swissmedic

Summary report on authorisation dated 4 July 2025

Vyloy® (active substance: zolbetuximab)

Authorisation in Switzerland: 19.02.2025

Powder for concentrate for solution for infusion for the treatment of adults with advanced unresectable or metastatic HER2-negative and claudin 18.2-positive gastric adenocarcinoma.

Information on authorisation

Vyloy contains the active substance zolbetuximab.

It is used in combination with certain chemotherapy regimens for the first-line treatment of adults with locally advanced or metastatic (has spread within the body) adenocarcinoma[1] of the stomach. Vyloy can be used for adenocarcinomas that are HER2 (human epidermal growth factor receptor 2)-negative and claudin 18.2-positive. This means that specific features must be present on the tumour cells to enable the treatment to be used effectively. Zolbetuximab binds to the protein claudin 18.2 on the cancer cells. As a result, the body's immune system is activated, enabling it to attack and destroy the cancer cells and thereby slow down or stop tumour growth.

Since this cancer, adenocarcinoma[1] of the stomach, is a rare and life-threatening disease, the medicine Vyloy has been authorised as an orphan drug. "Orphan drug" is a designation given to medicinal products for rare diseases.

Vyloy 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 2 of the 5 countries.
The authorisation application for Vyloy was submitted to the drug regulatory authorities in Singapore, Australia, and Switzerland. Each country assessed a part of the application and then shared and discussed the re-

[1] Adenocarcinoma is a malignant tumour of the glands, in this case the glands in the stomach and the junction between the oesophagus and stomach

sults. At the end of the process, each authority decided on the application independently.

Swissmedic considered the assessments by the foreign reference authorities in its decision on the authorisation. Accordingly, Swissmedic has not produced a complete SwissPAR (Swiss Public Assessment Report) and therefore cannot issue a complete Summary report on authorisation. Swissmedic therefore refers to the relevant publications issued by the authorities involved:

Further details of the Access joint initiative are published on the Swissmedic website: Access Consortium (swissmedic.ch).

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Vyloy®

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.