swissmedic

Summary report on authorisation dated 25 August 2026

Vyvgart® (active substance: efgartigimod alfa)

Indication extension in Switzerland: 12 May 2026

Solution for injection for subcutaneous administration for the treatment of adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP)

About the medicinal product

Vyvgart contains the active substance efgartigimod alfa and this indication extension means that it can be used to treat adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP).

CIDP is an autoimmune disease in which the immune system progressively attacks the body's nerve pathways. This results in increasing muscle weakness, loss of sensation (e. g. numbness), trouble walking, and signs of paralysis, particularly in the arms and legs.

Vyvgart (in the dosage form concentrate for solution for infusion) was first authorised by Swissmedic on 3 October 2024 for the treatment of adults with generalised myasthenia gravis (gMG).

Since this is a rare and life-threatening or chronically debilitating disease, the medicinal product Vyvgart was authorised as an orphan drug. The term "orphan drug" refers to medicinal products used to treat patients with rare diseases.

This indication extension for Vyvgart was authorised under Article 13 of the Therapeutic Products Act (TPA). This authorisation procedure is applied in certain circumstances when a medicinal product is already authorised in another country with comparable medicinal product control.

In such cases, Swissmedic may take account of the results of the assessments conducted by that country's medicinal products regulatory authority. These involve checks on the quality, efficacy, and safety of the medicinal product, and the extent to which the results can be accepted for Switzerland. The consideration of the results of foreign authorisation procedures is intended to help ensure that medicines that are already authorised abroad can be made available to patients in Switzerland as quickly as possible.

The approval of the indication extension for Vyvgart in Switzerland is based on the assessment and approval decision of the European Medicines Agency (EMA). Swissmedic has not conducted its own comprehensive scientific assessment of the study data.

Accordingly, in the SwissPAR (Swiss Public Assessment Report) and the resulting Summary report on authorisation, Swissmedic refers to the Assessment Report and summary report issued by the reference authority.

www.ema.europa.eu

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Vyvgart®

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