swissmedic

Summary report on authorisation dated 1 June 2026

Alhemo® (active substance: concizumab)

Indication extension in Switzerland: 15 December 2025

Solution for injection in pre-filled pen for the treatment of patients with haemophilia A and B

About the medicinal product

Alhemo, containing the active substance concizumab, is a medicinal product to prevent or reduce bleeding in patients with haemophilia A and B, a rare, hereditary, lifelong blood coagulation disorder. Haemophilia A is a congenital deficiency in clotting factor VIII and haemophilia B is a congenital deficiency in clotting factor IX.

Alhemo was first authorised by Swissmedic on 8 August 2023 to prevent or reduce bleeding in adults and adolescents aged 12 years and over with haemophilia B with factor IX inhibitors.

It was subsequently authorised on 22 August 2023 to prevent or reduce bleeding in adults and adolescents aged 12 years and over with haemophilia A with factor VIII inhibitors.

The application for the present indication extension requested that Alhemo also be used to prevent bleeding or reduce the number of bleeds in adults and adolescents aged 12 years and over with severe haemophilia A without inhibitors and moderate/severe haemophilia B without inhibitors.

Since this is a rare, life-threatening disease, the medicinal product Alhemo has been authorised as an orphan drug. The term "orphan drug" refers to medicinal products used to treat patients with rare diseases.

Mode of action

Alhemo blocks a natural factor in the blood, activating blood clotting even in the case of a factor VIII or factor IX deficiency. This helps to reduce or prevent bleeding in the case of a factor VIII or factor IX deficiency.

Administration

Alhemo is a prescription-only medicine.

Alhemo is available as a solution for injection in a pre-filled pen for subcutaneous (under the skin) administration in dosage strengths of 15 mg, 60 mg, 150 mg, and 300 mg. The usual starting dose is 1 mg per kg body weight on the first day and is followed by a daily dose of 0.2 mg per kg body weight. The individual maintenance dose is

determined after 4 weeks based on the concizumab concentration measured in the blood.

Injections should be administered by patients themselves or by a caregiver after relevant training by a healthcare professional. It is important that the injections are administered at the same time each day to ensure optimum efficacy. Intramuscular injections should be avoided.

Efficacy

The efficacy of Alhemo was investigated in a study in patients with haemophilia A and haemophilia B. The study compared needs-oriented treatment with factor VIII or factor IX products without prophylaxis (without prevention) and prophylaxis with Alhemo. The main part of the study lasted for 24 or 32 weeks, followed a further treatment phase of 136 weeks.

The study showed that bleeding frequency was significantly reduced in patients receiving prophylaxis with Alhemo. Compared to treatment without prophylaxis, Alhemo reduced both spontaneous and accident-related bleeding significantly.

Precautions, undesirable effects, & risks

Alhemo must not be used in those who are hypersensitive to the active substance or any of the excipients.

The most common undesirable effects (affecting more than 1 in 10 users) are injection site reactions.

Severe side effects, including allergic reactions and blood clots, can occur when using Alhemo. Allergic reactions can include symptoms such as itching, redness, swelling, and breathing difficulties, which require immediate medical treatment. Blood clots can form in various parts of the body, such as the legs, arms, or lungs, and also require immediate treatment.

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

Haemophilia A and B are rare genetic diseases that lead to blood clotting disorders, often with serious health consequences.

Alhemo provides an option to prevent the bleeding that frequently occurs in these patients. A pivotal study found that prophylaxis with Alhemo reduced the number of spontaneous and accident-related bleeds in the study population significantly.

Taking all the risks and precautions into account, and based on the available data, the benefits of Alhemo outweigh the risks.

Swissmedic has therefore approved the indication extension for Alhemo, containing the active substance concizumab, for adults and adolescents aged 12 years and over with:

- severe haemophilia A (where factor VIII levels in the blood are below 1%) without inhibitors
- moderate/severe haemophilia B (where factor IX levels in the blood are below or equal to 2%) without inhibitors

in Switzerland.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Alhemo®

Information for patients (package leaflet): Information for patients Alhemo®
Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.