Patient Information Leaflet

SCHEDULING STATUS

S4

Phesgo® 1 200 mg/600 mg solution for injection

Phesgo® 600 mg/600 mg solution for injection

pertuzumab/trastuzumab

Contains sugar (1 200 mg/600 mg contains 685 mg

and 600 mg/600 mg contains 342 mg)

Read all of this leaflet carefully before you start taking Phesgo

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- Phesgo has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What Phesgo is and what it is used for

Phesgo contains two active substances:

- pertuzumab and trastuzumab
- Phesgo is a medicine used to treat adult with breast cancer when:
  - The breast cancer has been identified to be of the “HER2-positive” form – your doctor will test you for this.
  - The cancer has spread to other parts of the body (metastasised) and has not previously been treated with anticancer medicines (chemotherapy) or other medicines designed to attach to HER2, or else the cancer has come back in the breast after previous treatment.
  - The cancer has not spread to other parts of the body and treatment will be given before surgery takes place (treatment before surgery is called neoadjuvant therapy).

Early stage breast cancer.

The cancer has not spread to other parts of the body and treatment is going to be given after surgery (treatment after surgery is called adjuvant therapy).

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

How Phesgo works

The active substances pertuzumab and trastuzumab are ‘monoclonal antibodies’. These are designed to recognise and attach themselves to specific targets in your body and on the cancer cells. Pertuzumab and trastuzumab recognise and attach to a target called “human epidermal growth factor receptor 2” (HER2).

- HER2 is found in large amounts on the surface of some cancer cells where it stimulates their growth. When pertuzumab and trastuzumab attach to the HER2 cancer cells, they may slow or stop the cancer cells from growing, or may kill them.

2. What you need to know before you use Phesgo

- If you are allergic to pertuzumab, trastuzumab or to any of the other ingredients of this medicine, listed in “What Phesgo contains”. If you are not sure, talk to your doctor, pharmacist or nurse before you receive Phesgo.

Take special care with Phesgo

Heart problems

Treatment with Phesgo may affect the heart. Talk to your doctor or healthcare professional before you receive 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 trastuzumab.
- You have ever had a chemotherapy medicine from a class 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 prior to treatment with Phesgo as it can increase the risk of heart problems.
- If any of the above applies to you (or if you are not sure), talk to your doctor or nurse before you receive 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.

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. See section 4 ‘‘Serious side effects’’ for more details about injection reactions to look out for during the injection and thereafter

Febrile neutropenia (Low levels of white blood cells associated with fever):

When Phesgo is given with other anticancer medicines known as chemotherapy, 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.

Diarrhoea:

Treatment with Phesgo may cause severe diarrhoea. Diarrhoea is a condition where your body produces more-watery stools than normal. Patients over 65 years of age have a higher risk of diarrhoea compared with patients younger than 65 years of age If you experience severe diarrhoea while receiving your anti-cancer treatment, your doctor may start you on anti-diarrhoeal treatment and may stop treatment with Phesgo until the diarrhoea is under control.

Use in children and adolescents:

Phesgo is not recommended if you are under 18 years of age because there is no information on how well it works in this age group.

Other medicines and Phesgo

Taking other medicines with Phesgo

If you are taking/using medicines on a regular basis, including complementary or traditional medicines, the use of Phesgo with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Pregnancy and breastfeeding

Before starting treatment, you must tell your doctor, pharmacist or nurse if you are pregnant or breastfeeding, or if you think you may be pregnant or are planning to have a baby. They will advise you about 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.
- Ask your doctor about whether you can breast-feed during or after treatment with Phesgo.

Phesgo may harm the unborn baby. You should use effective contraception during treatment with Phesgo and for 7 months after stopping treatment. Talk to your doctor about the best contraception for you.

Driving and using machines

Phesgo may affect your ability to drive a 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.

Important information about some of the ingredients of Phesgo

Phesgo contains sucrose. Patients with the rare hereditary conditions of sucrose intolerance should not take Phesgo.

Phesgo contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Phesgo.

3. How to take Phesgo

Phesgo will be given to you by a doctor or nurse in a hospital or clinic.

- It is given as an injection under your skin (subcutaneous injection) every three weeks.
- You will get the injection first in one thigh and then in the other. You will keep getting the injection on one thigh then the other.
- New injections are given at least 2.5 cm away from an old place of injection.
- Injections are not given where the skin is red, bruised, tender or hard.
- Different places for injection are used if other medicines for injection under the skin are used during treatment with Phesgo.

How much will be given

- The amount of medicine you are given and how long the injection will last are different for the first dose and following doses.
- The number of injections you will be given depends on:
- how you respond to treatment
- whether you are having treatment before surgery (neoadjuvant therapy) or after surgery (adjuvant therapy) or for disease which has spread.

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 other chemotherapy

Subsequent injections (maintenance doses), which will be given if the first injection was well tolerated:

- 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.

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

If you take more Phesgo than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take Phesgo:

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

If you stop taking Phesgo:

Do not stop your Phesgo treatment without talking to your doctor first. It is important that you are given all the injections that have been recommended at the right time every three weeks. If you have any further questions on the use of Phesgo talk to your doctor or nurse.

4. Possible side effects

Phesgo can have side effects.

Not all side effects reported for Phesgo are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Phesgo, please consult your doctor, pharmacist or healthcare professional for advice.

Serious side effects

Tell your 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) with symptoms that can include cough, shortness of breath, and swelling (fluid retention) in your legs or arms.
- Allergic reactions: swelling of your face and throat, with difficulty in breathing, this may be a sign of a serious allergic reaction.
- 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: 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.
- Tumour lysis syndrome (where cancer cells die quickly with changes shown in blood tests).

Symptoms may include:

- kidney problems - signs include weakness, shortness of breath, fatigue and confusion,
- heart problems - signs include fluttering of the heart of a faster or slower heart beat,
- seizures, vomiting or diarrhoea and tingling in the mouth, hands or feet.

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

Other side effects include:

Very common (may affect more than 1 in 10 people):

- Diarrhoea
- Hair loss
- Feeling sick, tired, or dizzy
- Rash
- Inflammation of your digestive tract (e.g. sore mouth)

- Decrease in the number of red blood cells as shown in a blood test
- Joint or muscle pain, muscle weakness
- Constipation
- Reduced appetite
- Loss of taste, or a change in the way things taste
- Fever
- Swollen ankles or other body parts - due to your body retaining too much water
- Not being able to sleep
- Headache
- Hot flushes
- Weak, numb, tingling or prickling sensations mainly affecting the feet and legs
- Nose bleeds
- Cough or shortness of breath
- Heartburn
- Dry, itchy or acne like skin
- Pain at the injection site, reddened skin (erythema) and bruising at the injection site
- Nail problems
- Sore throat, red, sore or runny nose, flu-like symptoms and fever
- Producing more tears
- Fever associated with dangerously low levels of a type of white blood cell (neutrophils)
- Pain in the body, arms, legs, and belly

Common (may affect up to 1 in 10 people):

- A feeling of numbness, prickling or tingling in your hands
- Sharp jabbing, throbbing, freezing or burning pain
- Feeling pain from something which should not be painful, such as a light touch

- Less able to feel changes in temperature
- Loss of balance or coordination
- Infection of the ear, nose or throat
- Inflammation of the nail bed where the nail and skin meet
- Condition in which the left ventricle of the heart is functionally impaired with or without symptoms

Uncommon (may affect up to 1 in 100 people):

- Chest symptoms such as a dry cough or breathlessness (possible signs of 'interstitial lung disease', acondition of damage to the tissues around the air sacs in the lungs)
- Fluid around the lungs causing difficulty in breathing

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

If you experience any of the above after treatment with Phesgo has been stopped, you should consult your doctor immediately and inform him or her 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

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reaction Report Form", found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8

5. How to store Phesgo

Phesgo will be stored by the healthcare professionals at the hospital or clinic

Store in a refrigerator (2 °C-8 °C).

Keep vial in the outer carton in order to protect from light until required for use.

Do not freeze. Do not shake.

Store all medicines out of reach of children.

Do not use this medicine after the expiry date which is stated on the outer carton after 'EXP'

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).

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 protect the environment.

6. Contents of the pack and other information

What Phesgo contains

The active substances are pertuzumab and 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.
- 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.

The other ingredients are vorhyaluronidase alfa, L-histidine, L-histidine hydrochloride monohydrate, α,α-trehalose dihydrate, Sucrose, L-methionine, Polysorbate 20 and water for injection

What Phesgo looks like and contents of the pack

Phesgo is a solution for subcutaneous injection. It is a clear to opalescent solution, colourless to slightly brown. Each pack contains one vial.

Phesgo 1200 mg/600 mg solution for subcutaneous injection (loading dose):

One 20 mL clear, glass, type I vial with butyl rubber stopper laminated with fluororesin containing 15 mL solution of 1200 mg of pertuzumab and 600 mg of trastuzumab.

Phesgo 600 mg/600 mg solution for subcutaneous injection (maintenance dose):

One 15 mL clear, glass, type I vial with butyl rubber stopper laminated with fluororesin containing 10 mL solution of 600 mg of pertuzumab and 600 mg of trastuzumab.

20 mm, aluminum seal with plastic flip-off cap (cool green flip-off color for the loading dose and orange flip-off color for maintenance dose).

7. Holder of Certificate of Registration

Roche Products (Pty) Ltd

90 Bekker Road, Hertford Office Park,

Building E, Vorna Valley,

Midrand,Johannesburg,1686

South Africa

Roche Ethical Assistance Line (REAL) toll-free: 0800 21 21 25

8. Registration number(s)

Phesgo 600 mg/600 mg: 550445

Phesgo 1 200 mg/600 mg: 550444

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Botswana	S2 BOT2203970/1
Namibia	S2 23/26/0013/4
Zimbabwe	PP 2023/9/7/6394/5