# Alhemo

## Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

| Application number | Scope | Opinion/ Notification [1] issued on | Commission Decision Issued[2] / amended on | Product Information affected[3] | Summary |
|---|---|---|---|---|---|
| Variation type II / | C.I.6 Change(s) to therapeutic indication(s) | 24/07/2025 | 22/08/2025 | SmPC and PL | Please refer to Scientific Discussion 'Alhemo-H-C- |

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

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| EMA/VR/0000244862 | - C.I.6.a Addition of a new therapeutic indication or modification of an approved one - Accepted<br><br>Extension of indication to include treatment of haemophilia A without inhibitors and haemophilia B without inhibitors for ALHEMO based on final results from study NN7415-4307; this is an interventional study to investigate efficacy and safety of concizumab prophylaxis in patients with haemophilia A or B without inhibitors. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor changes to the PI. | | | | 5938-VR/0000244862'. |
| Variation type IA / EMA/VR/0000267525 | B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.c Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - Accepted<br><br>B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.c Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - Accepted | 21/05/2025 | N/A | | |

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| Variation type IA / EMA/VR/0000267870 | B.II.e.7 Change in supplier of packaging components or devices (when mentioned in the dossier) - B.II.e.7.b Replacement or addition of a supplier - Accepted<br><br>B.II.e.7 Change in supplier of packaging components or devices (when mentioned in the dossier) - B.II.e.7.b Replacement or addition of a supplier - Accepted | 20/05/2025 | N/A | | |
| Variation type IB / EMA/VR/0000264546 | B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.z Other variation - Accepted | 29/04/2025 | N/A | | |
| Variation type IB / EMA/VR/0000261202 | B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.e Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate - Accepted | 14/04/2025 | N/A | | |
| Variation type IB / EMA/VR/0000245483 | B.II.d.2 Change in test procedure for the finished product - B.II.d.2.d Other changes to a test procedure (including replacement or addition) - Accepted | 20/03/2025 | N/A | | |