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EPAR summary for the public

Voncento

human coagulation factor VIII / human von Willebrand factor

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

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

What is Voncento and what is it used for?

Voncento is a medicine used for treating and preventing bleeding in patients with von Willebrand disease (an inherited bleeding disorder caused by lack of von Willebrand factor) when another medicine called desmopressin is ineffective or cannot be given. It is also used for the treatment and prevention of bleeding in patients with haemophilia A (an inherited bleeding disorder caused by lack of factor VIII). It contains two active substances, human coagulation factor VIII and human von Willebrand factor.

How is Voncento used?

Voncento can only be obtained with a prescription and treatment should be started by a doctor experienced in treating patients with bleeding disorders.

Voncento is available as a powder and solvent that are mixed together to make a solution for injection or infusion (drip) into a vein. Voncento is injected or infused slowly into a vein. If side effects develop during the injection or infusion, it may need to be given more slowly or stopped. The dose and duration of treatment depend on whether Voncento is used to treat or prevent bleeding or during surgery and whether it is used in patients with haemophilia A or von Willebrand disease. The dose and duration of treatment also depend on the patient's factor VIII levels, the severity of the disease, the extent and location of the bleeding and the patient's condition and bodyweight.

Patients or their carers may be able to inject or infuse the medicine themselves at home if their doctor considers it appropriate and once they have been trained appropriately. For full details, see the package leaflet.

How does Voncento work?

The active substances in Voncento, human coagulation factor VIII and human von Willebrand factor, are coagulation factors (substances that help the blood to clot). Patients with haemophilia A lack factor VIII and patients with von Willebrand disease lack von Willebrand factor. This causes problems with blood clotting, leading to bleeding in the joints, muscles or internal organs. Voncento is used to replace the missing coagulation factors, giving temporary control of the bleeding disorder.

What benefits of Voncento have been shown in studies?

Voncento has been studied in one main study involving 22 patients (including adolescents) with severe von Willebrand disease to assess its effects in stopping non-surgical bleeding episodes or as preventive treatment. Voncento was not compared with another treatment. The patients had previously been treated with desmopressin or von Willebrand factor and, in the first part of the study, received Voncento for 12 months. Voncento's effectiveness in stopping bleeding was measured using a grading scale. Voncento's effects were rated excellent in around 92% (371 out of 405) of the bleeding episodes and good in around 7% (27 out of 405) of episodes. The second part of this study, which lasted another 12 months, looked at the ability of Voncento to prevent bleeding episodes in 8 patients who had received Voncento during the first part of the study. This part of the study showed that the average number of bleeding events in patients on preventive treatment was reduced from between 18 and 82 events during the year before the preventive treatment to between 1 and 6 events.

The benefits of Voncento in preventing and treating bleeding episodes in haemophilia A were shown in a study of 81 patients who had previously been treated with human coagulation factor VIII. In this study, when used to treat bleeding, Voncento was rated excellent in 60% (396 out of 656) of the bleeding events and good in 36% (236 out of 656) of the bleeding events. Similar ratings were seen when Voncento was used for prevention. Among the 37 surgeries that occurred during the study, of which 12 were major, the blood loss was more than expected in only one case. Five patients in total – all of them undergoing major knee surgery – required blood transfusion.

What are the risks associated with Voncento?

The most common side effect of Voncento is headache (affecting more than 1 in 10 people). Other common side effects (affecting up to 1 in 10 people) include hypersensitivity (allergic) reactions and fever. Clotting in blood vessels, taste disturbances and abnormal results in liver function tests are uncommon effects (affecting between 1 and 10 in 1000 people).

There is a risk that some patients will develop inhibitors (antibodies) against factor VIII or von Willebrand factor, 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 Voncento, see the package leaflet.

Why is Voncento approved?

The Agency decided that Voncento's benefits are greater than its risks and recommended that it be approved for use in the EU. The Agency noted that Voncento was shown to be effective in treating and

preventing bleeding in patients with haemophilia A as well as in patients with von Willebrand disease. Voncento was also effective for preventing and treating bleeding related to surgery. Its side effects were generally mild to moderate and were considered typical for this type of medicine.

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

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

Other information about Voncento

The European Commission granted a marketing authorisation valid throughout the European Union for Voncento on 12 August 2013.

The full EPAR for Voncento can be found on the Agency's website: [ema.europa.eu/Find medicine/Human medicines/European public assessment reports](http://ema.europa.eu/Find/medicine/Human%20medicines/European%20public%20assessment%20reports). For more information about treatment with Voncento, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 10-2017.