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# Zercepac (*trastuzumab*)

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

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

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

- early breast cancer (when the cancer has spread within the breast or to the lymph nodes ['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, Zercepac 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: paclitaxel or docetaxel, or with another type of medicine called an aromatase inhibitor;
- metastatic gastric (stomach) cancer, in combination with cisplatin and either capecitabine or fluorouracil (other cancer medicines).

Zercepac 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.

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

Zercepac contains the active substance trastuzumab.

## How is Zercepac used?

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

It is given by infusion (drip) into a vein over 90 minutes either once a week or once every 3 weeks for breast cancer, and once 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 Zercepac 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 for signs such as fever and chills. 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 Zercepac, see the package leaflet or contact your doctor or pharmacist.

## How does Zercepac work?

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

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

In addition, one study involving 649 patients with previously untreated metastatic breast cancer that overexpressed HER2 showed that Zercepac was as effective as Herceptin in treating the condition. Patients received Zercepac or the reference medicine Herceptin, together with another cancer medicine, docetaxel. A response to treatment after 24 weeks was seen in around 71% of the patients treated with either medicine (231 of 324 given Zercepac, and 232 of 325 given Herceptin).

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

## What are the risks associated with Zercepac?

The safety of Zercepac has been evaluated and on the basis of all the studies carried out the side effects of the medicine are considered to be comparable to those of the reference medicine Herceptin. The most common or serious side effects with Zercepac are heart problems, reactions related to the infusion, reduced levels of blood cells (especially white blood cells), infections and lung problems.

Zercepac 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.

Zercepac 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 Zercepac authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Zercepac has a highly similar structure, purity and biological activity to Herceptin and is distributed in the body in the same way. In addition, studies in metastatic breast cancer that overexpressed HER2 have shown that the effectiveness of Zercepac infusion is equivalent to that of Herceptin infusion.

All these data were considered sufficient to conclude that Zercepac 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 Zercepac 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 Zercepac?

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

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

## Other information about Zercepac

Zercepac received a marketing authorisation valid throughout the EU on 27 July 2020.

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

This overview was last updated in 07-2020.