



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/191628/2018  
EMA/H/C/004361

## Kanjinti (*trastuzumab*)

An overview of Kanjinti and why it is authorised in the EU

### What is Kanjinti and what is it used for?

Kanjinti is a cancer medicine used to treat the following conditions:

- early breast cancer (when the cancer has spread within the breast or to the glands under the arm but not to other parts of the body) after surgery, chemotherapy (medicines to treat cancer), and radiotherapy (treatment with radiation) if applicable. It can also be used earlier in treatment, in combination with chemotherapy. For cancers that are locally advanced (including those that are inflammatory) or more than 2 cm wide, Kanjinti is used before surgery in combination with chemotherapy and then again after surgery on its own;
- metastatic breast cancer (cancer that has spread to other parts of the body). It is used on its own when other treatments have not worked or are not suitable. It is also used in combination with other cancer medicines: with paclitaxel or docetaxel, or with another class of medicines called aromatase inhibitors;
- metastatic gastric (stomach) cancer, in combination with cisplatin and either capecitabine or fluorouracil (other cancer medicines).

Kanjinti can only be used when the cancer 'overexpresses HER2': this means that the cancer produces a protein called HER2 in large quantities on the cancer cells. HER2 is overexpressed in about a quarter of breast cancers and a fifth of gastric cancers.

Kanjinti is a 'biosimilar medicine'. This means that Kanjinti is highly similar to another biological medicine (the 'reference medicine') that is already authorised in the EU. The reference medicine for Kanjinti is Herceptin. For more information on biosimilar medicines, see [here](#).

Kanjinti contains the active substance trastuzumab.

### How is Kanjinti used?

Kanjinti can only be obtained with a prescription and treatment should be started by a doctor who has experience in the use of cancer medicines.



It is given by infusion (drip) into a vein over 90 minutes every week or every 3 weeks for breast cancer, and every 3 weeks for gastric cancer. For early breast cancer, treatment is given for a year or until the disease comes back, and for metastatic breast or gastric cancer, treatment is continued for as long as it remains effective. The dose depends on the patient's body weight, on the condition being treated and on whether Kanjinti is given every week or every 3 weeks.

The infusion may cause allergic reactions, so the patient should be monitored during and after the infusion. Patients who do not have significant reactions to the first 90-minute infusion can receive subsequent infusions over 30 minutes.

For more information about using Kanjinti, see the package leaflet or contact a doctor or pharmacist.

## **How does Kanjinti work?**

The active substance in Kanjinti, trastuzumab, is a monoclonal antibody (a type of protein) designed to recognise and attach to the HER2 protein. By attaching to HER2, trastuzumab activates cells of the immune system, which then kill the tumour cells. Trastuzumab also stops HER2 from producing signals that cause the tumour cells to grow.

## **What benefits of Kanjinti have been shown in studies?**

Laboratory studies comparing Kanjinti with Herceptin have shown that the active substance in Kanjinti is highly similar to that in Herceptin in terms of structure, purity and biological activity. Studies have also shown that giving Kanjinti produces similar levels of the active substance in the body to giving Herceptin.

In addition, one study involving 696 patients with early breast cancer that overexpressed HER2 showed that Kanjinti was effective in treating the condition. After treatment of up to a year, 48% of those given Kanjinti (172 of 358) and 41% of those given the reference medicine Herceptin (137 of 338) had no invasive cancer cells in the breasts or surrounding lymph nodes. In the light of all the data provided the difference was not assessed to be relevant and it was concluded that Kanjinti would behave in the same way as Herceptin in its approved indications.

Because Kanjinti is a biosimilar medicine, the studies on effectiveness and safety of trastuzumab carried out with Herceptin do not all need to be repeated for Kanjinti.

## **What are the risks associated with Kanjinti?**

The most common or serious side effects with Kanjinti are heart problems, reactions related to the Kanjinti infusion, reduced levels of blood cells (especially white blood cells), infections and lung problems.

Kanjinti can cause cardiotoxicity (harm to the heart), including heart failure (when the heart does not work as well as it should). Care should be taken if it is given to patients who already have heart problems or high blood pressure, and all patients need to be monitored during and after treatment to check their heart.

Kanjinti must not be used in people who are hypersensitive (allergic) to trastuzumab, mouse proteins or to any of the other ingredients. It must not be used in patients whose advanced cancer causes serious breathing problems even when resting, or who need oxygen therapy.

For the full list of side effects and restrictions, see the package leaflet.

## **Why is Kanjinti authorised in the EU?**

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Kanjinti has been shown overall to have a comparable quality, safety and effectiveness to Herceptin. Therefore, the Agency's view was that, as for Herceptin, the benefit of Kanjinti outweighs the identified risk and it can be authorised.

## **What measures are being taken to ensure the safe and effective use of Kanjinti?**

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Kanjinti have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Kanjinti are continuously monitored. Side effects reported with Kanjinti are carefully evaluated and any necessary action taken to protect patients.

## **Other information about Kanjinti**

Kanjinti received a marketing authorisation valid throughout the EU on 16 May 2018.

Further information on Kanjinti can be found on the Agency's website: [ema.europa.eu/Find/medicine/Human\\_medicines/European\\_public\\_assessment\\_reports](http://ema.europa.eu/Find/medicine/Human_medicines/European_public_assessment_reports).

This overview was last updated in 05-2018.