Package leaflet: Information for the user

Phesgo®
1200 mg/600 mg
solution for injection

(pertuzumab/trastuzumab)

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information.
You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

The name of your medicine is Phesgo 1200 mg/600 mg solution for injection but will be referred to as Phesgo throughout this leaflet. Phesgo is available in two different strengths. See section 6 for more information. Please note that the leaflet also contains information about other strengths.

1. What Phesgo is and what it is used for

Phesgo is a cancer medicine that contains two active substances: pertuzumab and trastuzumab.
- Pertuzumab and trastuzumab are 'monoclonal antibodies'. They are designed to attach to a specific target on cells called "human epidermal growth factor receptor 2" (HER2).
- HER2 is found in large amounts on the surface of some cancer cells and stimulates their growth.
- By attaching to HER2 on cancer cells, pertuzumab and trastuzumab slow down their growth, or kill them.

Phesgo is used to treat adult patients with breast cancer that is of the "HER2-positive" type – your doctor will test you for this.
It can be used when:
- the cancer has spread to other parts of the body such as the lungs or liver (metastasised), or the cancer has come back in the breast and the area around breast, but cannot be operated, and no treatment with cancer medicines (chemotherapy) or other medicines designed to attach to HER2 has been given.
- the cancer has not spread to other parts of the body, and treatment is going to be given either before surgery (neoadjuvant therapy) or after surgery (adjuvant therapy).

As part of your treatment with Phesgo you will also receive other medicines called chemotherapy. Information about these medicines is described in separate package leaflets. Ask your doctor, pharmacist or nurse to give you information about these other medicines.

2. What you need to know before you are given Phesgo

You must not be given Phesgo
- if you are allergic to pertuzumab, trastuzumab, or to any of the other ingredients of this medicine (listed in section 6).

If you are not sure, talk to your doctor, pharmacist or nurse before you are given Phesgo.

Warnings and precautions
Heart problems
Treatment with Phesgo may affect the heart. Talk to your doctor, pharmacist or nurse before you are given Phesgo if:
- you have ever had heart problems (such as heart failure, treatment for serious irregular heart beats, uncontrolled high blood pressure, recent heart attack).Your doctor will run tests to check if your heart is working properly before and during treatment with Phesgo.
- you have ever had heart problems during previous treatment with a medicine containing trastuzumab.
- you have ever had a chemotherapy medicine from the class of cancer medicines called anthracyclines, e.g. doxorubicin or epirubicin – these medicines can damage heart muscle and increase the risk of heart problems with Phesgo.
- you have ever had a radiotherapy to the chest area, as it can increase the risk of heart problems.

If any of the above applies to you (or you are not sure), talk to your doctor or nurse before you are given Phesgo. See section 4 "Serious side effects" for more details about signs of heart problems to look out for.

Injection reactions
A reaction to the injection can happen. These are allergic reactions and can be severe.

If you get any serious reaction, your doctor may stop treatment with Phesgo. See section 4 ''Serious side effects'' for more details about injection related reactions to look out for during the injection and thereafter.

Your doctor or nurse will check for side effects during your injection and for:
- 30 minutes after the first injection of Phesgo.
- 15 minutes after subsequent injection of Phesgo.

If you get any serious reaction, your doctor may stop treatment with Phesgo.

Low levels of white blood cells and fever (Febrile neutropenia)
When Phesgo is given with chemotherapy medicines, the number of white blood cells may drop and fever may develop. If you have inflammation of the digestive tract (e.g. sore mouth or diarrhoea) you may be more likely to develop this side effect. If the fever persists for several days, this may be a sign of worsening of your condition and you should contact your physician.

Diarrhoea
Treatment with Phesgo may cause severe diarrhoea. Patients over 65 years of age have a higher risk of diarrhoea compared with patients younger than 65 years of age. If you get severe diarrhoea during your cancer treatment, your doctor may give you medicines to control diarrhoea. Your doctor may also stop your treatment with Phesgo until the diarrhoea is under control.

Children and adolescents
Phesgo should not be given to patients under the age of 18 years because there is no information on how it works in this age group.

Elderly patients over 65
Patients over 65 years of age are more likely to get side effects such as reduced appetite, decrease in the number of red blood cells, weight loss, tiredness, loss or altered taste, weakness, numbness, tingling or prickling sensations mainly affecting the feet and legs and diarrhoea, compared to patients younger than 65 years of age.

Other medicines and Phesgo
Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines.

Pregnancy, breast-feeding and contraception
Before starting treatment, you must tell your doctor, pharmacist or nurse if you are pregnant or breast-feeding, or if you think you may be pregnant or are planning to have a baby. They will discuss with you the benefits and risks for you and your baby of taking Phesgo while you are pregnant.
- Tell your doctor straight away, if you get pregnant during treatment with Phesgo or during the 7 months after stopping treatment. Phesgo may harm the unborn baby. You should use effective contraception during treatment with Phesgo and for 7 months after stopping treatment.
- Ask your doctor about whether you can breast-feed during or after treatment with Phesgo.

Driving and using machines
Phesgo may affect your ability to drive or operate machines.
If during treatment you experience symptoms, such as feeling dizzy, chills, fever or any injection or allergic reactions as described in section 4, you should not drive or use machines until these symptoms disappear.

Phesgo contains Sodium
Phesgo contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially sodium-free.

Phesgo contains Polysorbate
Phesgo contains polysorbate 20.
Each vial of 15 mL solution contains 6.0 mg of polysorbate 20.
Each vial of 10mL solution contains 4.0 mg of polysorbate 20.
Polysorbate may cause allergic reactions. Tell your doctor if you have any known allergies.

3. How you are given Phesgo

Phesgo will be given to you by a doctor or nurse as an injection under your skin (subcutaneous injection). The treatment will begin in a hospital or clinic. If you tolerate the treatment, your doctor may decide whether you receive Phesgo outside of the hospital or clinic, for example at your home.
- Injections will be given every three weeks.
- You will get the injection first in one thigh and then in the other. You will keep getting the injection in one thigh then the other.
- Your doctor or nurse will make sure that each injection is given in a new place (at least 2.5 cm away from any previous place of injection), and where the skin is not red, bruised, tender or hard.
- Different places for injection should be used for other medicines.

Start of the treatment (loading dose)
- Phesgo 1200 mg/600 mg will be given under your skin over 8 minutes. Your doctor or nurse will check for side effects during your injection and for 30 minutes afterwards.
- You will also be given chemotherapy

Subsequent injections (maintenance doses), which will be given if the first injection have not caused severe side effects:
- Phesgo 600 mg/600 mg will be given under your skin over 5 minutes. Your doctor or nurse will check for side effects during your injection and for 15 minutes afterwards.
- You will also be given chemotherapy, depending on the doctor's prescription.
- The number of injections you will be given depends on:
  - how you respond to treatment
  - whether you are having treatment before surgery or after surgery or for disease which has spread.

For further information on loading and maintenance dose see section 6.
For further information on dosing of chemotherapy (which can cause side effects as well), please read the package leaflet for these medicines. If you have questions about them, please ask your doctor, pharmacist or nurse.

Administration outside the clinical setting
Information for healthcare professionals on how to prepare and administer Phesgo is provided at the end of this leaflet.

If you forget to have Phesgo
If you miss your appointment to have Phesgo make another appointment as soon as possible. Depending on how much time passed between the two visits, your doctor will decide which strength of Phesgo to give you.

If you stop having Phesgo
Do not stop your treatment with this medicine without talking to your doctor first. It is important that you are given the full course of injections at the right time every three weeks. This helps your medicine work as well as it can.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

Tell a doctor or nurse straight away, if you notice any of the following side effects:
- **Heart problems:** a slower or faster heart beat than usual or fluttering of the heart and symptoms that can include cough, shortness of breath, and swelling (fluid retention) in your legs or arms.
- **Injection related reactions:** these may be mild or more severe and may include feeling sick, fever, chills, feeling tired, headache, loss of appetite, joint and muscle pains, and hot flushes.
- **Diarrhoea:** these may be mild or moderate but can be very severe or long-lasting diarrhoea, passing 7 or more watery stools in a day.
- **Low number of white blood cells** as shown in a blood test. This may or may not be with a fever.
- **Allergic reactions:** swelling of your face and throat, with difficulty in breathing, this may be a sign of a serious allergic reaction.

Tell a doctor or nurse straight away, if you notice any of the side effects above.

Other side effects
Very common (may affect more than 1 in 10 people):
- Hair loss
- Rash
- Inflammation of your digestive tract (e.g. sore mouth)
- Decrease in the number of red and white blood cells as shown in a blood test
- Muscle weakness
- Constipation
- Loss of taste, or a change in the way things taste
- Not being able to sleep
- Weak, numb, tingling or prickling sensations mainly affecting the feet, legs and hands
- Nose bleeds
- Heartburn
- Dry, itchy or acne like skin
- Pain at the injection site, reddened skin (erythema) and bruising at the injection site
- Nail problems, such as discoloration like white or dark streaks or change in nail color
- Sore throat, red, sore or runny nose, flu-like symptoms and fever which may lead to infection of the ear, nose or throat
- Producing more tears
- Pain in the body, arms, legs, and belly
- Sharp jabbing, throbbing, freezing or burning pain
- Feeling pain from something which should not be painful, such as a light touch
- Loss of balance or coordination

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Common (may affect up to 1 in 10 people):
- Difficulty in breathing
- Reduced ability to feel changes in temperature
- Inflammation of the nail bed where the nail and skin meet
- Condition in which the left part of the heart is not working properly with or without symptoms
- Condition in which the heart muscle becomes weak which may translate to difficulty in breathing
- Allergic reaction causing range of symptoms from mild to severe such as fever, chills, headache, and difficulties in breathing.

Uncommon (may affect up to 1 in 100 people):
- Chest symptoms such as a dry cough or breathlessness (possible signs of 'interstitial lung disease', a condition of damage to the tissues around the air sacs in the lungs)
- Fluid around the lungs causing difficulty in breathing

Rare side effects have been seen with intavenous pertuzumab but not with Phesgo such as Tumour Lysis Syndrome (where cancer cells die quickly). Symptoms of Tumour Lysis Syndrome may include: kidney problems - (signs include weakness, shortness of breath, fatigue and confusion), heart problems (signs include fluttering of the heart or a faster or slower heart beat, seizures (fits), vomiting or diarrhoea and tingling in the mouth, hands or feet).

If you get any of the side effects above, talk to your doctor, nurse or pharmacist.

If you get any of the above after treatment with Phesgo has been stopped, you should get in touch with your doctor immediately and say that you have previously been treated with Phesgo.

Some of the side effects which you get may be due to your breast cancer. If you are given Phesgo with chemotherapy at the same time, some side effects may also be due to these other medicines.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Phesgo

Phesgo will be stored by the health professionals at the hospital or clinic. The storage details are as follows:
- **Keep this medicine out of the sight and reach of children.**
- Do not use this medicine after the expiry date which is stated on the outer carton and the vial after 'EXP'. The expiry date refers to the last day of that month.
- **Store in a refrigerator** (2 °C-8 °C).
- Do not freeze.
- Keep the vial in the outer carton in order to protect from light.
- Once the vial is open, use the solution immediately. Do not use this medicine if you notice any particles in the liquid or it is the wrong colour (see section 6). If this medicine becomes discoloured or shows any signs of deterioration, please contact your pharmacist who will advise you on what to do.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Phesgo contains
The active substances are pertuzumab and trastuzumab.
- **Maintenance dose:** One vial of 10 mL solution contains 600 mg of pertuzumab and 600 mg of trastuzumab. Each mL contains 60 mg of pertuzumab and 60 mg of trastuzumab.
- **Loading dose:** One vial of 15 mL solution contains 1200 mg of pertuzumab and 600 mg of trastuzumab. Each mL contains 80 mg of pertuzumab and 40 mg of trastuzumab.

The other ingredients are vorhyaluronidase alfa, L-histidine, L-histidine hydrochloride monohydrate, α,α-trehalose dihydrate, sucrose, L-methionine, polysorbate 20 and water for injections (see section 2 "Phesgo contains sodium", "Phesgo contains polysorbate").

What Phesgo looks like and contents of the pack
Phesgo is a solution for injection. It is a clear to opalescent solution, colourless to slightly brown supplied in a glass vial. Each pack contains one vial with 15 mL solution.

Product Licence Holder and Manufacturer
Procured from within the EU by the Product Licence holder Orifarm UK Ltd., Ground Floor Suite A2, Breakspear Park, Breakspear Way, Hemel Hempstead, HP2 4TZ, UK

For any information about this medicine, please contact the Product Licence Holder on
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Phesgo 1200 mg/600 mg solution for injection
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POM

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Blind or partially sighted?
Is this leaflet
hard to see or read?
Call +45 63 95 27 00
to obtain the leaflet in a format
suitable for you

The following information is intended for healthcare professionals only:

Administration of Phesgo 600/600mg solution for injection outside of the clinical setting.

Any healthcare professional treating patients outside of the clinical setting should be well informed on both the administration method, and the potential risks associated with Phesgo.

Healthcare professionals should ensure that appropriate medications for the management of hypersensitivity reactions in line with local standard clinical practice (depending on severity and type of reaction e.g. epinephrine, beta-agonists, antihistamines and corticosteroids) are available with them for immediate use.

Phesgo should be stored at 2 °C-8 °C in the original carton until time of use.

Instructions for use
Phesgo should be administered as a subcutaneous injection only. Phesgo is not intended for intravenous administration.

In order to prevent medication errors, it is important to check the vial label to ensure that the medicinal product being prepared and administered is Phesgo 600/600 mg (15mL vial, containing 10mL solution).

Phesgo should be inspected visually to ensure there is no particulate matter or discolouration prior to the administration. If particulate matter or discolouration is observed, the vial should be discarded per local disposal guidelines. Do not shake the vial.

Before use, leave the Phesgo vial at room temperature for about 15 minutes before preparing an injection.

A syringe, a transfer needle and an injection needle are needed to withdraw Phesgo solution from the vial and inject it subcutaneously. Phesgo may be injected using hypodermic injection needles with gauges between 25G-27G and lengths between 3/8"(10 mm)-5/8"(16 mm). Phesgo is compatible with stainless steel, polypropylene, polycarbonate, polyethylene, polyurethane, polyvinyl chloride and fluorinated ethylene polypropylene.

As Phesgo does not contain any antimicrobial-preservative, the medicinal product should be used immediately.
The hypodermic injection needle must be attached to the syringe immediately prior to administration followed by volume adjustment to 10 mL.

The injection site should be alternated between the left and right thigh only. New injections should be given at least 2.5 cm from the previous site on healthy skin and never into areas where the skin is red, bruised, tender, or hard. The dose should not be split between two syringes or between two sites of administration.

The dose should be administered over a period of 5 minutes. The injection may be slowed or paused if the patient experiences injection-related symptoms.

An observation period of 15 minutes after completion of the injection is recommended, where patients should be observed for injection-related reactions and hypersensitivity reactions.

The patient should be given guidance on recognizing symptoms of hypersensitivity reactions or other possible serious side effects (as described in Section 4 of the patient leaflet), and recommendation given to contact a healthcare professional if symptoms occur after the healthcare professional has left the patient.

Phesgo is for single use only. Any unused medicine or waste material should be disposed of in accordance with local requirements. The name and the batch number of the administered product should be clearly recorded.