mixed together to make a solution for injection into a vein. The dose and duration of treatment depend on whether Nuwiq 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 bodyweight. Nuwiq is intended for either short-term or long-term use.

Patients or their carers may be able to administer Nuwiq themselves at home once they have been trained appropriately. For full details, see the package leaflet.

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How does Nuwiq work?

The active substance in Nuwiq, 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, such as bleeding in the joints, muscles or internal organs. Nuwiq is used to correct the factor VIII deficiency by replacing the missing factor VIII, giving temporary control of the bleeding disorder.

Simoctocog alfa is made by a method known as 'recombinant DNA technology': it is made by cells into which a gene (DNA) has been introduced that makes them able to produce it.

What benefits of Nuwiq have been shown in studies?

Nuwiq has been shown to be 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 Nuwiq for the treatment of bleeding episodes or to prevent bleeding during surgery. A total of 986 bleeding episodes were recorded, the majority of which resolved with one injection of Nuwiq. The main measure of effectiveness was based on patients' assessment of how well treatment worked. Treatment with Nuwiq was rated as 'excellent' or 'good' for 94% of bleeding episodes. In the two surgeries that occurred during the study, Nuwiq was rated as excellent in preventing bleeding episodes.

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

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

What are the risks associated with Nuwiq?

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

There is 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. In such cases, a specialised haemophilia centre should be contacted.

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

Why is Nuwiq approved?

The Agency decided that Nuwiq's benefits are greater than its risks and recommended that it be approved for use in the EU. The Agency concluded that Nuwiq has been shown to be effective at treating and preventing bleeding in patients with haemophilia A and has an acceptable safety profile.

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

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

Other information about Nuwiq

The European Commission granted a marketing authorisation valid throughout the European Union for Nuwiq on 24 July 2014.

The full EPAR for Nuwiq 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 Nuwiq, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 10-2017.