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# Phesgo (*pertuzumab / trastuzumab*)

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

**What is Phesgo and what is it used for?**

Phesgo is a cancer medicine for treating adults with 'HER2-positive' breast cancer (where a protein called HER2 is found on the cancer cells).

It is used in combination with other cancer medicines in:

- patients with early breast cancer (when the cancer has not spread to other parts of the body) at high risk of coming back, after they have surgery;
- patients with locally advanced, inflammatory breast cancer or with early breast cancer at high risk of coming back, before they have surgery;
- patients whose cancer that has come back locally after treatment and cannot be removed by surgery;
- patients with metastatic breast cancer (cancer that has spread to other parts of the body).

Phesgo contains the active substances pertuzumab and trastuzumab. For more information about the use of Phesgo and the other medicines the patients will receive, see the package leaflet.

## How is Phesgo used?

Phesgo 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.

Phesgo is given as an injection under the skin. The first dose is given over 8 minutes as an injection containing pertuzumab 1200 mg and trastuzumab 600 mg. This is followed by an injection containing pertuzumab 600 mg / trastuzumab 600 mg given over 5 minutes every 3 weeks. The duration of treatment depends on whether Phesgo is given before or after surgery, and on the type of breast cancer being treated.

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

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## How does Phesgo work?

The active substances in Phesgo, pertuzumab and trastuzumab, are monoclonal antibodies (a type of protein) that have been designed to attach to HER2. HER2 is a protein on cancer cells that makes the tumour cells grow more quickly and that is present in large quantities in about a quarter of breast cancers. By attaching to HER2, pertuzumab and trastuzumab stop HER2 from producing signals that cause the cancer cells to grow. They also activate cells of the immune system (the body's natural defences), which then kill the cancer cells.

Pertuzumab and trastuzumab attach to 2 different parts of HER2 and their actions have a complementary effect. These combined actions slow down cancer growth.

## What benefits of Phesgo have been shown in studies?

Pertuzumab and trastuzumab given by infusion (drip) into a vein are already authorised to be used together for treating HER2-positive breast cancer. A main study in 500 patients showed that Phesgo given under the skin was as effective as this combination.

The study showed that the levels of pertuzumab and trastuzumab in the blood were similar in patients who received Phesgo and those who received the combination by infusion. In addition, in both groups, about 60% of patients (150 out of 252 in the Phesgo group and 148 out of 248 in the pertuzumab plus trastuzumab group) had no signs of cancer in the breast and glands under the arm after one year of treatment.

## What are the risks associated with Phesgo?

The most common side effects with Phesgo (which may affect more than 3 in 10 people) are alopecia (hair loss), diarrhoea, nausea (feeling sick), anaemia (low red blood cell counts), weakness and joint pain.

The most common serious side effects with Phesgo (which may affect up to 1 in 10 people) are neutropenia (low white blood cell counts) with or without fever, heart failure (when the heart does not pump blood as well as it should), fever, infections of blood or lungs (sepsis, pneumonia) and decreased neutrophil (a type of white blood cell) count.

For the full list of side effects and restrictions of Phesgo, see the package leaflet.

## Why is Phesgo authorised in the EU?

Phesgo contains two active substances, pertuzumab and trastuzumab, which are already authorised for treating early and metastatic HER2-positive breast cancer and are available as infusion into a vein. Phesgo is as effective at treating breast cancer as the individual medicines given into a vein. Because it is given under the skin, it may be more convenient for patients and is less invasive and faster than being given the medicines by infusion. Apart from the reactions at the injection site, the side effects with Phesgo are similar to those seen with pertuzumab and trastuzumab medicines by infusion.

The European Medicines Agency therefore decided that Phesgo's benefits are greater than its risks and it can be authorised for use in the EU.

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

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

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

## Other information about Phesgo

Phesgo received a marketing authorisation valid throughout the EU on 21 December 2020.

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

This overview was last updated in 12-2020.