swissmedic

Summary report on authorisation dated 11 July 2025

Andembry® (active substance: garadacimab)

Authorisation in Switzerland: 24 February 2025

Pre-filled pen for long-term prophylaxis of recurrent acute flare-ups of hereditary angioedema (HAE) in adults and adolescents aged 12 years and older

About the medicinal product

Andembry contains the active substance garadacimab. The medicinal product Andembry is used for the long-term prevention of recurrent acute flare-ups of the disease hereditary[1] angioedema (HAE) in adult and adolescent patients aged 12 years and over.

HAE is a rare inherited disease that causes episodic, painful swellings in various parts of the body, such as the face, hands, arms, legs and feet, or the gastrointestinal tract. The swellings can be life-threatening if they occur around the mouth and neck (larynx).

The swellings associated with HAE are triggered when an excessive quantity of a messenger substance called bradykinin is excreted. Bradykinin causes dilation of the blood vessels, which allows fluid to leak into the surrounding tissue, resulting in the typical swelling and inflammation. Bradykinin production is controlled by a chain of reactions, which starts with a substance called factor XII. The active substance garadacimab blocks activated factor XIIa, thus also blocking the reaction path that results in bradykinin production. This mechanism of action enables Andembry to prevent HAE flare-ups.

Since HAE is a rare and life-threatening disease, Andembry has been authorised as an orphan drug. The term "orphan drug" is used to refer to important medicines for rare diseases.

Andembry 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 and the pharmaceutical industry. The joint initiative coordinates the assessment of authorisation applications for new active substances that have been submitted in at least two of the five countries.

[1] Hereditary means "inherited"

The authorisation application for Andembry was submitted for assessment to the regulatory authorities in Australia, Canada, the United Kingdom 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.

For the assessment of the authorisation application for Andembry containing the active substance garadacimab, Swissmedic conducted the full assessment of the preclinical data. The requirements for issuing a comprehensive SwissPAR (Swiss Public Assessment Report) and a Summary report on authorisation based on this SwissPAR have not been fulfilled. Swissmedic refers to the authorisation of the foreign reference authorities.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Andembry®

Information for patients (package leaflet): Information for patients Andembry®
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.