

## **PRODUCT MONOGRAPH**

**Pr** **HERCEPTIN<sup>®</sup> SC**

trastuzumab injection

600 mg / 5 mL single-dose vial

Sterile solution for subcutaneous use only

Professed Standard

Antineoplastic

Hoffmann-La Roche Limited

7070 Mississauga Road

Mississauga, Ontario

L5N 5M8

**Date of Approval:**

September 11, 2018

[www.rochecanada.com](http://www.rochecanada.com)

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## PART III: CONSUMER INFORMATION

Pr **HERCEPTIN® SC**

trastuzumab injection

**600 mg / 5 mL single dose vial**

**This leaflet is part III of a three-part “Product Monograph” published when HERCEPTIN SC was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about HERCEPTIN SC. Contact your doctor or pharmacist if you have any questions about the drug.**

### ABOUT THIS MEDICATION

#### **What the medication is used for:**

- HERCEPTIN SC is a cancer medicine that must be prescribed by a doctor.
- HERCEPTIN SC is used to slow down the growth of specific breast cancer cells that produce large amounts of HER2 protein. It is used only for patients whose tumours are growing more rapidly than normal because of a genetic problem in the cells. This occurs in about 25 to 30% of breast cancer tumours.

#### **What it does:**

- Our bodies have a natural defence system against cancer cells. When cancer cells appear, our bodies respond by making special proteins called antibodies. The antibodies attach to other proteins on the growing tumour cells. Researchers studied this to learn how to create antibodies that help with cancer treatment.
- Antibodies are now made that can target tumours to try to control the growth of cancer.
- HERCEPTIN SC belongs to a family of medicines called monoclonal antibodies. It is an antibody that targets the HER2 gene to stop its activity. It attaches to the HER2 receptor on the cancer cell. When it is in place, it works to stop the growth of the cancer cells and may destroy them.

#### **When it should be used:**

Patients whose breast cancer tumour cells produce large amounts of the HER2 protein can use HERCEPTIN SC.

HERCEPTIN SC is used for certain patients with early breast cancer following surgery and after chemotherapy OR following surgery and with taxane chemotherapy as well as for patients to whom breast cancer has spread to other parts or organs of the body.

#### **When it should not be used:**

Do not use HERCEPTIN SC if you are allergic to trastuzumab, Chinese Hamster Ovary (CHO) cell proteins, or any component of this product (see “What the non-medicinal ingredients are”).

#### **What the medicinal ingredient is:**

The medicinal ingredient in HERCEPTIN SC is trastuzumab. Each single dose vial of HERCEPTIN SC contains 600 mg trastuzumab.

#### **What the non-medicinal ingredients are:**

HERCEPTIN SC contains the following non-medicinal ingredients: Recombinant human hyaluronidase PH20 (rHuPH20), L-histidine, L-histidine hydrochloride monohydrate,  $\alpha, \alpha$ -trehalose dehydrate, L-methionine, Polysorbate 20, Water for injection.

#### **What dosage forms it comes in:**

HERCEPTIN SC is a solution that is given as an injection under the skin (subcutaneous injection).

### WARNINGS AND PRECAUTIONS

#### **Serious Warnings and Precautions**

##### **Medication Errors**

There is a risk of medication errors between HERCEPTIN (trastuzumab) and KADCYLA (trastuzumab emtansine). Verify with the healthcare provider that the recommended HERCEPTIN (trastuzumab) dose and NOT KADCYLA (trastuzumab emtansine) dose is used.

##### **Cardiotoxicity (harm to the heart)**

HERCEPTIN can result in the development of heart problems including heart failure. The appearance of heart failure can be delayed and can occur after treatment with HERCEPTIN is completed. In early breast cancer, the incidence of cardiac dysfunction was higher in patients who received HERCEPTIN plus chemotherapy versus chemotherapy alone, with higher risk when HERCEPTIN was administered together with a taxane following an anthracycline and cyclophosphamide. In patients with breast cancer that has spread to other parts or organs of the body, the incidence and severity of cardiac dysfunction was particularly high in patients who received HERCEPTIN at the same time as anthracyclines and cyclophosphamide.

**You should have your heart function evaluated by your doctor before and during treatment with HERCEPTIN.**

##### **Toxicity to Fetus (Unborn Baby)**

**HERCEPTIN can cause harm to the fetus (unborn baby), in some cases death of the fetus, when taken by a pregnant woman.** Women who could become pregnant need to use effective birth control methods during HERCEPTIN treatment and for at least 7 months after treatment with HERCEPTIN. Nursing mothers treated with HERCEPTIN should discontinue nursing or discontinue HERCEPTIN.

**BEFORE you use HERCEPTIN talk to your doctor or pharmacist if:**

- you have ever had a bad reaction to HERCEPTIN or any of the inactive ingredients;
- you are allergic to hyaluronidase (an enzyme that is part of the formulation that helps to increase the absorption of injected active substance)
- you are allergic to other medicines, food and dyes;
- you are taking any other medicines, including those not prescribed by your doctor;
- you have any other illness or diseases, such as heart problems, heart disease, breathing problems or lung disease; the risk of heart problems may be increased in geriatric patients in both early breast cancer and breast cancer that has spread to other parts or organs of the body; the risk of lung disease may increase if you have taken chemotherapy drugs which are toxic for the lungs;
- you have already been treated with chemotherapy drugs (especially anthracyclines such as doxorubicin, epirubicin or related drugs such as mitoxantrone) or radiation therapy;
- you are pregnant, plan to become pregnant or are breast-feeding a child. Please note that a reduction in the amount of [amniotic] fluid that surrounds the developing fetus within the amniotic sac has been observed in pregnant women receiving HERCEPTIN;
- you have difficulty breathing at rest.

This information will help your doctor and you decide whether you should use HERCEPTIN SC and what extra care may need to be taken while you are on the medication.

### **Driving and using machines**

We do not know whether HERCEPTIN SC could affect your ability to drive a car or operate machines. If you experience unwanted effects related to the HERCEPTIN SC administration (such as itching, wheezing, dizziness, racing heart) you should not drive or operate machinery until symptoms resolve completely.

### **INTERACTIONS WITH THIS MEDICATION**

Formal drug interaction studies with HERCEPTIN have not been done in humans. Important interactions with other medications were not seen during clinical trials with HERCEPTIN.

### **PROPER USE OF THIS MEDICATION**

Your doctor has prescribed HERCEPTIN SC after carefully studying your condition. Other people may not benefit from taking this medicine, even though their problems may seem similar to yours.

Verify with the healthcare provider that the correct formulation is being given as prescribed. HERCEPTIN SC fixed dose formulation is not for intravenous (IV) use and should be given as a subcutaneous (SC) injection only.

HERCEPTIN SC will be given to you by a health care professional who is experienced with the use of this treatment.

Your doctor may consider switching your HERCEPTIN treatment to HERCEPTIN SC treatment (and vice versa) if considered appropriate for you.

Also verify with the healthcare provider that the recommended HERCEPTIN (trastuzumab) dose and NOT KADCYLA (trastuzumab emtansine) dose is used.

### **Usual Dose:**

The recommended dose is 600 mg. HERCEPTIN SC is given as a subcutaneous injection (under the skin) over 2 to 5 minutes every three weeks.

The injection site should be alternated between the left and right thigh. New injections should be given at least 2.5 cm away from an old site. No injection should be given into areas where the skin is red, bruised, tender or hard.

If other medicines for subcutaneous use are used during the treatment course with HERCEPTIN SC, a different injection site should be used.

### **Overdose:**

It is unlikely that you will receive too much HERCEPTIN SC as you will be closely monitored by Healthcare Professionals during your administration. However, if you suspect you received too much HERCEPTIN SC contact your doctor and poison control centre immediately.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

For information on the risk of KADCYLA overdose due to medication errors, see the KADCYLA Product Monograph.

### **Missed Dose:**

If you miss a dose of HERCEPTIN SC, contact your doctor immediately. Your doctor will advise you on when your next administration of HERCEPTIN SC will be.

### **SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Unwanted effects are possible with all medicines. Talk to your doctor, nurse or pharmacist if you are worried about side effects or find them very bothersome, and report any new or continuing symptoms to your doctor immediately. Your doctor will be able to tell you what to do and may be able to help you with these side effects.

Some unwanted effects happen during the first administration or shortly after it is completed. The effects usually do not last long but may need treatment.

These unwanted effects related to the administration may include:

- Itching
- Wheezing
- Dizziness
- Racing heart

Giving certain medications before the next administration of HERCEPTIN may prevent these unwanted effects.

In clinical studies, the most common unwanted effects were fever and chills, nausea, vomiting, diarrhea, pain, and headache. The symptoms can easily be treated. Giving certain medications before HERCEPTIN can prevent some unwanted effects.

Less common unwanted effects are:

- Shortness of breath and water retention, which are symptoms of heart problems. These are caused by an effect on the heart muscle that reduces the strength of the pumping action of the heart. This unwanted effect is more common in women who have previously had anthracycline chemotherapy (e.g. doxorubicin, epirubicin). Heart failure as a result of HERCEPTIN treatment can vary in severity and may require treatment with heart medications and/or HERCEPTIN treatment may need to be stopped..
- Shortness of breath, fatigue, or a racing heart, which are symptoms of anemia. This is caused by a temporary decrease in the number of red blood cells.
- A temporary decrease in the number of white blood cells may increase your risk of infection and diarrhea.

Difficulty breathing, fatigue and weight loss are commonly seen with lung disease.

**Call your doctor immediately if you notice any of the following:**

- Shortness of breath;
- Increased cough;
- Swelling of the legs as a result of water retention;
- Diarrhea – if you have an extra four bowel movements each day or any diarrhea at night;
- Symptoms of infection that include:
  - fever: a temperature of 38°C or greater
  - sore throat
  - cough
  - any redness or swelling
  - pain when you pass urine
- Symptoms of an allergic reaction include:
  - closing of the throat
  - swelling of lips and tongue
  - hives
  - rash
  - dizziness
  - fast heartbeat

## SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
<b>MOST COMMON</b> (≥10%)	<b>Diarrhea</b> Where you have an extra four bowel movements each day or any diarrhea at night		✓	
<b>LESS COMMON</b> (≥ 1 AND ≤ 10%)	<b>Heart problems:</b> Symptoms include shortness of breath, water retention (swelling of the lower legs)		✓	
	<b>Anemia (reduced number of red blood cells of the blood):</b> Symptoms include: shortness of breath, racing heart, dizziness, light headedness		✓	
	<b>Reduced number of white blood cells may lead to an increase chance of infection:</b> Symptoms of infection include: fever (temperature above 38°C or 101°F), chills, sore throat, cough, any redness or swelling, pain when you pass your urine		✓	
	<b>Lung problems:</b> Symptoms include shortness of breath, wheezing or coughing		✓	

***This is not a complete list of side effects. For any unexpected effects while taking HERCEPTIN, contact your doctor, nurse or pharmacist.***

## HOW TO STORE IT

The hospital pharmacy will store HERCEPTIN SC in a refrigerator.

## REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/canada-vigilance-program.html>
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: **Canada Vigilance Program**  
**Health Canada**  
**Postal Locator 1908C**  
**Ottawa, Ontario**  
**K1A 0K9**

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect).

*NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.*

## MORE INFORMATION

**Reminder: This medicine has been prescribed only for you. Do not give it to anybody else. If you have any further questions, please ask your doctor or pharmacist.**

This document plus the full product monograph, prepared for health professionals can be found at:

[www.rochecanada.com](http://www.rochecanada.com)

or by contacting the sponsor, Hoffmann-La Roche Limited, at: 1-888-762-4388.

This leaflet was prepared by Hoffmann-La Roche Ltd.

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Hoffmann-La Roche Limited  
Mississauga, ON L5N 5M8