

# Patient / Carer Guide

Important safety information on the  
risk of blood clots

## **Alhemo® ▼(concizumab)**

This medicinal product is subject to additional monitoring.  
If you get any side effects, talk to your doctor, pharmacist or nurse.

Side effects can be reported directly to the Health Products  
Regulatory Authority (HPRA) Pharmacovigilance, website:  
[www.hpra.ie](http://www.hpra.ie).

Side effects can also be reported to the Novo Nordisk Medical  
Department at [complaintireland@novonordisk.com](mailto:complaintireland@novonordisk.com) or Tel: 01  
8629700.

This guide is part of the educational materials developed by Novo Nordisk and is a  
mandatory condition of the Marketing Authorisation to minimise the risk of  
thromboembolic events associated with the use of Alhemo®.

Risk minimisation materials for Alhemo® have been approved by the Health  
Products Regulatory Authority (HPRA), Kevin O'Malley House, Earlsfort Centre,  
Earlsfort Terrace, Dublin 2.

For more information on Alhemo®, please see the Package Leaflet that comes with  
your medicine.



# IMPORTANT SAFETY INFORMATION

## Please read this information carefully before taking this medicine

### What is Alhemo®?

Alhemo® contains the active substance concizumab, which belongs to a group of medicines called 'monoclonal antibodies'. Concizumab is a protein that recognises and binds to a target in the blood involved in the coagulation process.

Alhemo® is used to prevent or reduce the frequency of bleeds in adults and adolescents from 12 years with:

- Haemophilia A with inhibitors
- Severe haemophilia A (when the factor VIII blood level is less than 1%) without inhibitors
- Haemophilia B with inhibitors
- Moderate/severe haemophilia B (when the factor IX blood level is less than or equal to 2%) without inhibitors

### Risk of blood clots (thromboembolism)

- Serious blood clots (thromboembolism) have been observed in patients who were treated with Alhemo®.
- Blood clots can form anywhere in the body.
- These blood clots may in rare cases cause a life-threatening blockage of the blood vessels.

### Recognising the sign and symptoms of a blood clot

- **Stop using Alhemo® and contact your doctor immediately**, if you have symptoms of blood clots such as:
  - Swelling, warmth, pain, or redness of the skin – these could be symptoms of a blood clot in your legs or arms.
  - Feeling short of breath, severe chest pain – these could be symptoms of blood clots in your heart or lungs.
  - Headache, feeling confused, trouble with speech or movement, numbness in face, eye pain or swelling, or problems with your vision – these could be symptoms of a blood clot in your brain or eyes.
  - Sudden pain in stomach or lumbar (lower back) area – these could be symptoms of blood clots in your gut or kidneys.

### Patient alert card

- Your doctor, pharmacist or nurse should give you an Alhemo® Patient Alert Card prior to starting this medicine.
- Fill out the relevant information on the Patient Alert Card.
- Keep the Patient Alert Card with you all the time - you can keep it in your wallet or purse.
- Show the Patient Alert Card to anyone who is giving you medical care. This includes any doctor, pharmacist, nurse or dentist you see - not just the specialist who prescribes your Alhemo®.
- Tell your caregiver or anyone close to you about your treatment and show them the Patient Alert Card because they may notice side effects that you are not aware of.