

New Zealand Consumer Medicine Information - Phesgo®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Phesgo?

Phesgo contains the active ingredients pertuzumab and trastuzumab. Phesgo is used to treat the following stages of breast cancer;

- early breast cancer, either before or after surgery
- breast cancer that has spread to other parts of the body

For more information, see Section [1. Why am I using Phesgo?](#) in the full CMI.

2. What should I know before I am given Phesgo?

Do not use if you have ever had an allergic reaction to Phesgo or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I am given Phesgo?](#) in the full CMI.

3. What if I am taking other medicines?

Tell your doctor if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop

For more information, refer to Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is Phesgo given?

- Phesgo is given as an injection under the skin every 3 weeks
- A healthcare professional will prepare and give you the injection

More instructions can be found in Section [4. How is Phesgo given?](#) in the full CMI.

5. What should I know while using Phesgo?

Things you should do	<ul style="list-style-type: none">• Remind any doctor or dentist you visit that you are using Phesgo.• Tell your doctor as soon as possible if you do not feel well while you are receiving Phesgo• Tell your doctor as soon as possible if you think you are pregnant
Things you should not do	<ul style="list-style-type: none">• Do not use Phesgo if you are allergic to pertuzumab and trastuzumab, or any of the ingredients listed at the end of this leaflet• Do not use Phesgo if you are pregnant and do not breastfeed while you are given Phesgo
Driving or using machines	<ul style="list-style-type: none">• Phesgo may cause dizziness in some people. Be careful before you drive or use any machines or tools until you know how Phesgo affects you.
Drinking alcohol	<ul style="list-style-type: none">• There are no known effects of being given Phesgo and taking alcohol

For more information, see Section [5. What should I know while using Phesgo?](#) in the full CMI.

6. Are there any side effects?

There are some serious side effects that you should be aware of. Reactions such as swelling of the face, lips, tongue, throat or other parts of the body, trouble breathing, abnormal heartbeat, wheezing, coughing, rash, itching or hives on the skin, feeling sick, fever, chills, feeling tired and/or headache are serious side effects. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Phesgo®

Active ingredients: pertuzumab (rch) and trastuzumab (rch)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Phesgo. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Phesgo.**

Where to find information in this leaflet:

- [1. Why am I using Phesgo?](#)
- [2. What should I know before I am given Phesgo?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is Phesgo given?](#)
- [5. What should I know while using Phesgo?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Phesgo?

Phesgo contains the active ingredients pertuzumab and trastuzumab. Pertuzumab and trastuzumab belong to a group of medicines known as anti-neoplastic (or anti-cancer) agents. There are many different classes of anti-neoplastic agents. Pertuzumab and trastuzumab belong to a class called monoclonal antibodies.

Pertuzumab and trastuzumab recognise and attach to a protein called human epidermal growth factor receptor 2 (HER2). HER2 is found in large amounts on the surface of some cancer cells. When pertuzumab and trastuzumab attach to HER2 cancer cells it may kill them or slow/stop the cancer cells from growing.

Phesgo is used to treat the following stages of breast cancer;

- early breast cancer either before or after surgery
- breast cancer that has spread to other parts of the body

It is only used for patients whose tumour has tested positive for HER2.

2. What should I know before I am given Phesgo?

Warnings

Do not use Phesgo if:

- you are allergic to pertuzumab, trastuzumab, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

Tell your doctor if:

- you have a history of heart problems such as heart failure, abnormal beating of the heart, poorly

controlled blood pressure or have had a recent heart attack

- you have previously been treated with chemotherapy medicines known as anthracyclines (e.g. doxorubicin) or radiation therapy; these medicines or treatment can damage heart muscle and increase the risk of heart problems with Phesgo
- you take any medicines for any other condition
- you are allergic to any other medicines or any other substances such as foods, preservatives or dyes. Allergic or anaphylactic (more severe allergic) reactions can occur with Phesgo treatment (known as injection related reactions). Your doctor or nurse will check for side effects while you are receiving Phesgo and for 15- 30 minutes afterwards. If you get any serious reactions, your doctor may stop treatment with Phesgo. See Section [6. Are there any side effects](#) for symptoms to look out for.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects](#)?

Pregnancy and breastfeeding

Tell your doctor if you are pregnant or intend to become pregnant.

- Do not use Phesgo if you are pregnant. Phesgo may be harmful to your unborn baby. Your doctor will advise you about using effective contraception to avoid becoming pregnant while you are being treated with Phesgo and for 7 months after stopping treatment.
- Use contraception if your female partner is of childbearing age

Talk to your doctor if you are breastfeeding or intend to breastfeed.

- It is not known if Phesgo passes into breast milk. You should talk to your doctor about whether you can breast feed while you are being treated with Phesgo.

If you have not told your doctor about any of the above, tell them before you are given Phesgo.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Phesgo.

4. How is Phesgo given?

How is it given

- Follow all directions given to you by your doctor or nurse carefully. They may differ from the information contained in this leaflet
- Phesgo must be prepared by a healthcare professional and will be given in a hospital or clinic by a doctor or nurse
- Phesgo 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 and it will swap with each injection

How much will you 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)

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)

If the first injection was well tolerated, you will be given 600 mg/600 mg of Phesgo 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 about the dose of other anti-cancer medicines given, please ask your doctor, nurse or pharmacist for the Consumer Medicine Information (CMI) leaflets for these medicines.

If you miss a dose

As Phesgo is given under the supervision of your doctor, you are unlikely to miss a dose. However, 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 are given too much Phesgo

As Phesgo is given under the supervision of your doctor, it is unlikely that you will be given too much. However, if you experience any side effects after being given Phesgo, tell your doctor immediately.

5. What should I know while using Phesgo?

Things you should do

Tell your doctor or nurse immediately if you have any signs and symptoms of an allergic or anaphylactic reaction.

Some signs and symptoms include;

- swelling of your face, lips, tongue or throat with difficulty breathing
- swelling of other parts of your body
- shortness of breath, wheezing or trouble breathing
- rash, itching or hives on the skin
- feeling sick (nausea)
- fever, chills
- feeling tired
- headache

Tell your doctor or nurse immediately if you have any signs and symptoms of heart problems.

Some signs and symptoms of heart problems are;

- shortness of breath or getting tired easily after light physical activity (such as walking)
- shortness of breath at night, especially when lying flat
- swelling of the hands or feet due to fluid build up
- cough
- abnormal or irregular heartbeat

Please follow all your doctors' instructions if any of these symptoms require medication.

Tell all doctors, dentists and pharmacists who are treating you, that you are receiving Phesgo.

Things you should not do

- Do not stop your treatment with Phesgo without talking to your doctor first
- Do not take any other medicines, whether they require a prescription or not, without first telling your doctor or consulting with a pharmacist

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Phesgo affects you.

Phesgo may cause dizziness in some people.

Drinking alcohol

Alcohol is unlikely to interact with Phesgo.

6. Are there any side effects?

Tell your doctor as soon as possible if you do not feel well while you are receiving Phesgo. All medicines can have side effects. Phesgo may have some unwanted side effects in some people. You may need medical treatment if you get some of the side effects.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Because Phesgo may be used with other medicines that treat breast cancer, it may be difficult for your doctor to

tell whether the side effects are due to Phesgo or due to the other medicines.

For further information about the side effects of Phesgo and chemotherapy, please ask your doctor, nurse or pharmacist for the Consumer Medicine Information (CMI) leaflets for these medicines.

Serious side effects

Tell your doctor or immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- **signs and symptoms of allergic or anaphylactic reactions:**
 - swelling of your face, lips, tongue or throat with difficulty breathing, or swelling of other parts of your body
 - shortness of breath, wheezing or trouble breathing
 - rash, itching or hives on the skin
 - feeling sick (nausea)
 - fever or chills
 - headache
 - feeling tired
- **signs and symptoms of injection related reactions;** these may be mild or more severe and may include:
 - feeling sick or vomiting
 - fever
 - chills
 - feeling tired
 - headache
 - loss of appetite
 - joint and muscle pains
 - hot flushes
- **signs and symptoms of heart problems:**
 - slower or faster heartbeat than usual
 - fluttering of the heart
 - abnormal or irregular heartbeat
 - cough
 - shortness of breath
 - swelling (fluid retention) in your legs or arms
- **signs and symptoms of tumour lysis syndrome (where cancer cells die quickly):**
 - 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
- **severe chest pain**, spreading out to the arms, neck, shoulder or back
- **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.

- decrease in the number of red blood cells as shown in a blood test

These are serious side effects. You may need medical attention.

Less serious side effects

- constipation
- indigestion or stomach pain
- sore mouth, throat or gut
- fatigue or tiredness
- getting tired more easily after light physical activity such as walking
- shortness of breath especially when lying down or being woken from your sleep with shortness of breath
- nail problems especially inflammation where the nail meets the skin
- hair loss
- feeling dizzy, tired, looking pale
- hot flushes
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- nose bleeds
- heartburn
- eye problems such as producing more tears
- insomnia (trouble sleeping)
- weak, numb, tingling, prickling or painful sensations mainly affecting the feet and legs
- dry, itchy or acne like skin
- loss of appetite
- loss of or altered taste
- joint or muscle pain, muscle weakness
- sore throat, red, sore or runny nose, flu-like symptoms and fever which may lead to infection of the ear, nose or throat
- pain at the injection site, reddened skin (erythema) and bruising at the injection site
- general pain in the body, arms, legs and/or belly including sharp jabbing, throbbing, freezing or burning pain
- feeling pain from something which should not be painful, such as a light touch
- reduced ability to feel changes in temperature
- loss of balance or coordination

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

After you have received medical advice for any side effects you experience, you can report side effects to the Centre for Adverse Reactions Monitoring (CARM) online at <https://nzphvc.otago.ac.nz/consumer-reporting/>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

What Phesgo contains

Active ingredients (main ingredient)	pertuzumab, trastuzumab
Other ingredients (inactive ingredients)	hyaluronidase alfa, histidine, histidine hydrochloride monohydrate, trehalose dihydrate, sucrose, polysorbate 20, methionine

Do not take this medicine if you are allergic to any of these ingredients.

What Phesgo looks like

Phesgo is a solution for injection for subcutaneous use. It is a clear to opalescent solution, colourless to slightly brown supplied in a glass vial. Each pack contains one vial with either 10 mL or 15 mL solution.

Phesgo is only given in hospital.

Who distributes Phesgo

Phesgo is distributed in New Zealand by:

Roche Products (NZ) Limited
PO Box 109113 Newmarket
Auckland 1149
NEW ZEALAND

Medical enquiries: 0800 276 243

This leaflet was prepared on 22 September 2022.