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EPAR summary for the public

# Herzuma

trastuzumab

This is a summary of the European public assessment report (EPAR) for Herzuma. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Herzuma.

For practical information about using Herzuma, patients should read the package leaflet or contact their doctor or pharmacist.

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

Herzuma 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 tumours that are locally advanced (including those that are inflammatory) or more than 2 cm wide, Herzuma 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 in patients in whom previous treatments have failed. 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).

Herzuma can only be used when the cancer has been shown to ‘overexpress HER2’: this means that the cancer produces a protein called HER2 in large quantities on the surface of the tumour cells. HER2 is overexpressed in about a quarter of breast cancers and a fifth of gastric cancers.

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

Herzuma contains the active substance trastuzumab.

## How is Herzuma used?

Herzuma 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 available as a powder used to make up a solution for adding to an infusion (drip) into a vein. The infusion is given over 90 minutes every week or every three weeks for breast cancer, and every three 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 recommended dose depends on the patient's body weight, on the condition being treated and on whether Herzuma is given weekly or three-weekly.

The infusion may be associated with allergic reactions, so the patient should be monitored during and after the infusion. Patients who tolerate the first 90-minute infusion can receive subsequent infusions over 30 minutes.

For further information, see the package leaflet.

## How does Herzuma work?

The active substance in Herzuma, trastuzumab, is a monoclonal antibody (a type of protein) that has been 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 producing signals that cause the tumour cells to grow.

## What benefits of Herzuma have been shown in studies?

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

In addition, one main study involving 549 patients with early breast cancer that overexpressed HER2 showed that Herzuma was as effective as Herceptin. Patients were given either Herzuma or Herceptin with other cancer medicines before surgery to remove the cancer, and then the same medicine on its own every three weeks for 1 year. There were no relevant differences in the main measure of effectiveness (absence of invasive cancer cells in the breast or in linked tissues called lymph nodes) between the two products: this was seen in nearly 44% of those given Herzuma (118 of 271) and 47% of those given Herceptin (131 of 278).

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

## What are the risks associated with Herzuma?

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

Herzuma 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.

Herzuma 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 who have serious breathing problems because of advanced cancer, even when resting, or who need oxygen therapy.

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

## Why is Herzuma approved?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Herzuma has been shown to have a comparable quality, safety and effectiveness to Herceptin.

Therefore, the Agency's view was that, as for Herceptin, the benefit outweighs the identified risk and Herzuma should be given marketing authorisation.

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

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

## Other information about Herzuma

The European Commission granted a marketing authorisation valid throughout the European Union for Herzuma on 9 February 2018.

The full EPAR for Herzuma can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Herzuma, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 02-2018.