swissmedic

Summary report on authorisation dated 28 November 2025

Enhertu® (active substance: trastuzumab deruxtecan)

Indication extension in Switzerland: 6 June 2025

Infusion for the treatment of adults with metastatic, hormone receptor-positive breast cancer and low or ultralow HER2 expression

About the medicinal product

Enhertu, containing the active substance trastuzumab deruxtecan, is used for the treatment of adults with metastatic (that has spread to other parts of the body) hormone receptor-positive[1] breast cancer with HER2-low (IHC 1+ or IHC 2+/ISH negative)[2] or HER2-ultralow (IHC 0 with membrane staining) expression.

HER2 is the abbreviation for human epidermal growth factor receptor 2. These receptors trigger division of cancer cells.

Enhertu is used in patients whose disease has progressed under 1 or more endocrine therapies[3] and for whom a further endocrine therapy in the next line of therapy is not an option.

The medicinal product Enhertu has already been authorised by Swissmedic for other indications.

Mode of action

Enhertu contains the active substance trastuzumab deruxtecan. This active substance combines an antibody (a protein) that can recognise and bind to the HER2 receptor on cancer cells with a substance known as a topoisomerase I inhibitor, which is effective against malignant tumours. As a result, the DNA (genetic material) of the tumour cells is damaged, leading to the death of the cancer cells.

[1]Hormone receptor-positive: Breast cancer has specific docking sites for hormones such as oestrogen or progesterone. These hormones can promote tumour growth.

[2]IHC: A laboratory test to make proteins on cancer cells visible. It uses a special dye which binds to the protein (in this case, HER2) so that the amount present on the tumour cells can be seen. The results are given as levels: 0 = almost no HER2, 1+ = little HER2, 2+ = moderate HER2. HER2-ultralow breast cancer is defined as IHC 0 with membrane staining, i.e. weak, partial membrane staining in ≤ 10% of the tumour cells

[3] Endocrine therapies: Medicinal products that inhibit the growth of hormone-sensitive cancer cells by blocking hormones or reducing their production.

Administration

Enhertu is a prescription-only medicine and is used as a powder for solution for infusion. Before use, the powder must be dissolved and diluted by a healthcare professional according to the instructions and then administered slowly via a vein.

The recommended dose for metastatic breast cancer is 5.4 mg/kg body weight. This dose is administered as an infusion once every 3 weeks and should be continued for as long as there is no further progression of the disease and no unacceptable side effects occur.

Efficacy

The efficacy of Enhertu was investigated in the Phase III DESTINY-Breast06 trial. This trial compared Enhertu with a standard chemotherapy in adults with hormone receptor-positive metastatic HER2-low or HER2-ultralow breast cancer. It included a total of 866 female patients who had already received 1 or more endocrine therapies. Progression-free survival (PFS)[4] was evaluated as a primary endpoint by an independent review. Enhertu demonstrated a significantly longer median PFS compared to the chemotherapy: 13.2 months versus 8.1 months for the chemotherapy.

Precautions, undesirable effects, & risks

Enhertu must not be used in those who are hypersensitive to the active substance or any of the excipients.

While undergoing treatment with Enhertu, there is a risk of lung disease (interstitial lung disease, ILD) that can be potentially fatal. Patients should be monitored for symptoms such as cough, fever, or other respiratory symptoms.

Some other very common undesirable effects after administration of Enhertu include changes in blood count, nausea, vomiting, fatigue, constipation, diarrhoea, and neutropenia[5].

All precautions, risks, and other possible undesirable effects are listed in the Information for healthcare professionals.

Why the medicinal product has been authorised

There is a considerable need for effective therapies in the treatment of metastatic breast cancer, as the disease is incurable at an advanced stage and many patients die due to progression of the disease. Enhertu, containing the active substance trastuzumab deruxtecan, offers a new treatment option for patients with HER2-low or HER2-ultralow breast cancer, whose unresectable or metastatic disease has progressed under 1 or more endocrine therapies and for whom a further endocrine therapy in the next line of therapy is not an option. The DESTINY-Breast06 clinical trial showed that Enhertu demonstrated a significant improvement in progression-free survival (PFS) versus traditional chemotherapies.

Taking all the risks and precautions into account, and based on the available data, the

[4] Progression-free survival (PFS): Period between the start of a treatment or a clinical trial and the onset of disease progression or the death of the patient.

[5] Neutropenia: Reduction of certain white blood cells, which are important for fighting infection. This results in an increased risk of infections.

benefits of Enhertu in this indication outweigh the risks. Swissmedic has therefore extended the indication for the medicinal product Enhertu, containing the active substance trastuzumab deruxtecan, for use in Switzerland.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Enhertu®

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.