EMA/737536/2017
EMEA/H/C/004323

EPAR summary for the public

Ontruzant

trastuzumab

This is a summary of the European public assessment report (EPAR) for Ontruzant. 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 Ontruzant.

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

What is Ontruzant and what is it used for?

Ontruzant 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, Ontruzant 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 5-fluorouracil (other cancer medicines).

Ontruzant 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, which makes the tumour cells grow more quickly. HER2 is overexpressed in about a quarter of breast cancers and a fifth of gastric cancers.

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

Ontruzant contains the active substance trastuzumab.

How is Ontruzant used?

Ontruzant 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 and depends on the condition to be treated and whether Ontruzant is given weekly or three-weekly.

The infusion can 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 Ontruzant work?

The active substance in Ontruzant, trastuzumab, is a monoclonal antibody (a type of protein) that has been designed to recognise and 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 Ontruzant have been shown in studies?

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

In addition, a study involving 875 patients with early or locally advanced breast cancer looked at the effectiveness of Ontruzant and Herceptin. The women received one or the other trastuzumab medicine before and after surgery, with other cancer medicines and radiotherapy according to standard practice. The study showed that 94% of women given Ontruzant and 93% of those given Herceptin survived without return or worsening of their disease when followed up for around 14 months. Absence of invasive cancer cells was noted in the tissue removed at surgery in 52% of women given Ontruzant and 42% of those given Herceptin, but in the light of all the available information from the study this difference was not assessed to be relevant. On the basis of all the data provided it was concluded that Ontruzant would behave in the same way as Herceptin in its approved indications.

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

What are the risks associated with Ontruzant?

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

Ontruzant 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.

Ontruzant 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 Ontruzant approved?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Ontruzant 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 Ontruzant should be given marketing authorisation.

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

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

Other information about Ontruzant

The European Commission granted a marketing authorisation valid throughout the European Union for Ontruzant on 15 November 2017.

The full EPAR for Ontruzant 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 Ontruzant, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2017.