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Public Summary SwissPAR dated 29 November 2023

Alhemo® (active substance: concizumab)

First authorisation in Switzerland: 8 August 2023

Medicinal product (solution for injection in pre-filled pen) for the treatment of patients with haemophilia B and factor IX inhibitors.

Information on authorisation

The medicinal product Alhemo contains the active substance concizumab.

It is used to treat adults and adolescents aged 12 years and over with haemophilia B (congenital factor IX deficiency) and factor IX inhibitors to prevent bleeding or reduce the number of bleeds.

Haemophilia is a hereditary blood coagulation disorder (also known as a bleeding disorder). Haemophilia B is a form of haemophilia characterised by spontaneous or prolonged bleeding due to a lack of factor IX (coagulation factor). Alhemo restores the balance between the factors that contribute to blood clotting and those that prevent it.

Since haemophilia B is a rare and life-threatening disease, the medicinal product Alhemo has been authorised as an orphan drug. The term "orphan drug" is used to refer to important medicines for rare diseases.

Alhemo was authorised as part of the joint initiative of the Access Consortium. This joint initiative is a collaborative project between the drug regulatory authorities in Australia (Therapeutic Goods Administration, TGA), Canada (Health Canada, HC), Singapore (Health Sciences Authority, HSA), the United Kingdom (Medicines & Healthcare products Regulatory Agency, MHRA) and Swissmedic. The joint initiative coordinates the assessment of authorisation applications for new active substances that have been made in at least two of the five countries.

The authorisation application for Alhemo was submitted to the drug regulatory authorities in Canada, Australia and Switzerland. Each country assessed a part of the application and then shared and discussed the results. At the end of the process, each authority decided on the application independently.

Swissmedic considered the assessments by the foreign reference authorities in its decision on the authorisation. Accordingly, and since Swissmedic has not produced a complete SwissPAR (Swiss Public Assessment Report), it cannot issue a complete Public Summary SwissPAR. Swissmedic therefore refers to the relevant publications issued by the authorities involved:

Further details of the Access joint initiative are published on the Swissmedic website. Access Consortium (swissmedic.ch).

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 Public Summary SwissPAR.

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.