PRODUCT MONOGRAPH

INCLUDING PATIENT MEDICATION INFORMATION

[Pr]PHESGO®

pertuzumab and trastuzumab injection

Sterile solution, 80 mg/mL pertuzumab (1200 mg) and 40 mg/mL trastuzumab (600 mg)

Sterile solution, 60 mg/mL pertuzumab (600 mg) and 60 mg/mL trastuzumab (600 mg)

For subcutaneous injection

Professed Standard

ATC Code: L01XY

Antineoplastic

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PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrPHESGO®

pertuzumab and trastuzumab injection

Read this carefully before you start taking **PHESGO** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **PHESGO**.

Serious Warnings and Precautions

- **Heart Problems:** PHESGO may cause heart problems, including those without symptoms (such as reduced heart function) and those with symptoms (such as congestive heart failure). Your health professional may run tests to monitor your heart function before and during treatment with PHESGO. Based on test results your doctor may hold or discontinue treatment with PHESGO. See *"Serious side effects"* for more details about signs of heart problems to look out for.
- **Toxicity to Fetus (Unborn baby):** Exposure to PHESGO can result in harm to the fetus (unborn baby) in some cases death of the fetus, when taken by a pregnant woman. Your health professional will advise you of these risks and the need for effective contraception while you are taking PHESGO and 7 months after the last dose of treatment because of the length of time PHESGO can remain in the body.

What is PHESGO used for?

PHESGO is used to treat people with breast cancer when:

- There are a large number of "HER2-positive" cancer cells involved - your health professional will test your cancer for this;
- the cancer has spread to areas near the breast or to other parts of your body (metastasized);
- the cancer may have advanced in one region and has not spread to other parts of the body and treatment is going to be given before surgery (treatment before surgery is called neoadjuvant therapy); or
- 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 well as PHESGO you will also receive medicines called chemotherapy. Information about these medicines is described in separate patient information leaflets. Ask your doctor or nurse to give you information about these other medicines.

How does PHESGO work?

PHESGO is made up of two medicines combined together that belong to a group of medicines called monoclonal antibodies (pertuzumab and trastuzumab).

- PHESGO recognizes the cancer cells in the body called "human epidermal growth factor 2" or HER2 for short. HER2 is found in large amounts on the surface of some cancer cells where it stimulates their growth. When PHESGO attaches to the HER2 cancer cells, it may slow or stop the cancer cells from growing, or may kill them.

What are the ingredients in PHESGO?

Medicinal ingredients: pertuzumab and trastuzumab.

Non-medicinal ingredients: α,α-trehalose dihydrate; L-histidine; L-histidine hydrochloric monohydrate; L-methionine; polysorbate 20; recombinant human hyaluronidase (rHuPH20); and sucrose.

PHESGO comes in the following dosage forms:

- **Loading dose:** Sterile solution in a 20 mL vial containing 1200 mg pertuzumab (80 mg/mL) and 600 mg trastuzumab (40 mg/mL).
- **Maintenance dose:** Sterile solution in a 15 mL vial containing 600 mg pertuzumab (60 mg/mL) and 600 mg trastuzumab (60 mg/mL).

Do not use PHESGO if:

You should not be given PHESGO if you are allergic to this drug or to any ingredients in the formulation (see 'What are the ingredients in PHESGO?'). If you are not sure, talk to your health professional before you are given PHESGO.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take PHESGO. Talk about any health conditions or problems you may have, including if you:

- have ever had heart problems (such as heart failure, heart attack, treatment for serious irregular heartbeats, uncontrolled high blood pressure) – your doctor will run tests to check if your heart is working properly;
- you have ever had heart problems during previous treatment with trastuzumab;
- you have ever had chemotherapy medicine from the class called anthracycline, e.g. doxorubicin – these medicines can damage heart muscle and increase the risk of heart problems with PHESGO;
- you have ever had radiotherapy to the chest area prior to treatment with PHESGO as it can increase the risk of heart problems; or
- you have ever had a serious infusion-related (allergic) reaction when treated with pertuzumab or trastuzumab.

Other warnings you should know about:

PHESGO can cause side effects. See 'What are the possible side effects of using PHESGO?' below.

Patients aged below 18 years: PHESGO should not be used in these patients as there is no information on how well it works and if it is safe to use in these younger patients.

Pregnancy, breast-feeding and fertility: PHESGO is not recommended if you are pregnant. Tell your health professional straight away if you get pregnant during treatment with PHESGO or during the 7 months after stopping treatment.

Before starting treatment, you must tell your health professional if you are pregnant, think you may be pregnant or are planning to have a baby. You should also tell your health professional if you are breast-feeding.

- Tell your health professional straight away if you get pregnant during treatment with PHESGO or during the 7 months after stopping treatment.
- Ask your health professional 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. If you are a male patient taking PHESGO with a female partner who can become pregnant you should use effective contraception during treatment with PHESGO and for 7 months after stopping treatment. Talk to your health professional about the best contraception for you.

Driving and using machines: PHESGO may affect your ability to drive or use machines. If you experience infusion-related reactions (e.g. flushing, shivering fits, fever, trouble breathing, low blood pressure, rapid heartbeat, sudden swelling of your face, tongue, or trouble swallowing) do not drive and use machines until symptoms stop completely.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with PHESGO:
There is no information on drug interactions with PHESGO.

Tell your health professional if you are taking, have recently taken or might take any other medicines.

This includes medicines obtained without a prescription and herbal medicines.

How to take PHESGO:

PHESGO will be given to you by a health professional.

Usual dose:

- It is given by injection under the skin (subcutaneous injection) once every 3 weeks.
- The first dosage, which is a **loading dose** of PHESGO (1200 mg pertuzumab and 600 mg trastuzumab) will be given to you over 8 minutes. You will be watched by a health professional while it is being given for at least 30 minutes following the initial dose, in case you have any side effects.
- If this initial dose is well tolerated, a **maintenance dose** of PHESGO (600 mg pertuzumab and 600 mg trastuzumab) on your next visit may be given over 5 minutes. This maintenance dose will follow every 3 weeks. You will be watched by a health professional while it is being given for at least 15 minutes following the dose, in case you have any side effects.
- You will also be given other chemotherapy.
- Your doctor may consider switching your intravenous pertuzumab and trastuzumab treatment to PHESGO treatment (and vice versa) if considered appropriate for you.

Overdose:

If you think you, or a person you are caring for, have taken too much PHESGO, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if

there are no symptoms.

Missed Dose:

If you forget or miss your PHESGO appointment, discuss this as soon as possible with your health professional to make another appointment.

Do not stop having this medicine without talking to your health professional first. If you have any further questions on the use of this medicine, ask your health professional.

What are possible side effects from using PHESGO?

These are not all the possible side effects you may have when taking PHESGO. If you experience any side effects not listed here, tell your healthcare professional.

Like all medicines, this medicine can cause unwanted effects. Tell your health professional if you notice any of the side effects given below.

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

- Feeling sick (nausea, vomiting)
- Hair loss
- Nail disorders
- Diarrhea
- Constipation
- Indigestion
- Anemia (decreased red blood cells shown in a blood test)
- Decreased white blood cells (shown in a blood test)
- Physical weakness
- Feeling tired
- Inflammation of mouth and lips
- Fever
- Muscle pain
- Decreased appetite
- Altered taste
- Joint pain
- Difficulty sleeping
- Headache
- Pins and needle sensation
- Cough
- Upper respiratory tract infection
- Dry Skin
- Rash
- Liver enzymes increased
- Nose bleeds

- Procedural pain

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

- Weight decreased
- Dizziness
- Back pain
- Chills or flu like symptoms
- Hot flush
- Redness of the skin
- Bone pain
- White blood cell count decreased (shown in a blood test)
- Decrease in your potassium levels (shown in a blood test)
- Runny nose
- Pain in hands and feet
- Urinary tract infection
- Itching
- Injection site reaction
- Acid reflux disease
- Mouth sores
- Swelling
- Chest Pain
- Low platelet count (shown in a blood test)
- High white blood cell count (shown in blood test)
- Damage to the nervous system (brain or nerves)
- Elevated liver enzyme may be a sign of inflamed liver
- Muscle spasms
- Dry nose
- Pink eye
- Increased tearing
- Inflammation of the bladder
- Sore throat
- Thrush
- Increased blood cholesterol or lipid levels
- Depression
- Anxiety
- Dry eye
- High blood pressure (Hypertension)
- Breast pain
- Heart palpitations
- Hemorrhoids
- Heartburn
- Stomach pain
- Dry mouth
- Muscle pain

- Pain at injection site
- Increased blood sugar
- Increase in your chloride levels (shown in a blood test)
- Low blood pressure (Hypotension)
- Bruising
- Irregular menstrual periods
- Dryness of the vulva or vagina
- Rapid heart rate
- Difficult or painful to urinate (pass water)
- Inflammation or infection around the nail bed
- Difficulty breathing
- Heart pumping less blood as determined on testing
- Wounds not healing well
- Hand-foot syndrome (redness, swelling, tingling, pain on the palms of the hands and/or the soles of the feet)
- Not feeling well
- Pain

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
VERY COMMON			
Raised body temperature, fever		✓	
Chills, sore throat, cough, any redness or swelling, pain when you pass your urine		✓	
COMMON			
Fever with signs of infection		✓	
Flushing, shivering fits, fever, trouble breathing, low blood pressure, rapid heartbeat, sudden swelling of your face, tongue, trouble swallowing		✓	
If you become pregnant		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store vials in the refrigerator (2 - 8°C).
- Do not freeze. Do not shake.
- Keep vial in the outer carton to protect from light.
- Do not use this medicine after the expiry date which is stated on the outer carton after EXP. The expiry date refers to the last day of that month.
- Keep out of reach and sight of children.

If you want more information about PHESGO:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html; the manufacturer's website www.rochecanada.com, or by calling 1-888-762-4388 number.

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