EMA/364376/2024
EMEA/H/C/006252

Tuznue (*trastuzumab*)

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

What is Tuznue and what is it used for?

Tuznue 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). It is used 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 tumours more than 2 cm wide, Tuznue 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).

Tuznue 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.

Tuznue contains the active substance trastuzumab and is a biological medicine. It is a 'biosimilar medicine'. This means that Tuznue is highly similar to another biological medicine (the 'reference medicine') that is already authorised in the EU. The reference medicine for Tuznue is Herceptin.

How is Tuznue used?

Tuznue 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 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. For metastatic breast or gastric cancer, treatment is continued for as long as it remains effective.

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 Tuznue, see the package leaflet or contact your doctor or pharmacist.

How does Tuznue work?

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

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

In addition, a study involving 502 women with newly diagnosed early breast cancer that overexpressed HER2 showed that Tuznue was as effective as Herceptin in treating the condition. Before surgery to remove the cancer, people were given either Tuznue or Herceptin, each with docetaxel. A complete response (based on no sign of cancer in the breast and lymph nodes in the armpit) was seen in 45% of people treated with Tuznue and 49% of those treated with Herceptin.

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

What are the risks associated with Tuznue?

The safety of Tuznue has been evaluated and, based on all the studies carried out, 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 Tuznue, see the package leaflet.

The most common or serious side effects with Tuznue include heart problems, infections, lung and blood problems, and reactions related to the infusion.

Tuznue can cause cardiotoxicity (damage 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.

Tuznue must not be used in people who are hypersensitive (allergic) to trastuzumab, mouse proteins or any of the other ingredients. It must not be used in people who have serious breathing problems when they are at rest because of advanced cancer, or who need oxygen therapy.

Why is Tuznue authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Tuznue 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 early breast cancer have shown that Tuznue and Herceptin are equivalent in terms of safety and effectiveness in treating this condition.

All these data were considered sufficient to conclude that Tuznue will have the same effects as Herceptin in its authorised uses. Therefore, the Agency's view was that, as for Herceptin, the benefits of Tuznue 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 Tuznue?

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

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

Other information about Tuznue

Tuznue received a marketing authorisation valid throughout the EU on 19 September 2024.

Further information on Tuznue can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/tuznue-0.

This overview was last updated in 09-2024.