



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Trazimera (*trastuzumab*)

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

What is Trazimera and what is it used for?

Trazimera 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, Trazimera 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).

Trazimera 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.

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

Trazimera contains the active substance trastuzumab.

How is Trazimera used?

Trazimera 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 Trazimera 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 Trazimera, see the package leaflet or contact a doctor or pharmacist.

How does Trazimera work?

The active substance in Trazimera, 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 Trazimera have been shown in studies?

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

In addition, a main study involving 707 patients with metastatic breast cancer that overexpressed HER2 showed that Trazimera was as effective in treating the condition as Herceptin. In this study, 63% of patients given Trazimera had a complete or partial response to treatment compared with 67% of those given Herceptin.

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

What are the risks associated with Trazimera?

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

Trazimera 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.

Trazimera 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 Trazimera authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Trazimera 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 Trazimera outweighs the identified risk and it can be authorised.

What measures are being taken to ensure the safe and effective use of Trazimera?

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

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

Other information about Trazimera

Trazimera received a marketing authorisation valid throughout the EU on 26.07.2018.

Further information on Trazimera can be found on the Agency's website: ema.europa.eu/Find/medicine/Human_medicines/European_public_assessment_reports.

This overview was last updated in 06-2018.