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Perjeta (*pertuzumab*)

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

What is Perjeta and what is it used for?

Perjeta is a cancer medicine for treating adults with 'HER2-positive' breast cancer (where a protein called HER2 is found on the cancer cells). Perjeta is used in the following situations:

- treatment of metastatic breast cancer (cancer that has spread to other parts of the body) that has not already been treated with chemotherapy medicines or medicines designed to target HER2, or for breast cancer that has come back locally after treatment and cannot be removed by surgery. In these cases, Perjeta is used with trastuzumab and docetaxel (other cancer medicines);
- treatment of locally advanced, inflammatory or early-stage breast cancer at high risk of coming back, in combination with trastuzumab and chemotherapy, before the patient undergoes surgery;
- treatment of early breast cancer at high risk of coming back, in combination with trastuzumab and chemotherapy, after the patient has had surgery.

Perjeta contains the active substance pertuzumab.

How is Perjeta used?

Perjeta can only be obtained with a prescription and treatment should be started under the supervision of a doctor who is experienced in using cancer medicines and in a hospital setting where resuscitation equipment is available.

Perjeta is given by infusion (drip) into a vein. The recommended first dose is 840 mg given over one hour. This is followed by a dose of 420 mg every three weeks, with each dose given over half an hour to one hour. Treatment with Perjeta should be interrupted or stopped permanently if the patient gets certain side effects.

For more information about using Perjeta, see the package leaflet or contact a doctor or pharmacist.

How does Perjeta work?

The active substance in Perjeta, pertuzumab, is a monoclonal antibody, a type of protein that has been designed to attach to HER2, a protein found on HER2-positive cancer cells. By attaching to HER2,

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pertuzumab stops HER2 producing signals that cause the cancer cells to grow. It also activates cells of the immune system (the body's natural defences), which then kill the cancer cells.

What benefits of Perjeta have been shown in studies?

Perjeta has been studied in one main study involving 808 adults with previously untreated HER2-positive metastatic breast cancer. The effects of Perjeta were compared with placebo (a dummy treatment) when given together with other cancer medicines (trastuzumab and docetaxel). Patients were treated until their disease got worse or the side effects of treatment became unmanageable. The main measure of effectiveness was progression-free survival (how long the patients lived without their disease getting worse). Patients treated with Perjeta lived for 18.5 months without their disease getting worse, compared with 12.4 months for patients given placebo.

Perjeta has also been studied in two main studies involving a total of 642 patients with earlier stages of breast cancer who were to undergo surgery. In these studies, Perjeta was given with trastuzumab or chemotherapy or both. The studies looked at how many patients responded to treatment (i.e. patients who had no cancer cells in the breast after surgery). In the first study, 46% of the patients treated with Perjeta plus trastuzumab and docetaxel responded to treatment, compared with 29% of patients who received trastuzumab and docetaxel alone. Response to treatment in the second study ranged from 57% to 66% where Perjeta was given with trastuzumab and chemotherapy medicines.

A fourth ongoing study compared Perjeta with placebo (both given with trastuzumab and chemotherapy) in 4,805 women with early breast cancer who had had surgery to remove the cancer. Perjeta was shown to be of benefit in patients whose cancer was at a high risk of coming back: after 4 years, the disease had not spread in 90% of patients with 'node-positive' cancer treated with Perjeta compared with 87% of those receiving placebo; for those with 'hormone-receptor negative' cancer, this figure was 91% of patients treated with Perjeta, and 89% of patients given placebo.

What are the risks associated with Perjeta?

The most common side effects (affecting more than 3 in 10 people) with Perjeta when given with trastuzumab and chemotherapy are neutropenia (low levels of neutrophils, a type of white blood cell important for fighting infections), diarrhoea, nausea (feeling sick), vomiting, hair loss and tiredness. The most common severe side effect (affecting more than 1 in 10 people) is neutropenia, with or without fever.

For the full list of all side effects and restrictions with Perjeta, see the package leaflet.

Why is Perjeta authorised in the EU?

HER2-positive breast cancer is an aggressive form of breast cancer which occurs in around one in five cases. The European Medicines Agency considered that Perjeta has been shown to benefit patients with metastatic cancer by extending the amount of time patients lived without their disease getting worse as well as how long they lived. It considered that this would provide an additional benefit when added to other medicines for HER2-positive cancer, notably trastuzumab. Perjeta has also been shown to improve the outcome of patients with earlier stages of breast cancer, when used with trastuzumab and chemotherapy. The Agency considered that, despite the side effects of Perjeta, the overall safety profile was acceptable.

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

The company that markets Perjeta will carry out a study to assess the effects of using Perjeta and trastuzumab together with a type of cancer medicines called taxanes, in previously untreated patients with HER2-positive metastatic or locally advanced breast cancer.

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

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

Other information about Perjeta

Perjeta received a marketing authorisation valid throughout the European Union on 4 March 2013.

The full EPAR for Perjeta can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports.

This overview was last updated in 06-2018.