swissmedic

Summary report on authorisation dated 10 June 2025

Elahere® (active substance: mirvetuximab soravtansine)

First authorisation in Switzerland: 13 March 2025

Concentrate for solution for infusion for the treatment of adults with folate receptor alpha (FRα)-positive, platinum-resistant high-grade serous epithelial ovarian, fallopian tube or primary peritoneal cancer who have received one to three prior systemic treatment regimens

About the medicinal product

The medicinal product Elahere contains the active substance mirvetuximab soravtansine.

Elahere is used to treat adult patients with a certain type of ovarian, fallopian tube or peritoneal cancer. These cancers must have tested positive for folate receptor alpha (FRα)[1] and be resistant to platinum-based chemotherapy. Resistance means that the cancer has recurred within six months of the end of platinum-based chemotherapy.
Patients who receive this medicinal product should already have received one to three previous systemic treatment regimens. Systemic regimens are treatments that affect the entire body, such as chemotherapy, which acts via the blood circulation.
Elahere is administered as monotherapy, i.e. without any other cancer medicines.

Since the certain types of ovarian, fallopian tube or peritoneal cancer are rare, life-threatening diseases, Elahere has been authorised as an orphan drug. The term "orphan drug" is used to refer to important medicines for rare diseases.

Elahere has been authorised by Swissmedic 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 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

[1] Folate receptor alpha (FRα): Folate receptor alpha is a protein that occurs on the surface of certain cancer cells, such as those found in ovarian cancer, and to which active substances can bind so they can target and attack these cancer cells.

available to patients in Switzerland as quickly as possible.

In deciding whether to authorise Elahere in Switzerland, Swissmedic accepted the assessment and approval decision of the European Medicines Agency EMA (EMEA/H/C/005036/0000) and has only conducted a limited scientific review.

Since the assessment was based on the assessment report of a foreign partner authority, the preconditions for a full SwissPAR (Swiss Public Assessment Report) and a resulting Summary report on authorisation are not met. Swissmedic refers to the authorisation of the foreign comparator product.

www.ema.europa.eu

Further information on the medicinal product

Information for healthcare professionals: E-lahere® – Information for healthcare professionals

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.