EMA/516922/2023
EMEA/H/C/005769

Herwenda (*trastuzumab*)

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

What is Herwenda and what is it used for?

Herwenda is a medicine used to treat the following types of cancer:

- 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, Herceptin is used before surgery in combination with chemotherapy and then again after surgery on its own; Herwenda should only be used in patients with metastatic or EBC whose tumours have either HER2 overexpression or HER2 gene amplification
- 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 anticancer medicines: with paclitaxel or docetaxel, or with an aromatase inhibitor;
- metastatic gastric (stomach) cancer, in combination with cisplatin and either capecitabine or 5-fluorouracil (other anticancer medicines).

Herwenda 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.

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

Herwenda contains the active substance trastuzumab.

How is Herwenda used?

Herwenda treatment should only be started by a doctor who has experience in the use of anticancer medicines.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

When given as an infusion into a vein, Herwenda 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. 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 and depends on the condition to be treated and whether Herwenda is given weekly or every three weeks.

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

How does Herwenda work?

The active substance in Herwenda, trastuzumab, is a monoclonal antibody. A monoclonal antibody is an antibody (a type of protein) that has been designed to recognise and attach to a specific structure (called an antigen) that is found on certain cells in the body. Trastuzumab has been designed to attach to the HER2 protein, which is overexpressed in about a quarter of breast cancers and a fifth of gastric cancers. 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 Herwenda have been shown in studies?

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

In addition, a study involving 807 patients showed that Herwenda had similar effects as Herceptin in the treatment of early HER2-positive breast cancer. Patients were given either Herwenda or Herceptin with other cancer medicines before surgery to remove the cancer. In this study, 47% of patients treated with Herwenda and 48% of those treated with Herceptin had no actively growing cancer cells in the breast tissue and lymph nodes removed during surgery.

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

What are the risks associated with Herwenda?

The safety of Herwenda has been evaluated and on the basis of all the studies assessed the side effects of the medicine are considered to be comparable to those of the reference medicine Herceptin.

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

The most common side effects with Herwenda (which may affect more than 1 in 10 people) include heart problems, infusion-related reactions, blood problems (in particular low levels of neutrophils, a type of white blood cell), infections and lung problems.

Why is Herwenda authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Herwenda has a highly similar structure, purity and biological activity to Herceptin and is

distributed in the body in the same way. In addition, a study in early HER2-positive breast has shown that the safety and effectiveness of Herwenda is equivalent to that of Herceptin.

All these data were considered sufficient to conclude that Herwenda will behave in the same way as Herceptin in terms of effectiveness and safety in its authorised uses. Therefore, the Agency's view was that, as for Herceptin, the benefits of Herwenda outweigh the identified risks and it can be authorised for use in the EU.

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

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

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

Other information about Herwenda

Herwenda received a marketing authorisation valid throughout the EU on 15 November 2023.

Further information on Herwenda can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/herwenda

This overview was last updated in 11-2023.