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Alhemo (*concizumab*)

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

What is Alhemo and what is it used for?

Alhemo is a medicine used to prevent bleeding episodes (prophylaxis) in people aged 12 years and older with haemophilia A or B. People with haemophilia A or B are at risk of bleeding because they lack proteins that help the blood clot (factor VIII for haemophilia A and factor IX for haemophilia B).

Alhemo is used:

- in people with haemophilia A or B who have developed antibodies (proteins made by the body's natural defences) called inhibitors that stop factor VIII or factor IX medicines from working properly;
- in people who have severe haemophilia A or moderate to severe haemophilia B and have not developed antibodies.

Alhemo contains the active substance concizumab.

How is Alhemo used?

The medicine can only be obtained with a prescription. Treatment should be started under the supervision of a doctor experienced in the treatment of haemophilia or bleeding disorders.

Alhemo is given by injection under the skin of the abdomen (belly) or thigh once a day, using a pre-filled pen. Patients and caregivers can inject the medicine themselves if they have been trained appropriately. Alhemo is given continuously to prevent episodes of bleeding.

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

How does Alhemo work?

In addition to factor VIII and IX, the body uses other proteins to help the blood clot, such as factor Xa. Normally, a protein called tissue factor pathway inhibitor (TFPI) prevents factor Xa from triggering the clotting.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

The active substance in Alhemo, concizumab, is a monoclonal antibody (a type of protein). It attaches to TFPI and stops it from blocking factor Xa. This allows factor Xa to help the blood clot and prevent bleeding in people with haemophilia A or B.

What benefits of Alhemo have been shown in studies?

In two main studies, preventive treatment with Alhemo was effective in reducing the number of bleeding episodes in people aged 12 years and older with haemophilia A or B who have inhibitors, as well as in those without inhibitors.

The first study involved 127 participants who had developed inhibitors, of which 33 were included in the analysis. The estimated average number of bleeding episodes per year was 1.7 in those treated with Alhemo, compared with 11.8 in those who received on-demand treatment with factor medicines when a bleeding episode occurred.

People treated with Alhemo also had slight improvements in pain and physical functioning, based on a standardised scoring system called SF-36v2. Their scores improved by 9.2 and 4.5 points respectively (on a 100-point scale), compared with 2.2 and 1.2 points in those who did not receive preventive treatment.

The second main study involved 148 people with severe haemophilia A or moderate-to-severe haemophilia B who had not developed inhibitors against factor medicines. For 27 participants with haemophilia A, the estimated average bleeding per year was 2.7 in those treated with Alhemo, compared with 19.3 in those who only received on demand treatment with factor medicines when a bleeding episode occurred. For 36 participants with haemophilia B, these figures were 3.1 with Alhemo and 14.8 with on-demand treatment. Additionally, in participants previously treated with preventive factor VIII or IX replacement therapy, the number of bleedings per year did not change significantly when switched to Alhemo.

What are the risks associated with Alhemo?

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

The most common side effects with Alhemo (which may affect more than 1 in 10 people) include reactions at the injection site such as redness, bruising and haematoma (a collection of blood under the skin).

Some side effects can be serious. The most common (which may affect up to 1 in 100 people) include thromboembolic events (problems due to the formation of blood clots in the blood vessels) and hypersensitivity (allergic) reactions.

Why is Alhemo authorised in the EU?

Alhemo is effective at preventing bleeding episodes in patients aged 12 years and older with haemophilia A or B who have inhibitors, as well as in those without inhibitors whose haemophilia A is severe or haemophilia B is moderate to severe.

At the time of authorisation, most treatments for patients without inhibitors involved frequent infusions (drips) of factor VIII or IX replacement therapy into a vein. Alhemo is given once daily as an injection under the skin, and patients or caregivers can inject the medicine themselves at home, which may be more convenient and comfortable. Because treatment options were limited for patients with inhibitors, Alhemo provided them with an additional choice.

Regarding safety, Alhemo is generally well tolerated. The main safety issue is the risk of thromboembolic events, which was considered manageable.

The European Medicines Agency therefore decided that Alhemo's benefits are greater than its risks and that it can be authorised for use in the EU.

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

The company marketing Alhemo will provide healthcare professionals with educational materials on its safety, including the potential risk of thromboembolic events and the need to monitor patients for signs and symptoms. Patients will also receive a guide and a card that they should always carry with them.

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

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

Other information about Alhemo

Alhemo received a marketing authorisation valid throughout the EU on 13 December 2024.

Further information on Alhemo can be found on the Agency's website: https://www.ema.europa.eu/en/medicines/human/EPAR/alhemo.

This overview was last updated in 08-2025.