swissmedic

Summary report on authorisation dated 27 December 2024

Vyvgart® (active substance: efgartigimod alfa)

Authorisation in Switzerland: 3 October 2024

Concentrate for solution for infusion for the treatment of adults with generalised myasthenia gravis (gMG) who are anti-acetylcholine receptor antibody positive, in addition to the standard therapy

About the medicinal product

Vyvgart contains the active substance efgartigimod alfa.

Vyvgart is used in addition to the standard therapy for the treatment of adult patients with generalised myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive.

Myasthenia gravis is a chronic, neuromuscular autoimmune disease that leads to muscle weakness. The immune system's antibodies attack the body's own acetylcholine receptors, which are responsible for muscle contraction. Vyvgart reduces the quantity of these antibodies, thereby improving muscle activity.

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

Vyvgart has been authorised by Swissmedic under Article 13 of the Therapeutic Products Act (TPA). This means that the medicinal product is already authorised in at least one other country with comparable medicinal product control.

In this case, Swissmedic takes into consideration the results of checks carried out by foreign regulatory agencies, provided certain requirements are fulfilled. 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.

In deciding whether to authorise Vyvgart in Switzerland, Swissmedic accepted the assessment and approval decision of the European Medicines Agency (EMA) and has only conducted a limited scientific review.
Accordingly, in the SwissPAR (Swiss Public Assessment Report) and the resulting Summary report on authorisation, Swissmedic refers to the Assessment Report issued by the reference authority: EMA Procedure Number EMEA/H/C/005849/0000 www.ema.europa.eu.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals 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.