swissmedic

Summary report on authorisation dated 17 January 2025

Altuvoct® (active substance: efanesoctocog alfa)

Authorisation in Switzerland: 2 September 2024

Powder and solvent for solution for injection for the treatment and prevention of bleeding in patients with haemophilia A (congenital factor VIII deficiency)

About the medicinal product

Altuvoct contains the active substance efanesoctocog alfa. It is used to treat and prevent bleeding in patients with haemophilia A. Haemophilia A is a hereditary (congenital) blood disorder involving a lack of factor VIII. Factor VIII is a protein in the body that is needed for clotting. It helps to form blood clots and stop bleeding.

Altuvoct can be used in patients in all age groups. Altuvoct replaces the missing or defective factor VIII, thereby improving clotting and preventing bleeding.

Since haemophilia A is a rare and life-threatening disease, the medicinal product Altuvoct has been authorised as an orphan drug. "Orphan drug" is a designation given to medicinal products for rare diseases.

In deciding whether to authorise the medicinal product Altuvoct, Swissmedic took into account the assessments of the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA), and the corresponding medicinal product information texts.

Since the assessment of the clinical data was based on the assessment reports of these foreign authorities, the preconditions for a full SwissPAR (Swiss Public Assessment Report – a detailed report for professionals) and a resulting Summary report on authorisation are not met. Swissmedic refers to the authorisations by the foreign reference authorities.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Altuvoct®

Information for patients (package leaflet): Information for patients Altuvoct®

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.