

Summary report on authorisation dated 26 February 2026

Hetronifly[®] (active substance: serplulimab)

Authorisation in Switzerland: 27 November 2025

Concentrate for solution for infusion in combination with carboplatin and etoposide for the first-line treatment of adult patients with extensive-stage small cell lung cancer

About the medicinal product

Hetronifly is a cancer treatment containing the active substance serplulimab. The medicinal product Hetronifly is used in combination with carboplatin and etoposide for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).

Patients with extensive-stage small cell lung cancer have a poor prognosis. The cancer cells divide rapidly and the disease quickly progresses further.

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

Hetronifly was authorised under Article 13 of the Therapeutic Products Act (TPA). This means that the medicinal product is already authorised in another country with comparable medicinal product control.

In this case, Swissmedic takes into consideration the results of checks carried out by for-

foreign regulatory agencies, provided certain requirements are fulfilled. These involve checks on the quality, efficacy, and safety of the medicinal products, 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 Hetronifly in Switzerland, Swissmedic accepted the assessment and approval decision of the European Medicines Agency (EMA; reference number EMA/48095/2025) and has not conducted its own scientific review.

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

At the time of publication of the Summary report on authorisation for Hetronefly, the Information for healthcare professionals was not yet available. As soon as the medicinal product becomes available in Switzer-

land, the Information for healthcare professionals will be made available on the following website:

www.swissmedicinfo.ch

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.