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Dazublys (*trastuzumab*)

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

What is Dazublys and what is it used for?

Dazublys is used to treat adults with certain types of breast or gastric cancers. Dazublys can only be used when the cancer is HER2-positive. HER2-positive means that cancer cells have large quantities of the HER2 protein on their surface, which makes the tumour cells grow more quickly.

Early breast cancer

In patients with 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), Dazublys is used:

- on its own after surgery, chemotherapy and radiotherapy (treatment with radiation), if applicable;
- in combination with chemotherapy (docetaxel and carboplatin) after surgery;
- in combination with chemotherapy (paclitaxel or docetaxel), following a course of chemotherapy with doxorubicin and cyclophosphamide given after surgery;
- when the cancer is locally advanced (has spread nearby), including when it is inflammatory, or when the cancer is larger than 2 cm. In these cases, it is used in combination with chemotherapy before surgery and then on its own after surgery.

Metastatic breast cancer

In patients with metastatic breast cancer (cancer that has spread to other parts of the body), Dazublys is used:

- on its own in patients who have had two courses of chemotherapy for metastatic breast cancer, including an anthracycline and a taxane, unless patients cannot take these medicines;
- on its own when cancer cells have receptors (target) for certain hormones on their surface (HR-positive) and patients have previously received at least one endocrine therapy (treatment which blocks the effect of oestrogens, a female sex hormone), unless they cannot receive this type of treatment;
- in combination with other chemotherapy (docetaxel or paclitaxel) in patients who have not been previously treated for metastatic breast cancer;

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- in combination with an aromatase inhibitor (endocrine therapy) in patients who have been through menopause and whose tumour is HR-positive, when they have not previously had trastuzumab.

Metastatic gastric cancer

In patients with adenocarcinoma (a type of cancer) of the stomach or gastro-oesophageal junction (cancer at the junction between the stomach and the oesophagus) who have not previously been treated for metastatic disease, Dazublys is used in combination with chemotherapy (cisplatin and either capecitabine or 5-fluorouracil chemotherapy).

Dazublys contains the active substance trastuzumab and is a biological medicine. It is a 'biosimilar medicine'; this means that Dazublys is highly similar to another biological medicine (the 'reference medicine') that is already authorised in the EU. The reference medicine for Dazublys is Herceptin. For more information on biosimilar medicines, see here.

How is Dazublys used?

Dazublys can only be obtained with a prescription and treatment should be started by a doctor who has experience in the use of anticancer medicines.

Dazublys is given by infusion (drip) into a vein over 90 minutes, every week or every three weeks depending on the condition being treated. 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 patient should be monitored for signs of allergic reaction during and after each infusion. Patients who tolerate the first 90-minute infusion can receive subsequent infusions over 30 minutes.

For more information about using Dazublys, see the package leaflet or contact your doctor or pharmacist.

How does Dazublys work?

The active substance in Dazublys, trastuzumab, is a monoclonal antibody (a type of protein) that has been designed to recognise and attach to HER2. About a quarter of breast cancers and a fifth of gastric cancers have large quantities of HER2 on the surface of cancer cells. By attaching to HER2, trastuzumab activates cells of the immune system, which then kill the tumour cells. It also stops HER2 from sending signals that cause cancer cells to grow.

What benefits of Dazublys have been shown in studies?

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

In addition, a main study involving 690 patients with HER2-positive metastatic breast cancer showed that Dazublys was as effective as Herceptin in treating the condition. In this study, 67% of patients given Dazublys had a complete response (no sign of cancer after treatment) or partial response (shrinkage of the tumour), compared with 69% of those given Herceptin.

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

What are the risks associated with Dazublys?

The safety of Dazublys 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.

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

The most common side effects with Dazublys (which may affect more than 1 in 10 people) include heart problems, infections, lung and blood problems, and reactions at the site of infusion.

Dazublys must not be used in patients who have severe dyspnoea (difficulty breathing) when they are at rest because of advanced cancer, or in patients who need oxygen therapy.

Dazublys can cause cardiotoxicity (harm to the heart), including heart failure (when the heart does not work as well as it should). It should be used with caution in patients who have heart problems or high blood pressure. All patients should have their heart monitored during and after treatment with Dazublys.

Why is Dazublys authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Dazublys 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 patients with metastatic breast cancer has shown that Dazublys and Herceptin are equivalent in terms of safety and effectiveness in this indication.

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

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

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

Other information about Dazublys

Dazublys received a marketing authorisation valid throughout the EU on 30 June 2025.

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

This overview was last updated in 07-2025.