

HERCEPTIN SC[®]

subcutaneous injection

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 Herceptin SC?

Herceptin SC contains the active ingredient trastuzumab. Herceptin SC is used to treat breast cancer whose tumour has tested positive to HER2. For more information, see Section [1. Why am I using Herceptin SC?](#) in the full CMI.

2. What should I know before I use Herceptin SC?

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

Tell your doctor if you have previously been treated with chemotherapy medicines known as anthracyclines (e.g. doxorubicin); these medicines can damage heart muscle and increase the risk of heart problems with Herceptin SC.

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 use Herceptin SC?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Herceptin SC and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is Herceptin SC given?

Herceptin SC will be given to you in a hospital or clinic by a doctor or nurse. Herceptin SC is given as a subcutaneous injection (under the skin) over 2 to 5 minutes every three weeks. More instructions can be found in Section [4. How do I use Herceptin SC?](#) in the full CMI.

5. What should I know while using Herceptin SC?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using Herceptin SC.Keep all your appointments with your doctor so that you do not miss a dose and your progress is monitored.Tell your doctor or nurse immediately if you have any signs and symptoms of an allergic or anaphylactic reactionTell your doctor or nurse immediately if you have any signs and symptoms of heart problems.
Things you should not do	<ul style="list-style-type: none">Do not stop your Herceptin SC treatment 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.
Pregnancy and Breastfeeding	<ul style="list-style-type: none">Avoid becoming pregnant by using effective contraception while you are being treated with Herceptin SC and for 7 months after stopping treatment.It is recommended that you discontinue breastfeeding while you are being treated with Herceptin SC and not restart breastfeeding until 7 months after completing Herceptin SC treatment.

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

6. Are there any side effects?

Tell your doctor or nurse immediately or go to the nearest hospital Emergency Department if you experience any side effects. Some serious side effects that may occur during or after the treatment includes swelling of your face, lips, tongue or throat with difficulty breathing, swelling of other parts of your body such as hands or feet, shortness of breath, wheezing or trouble breathing, abnormal or irregular heartbeat, rash, itching, hives on the skin, nausea, vomiting, diarrhoea, stomach pain, back pain, chest, shoulder or neck pain, fever or chills, headache, fatigue, tiredness, severe coughing. 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.

HERCEPTIN SC[®]

subcutaneous injection

Active ingredient(s): *trastuzumab (rch)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Herceptin SC. **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 Herceptin SC.**

Where to find information in this leaflet:

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

1. Why am I using Herceptin SC?

Herceptin SC contains the active ingredient trastuzumab. Herceptin SC belongs to a group of medicines known as anti-neoplastic (or anti-cancer) agents. There are many different classes of anti-neoplastic agents. Herceptin SC belongs to a class of anti-neoplastic agents called monoclonal antibodies.

Monoclonal antibodies are proteins made in a laboratory. These proteins are designed to recognise and bind to other unique proteins in the body.

Herceptin SC binds selectively 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 Herceptin SC binds to HER2 receptors it stops the growth and spread of the cancer cells.

Herceptin SC is used to treat the following stages of breast cancer;

- **early breast cancer after surgery**
- **locally advanced breast cancer**
- **metastatic (spreading) breast cancer**

Herceptin SC is only used for patients whose tumour has tested positive to HER2.

Herceptin SC may be used alone or in combination with other medicines that treat breast cancer, such as an aromatase inhibitor (hormone receptor positive breast cancer) or a taxane (e.g. paclitaxel or docetaxel).

For further information about the other medicines you are receiving with Herceptin SC, please ask your doctor, nurse or pharmacist for the CMI leaflet.

Ask your doctor if you have any questions why Herceptin SC has been prescribed for you.

2. What should I know before I use Herceptin SC?

Warnings

Do not use Herceptin SC if:

- you are allergic to trastuzumab, or any of the ingredients listed at the end of this leaflet or any protein of Chinese hamster origin
- you have breast cancer that has not spread (non-metastatic) and
 - you have had an LVEF test result (which measures how well your heart can pump blood) of less than 45% or
 - you have symptoms of heart failure. Symptoms of heart failure may include shortness of breath or tire 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 buildup, abnormal or irregular heartbeat.

Check with your doctor if:

- **you have a history of heart problems such as;** heart disease with angina (chest pain), cardiac arrhythmias (abnormal beating of the heart), heart failure (where the heart cannot pump blood normally), coronary artery disease (also known as CAD, a condition where plaque builds up inside the arteries), poorly controlled high blood pressure.

Your doctor will monitor your heart function closely before and during your treatment with Herceptin SC. Your heart function may also be monitored for years after ceasing Herceptin SC treatment.

- **you have previously been treated with chemotherapy medicines known as anthracyclines** (e.g. doxorubicin); these medicines can damage the heart muscle and increase the risk of heart problems with Herceptin SC
- **you have any breathing or lung problems**
- **you are allergic to any other medicines or any other substances such as foods, preservatives or dyes.**

Allergic or anaphylactic reactions can occur with Herceptin SC treatment (known as administration related reactions). Your doctor or nurse will monitor you for side effects during treatment. 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

Check with your doctor if you are pregnant or intend to become pregnant.

Herceptin SC may be harmful to an unborn baby. If there is a need for Herceptin SC treatment when you are pregnant your doctor will discuss the risks and benefits to you and the unborn baby.

You should use effective contraception to avoid becoming pregnant while you are being treated with Herceptin SC and for 7 months after stopping treatment.

Tell your doctor right away if you become pregnant during treatment with Herceptin.

Breastfeeding

Check with your doctor if you are breastfeeding or intend to breastfeed.

It is not known if Herceptin SC passes into breast milk.

It is recommended that you discontinue breast-feeding while you are being treated with Herceptin SC and not restart breast-feeding until 7 months after completing Herceptin SC treatment.

Use in children

The safety and effectiveness of Herceptin SC in children under 18 years of age have not been established.

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 and/or health food shop.

Herceptin SC treatment in combination with certain medicines used in the treatment of cancer, such as gemcitabine, vinorelbine, a taxane or radiation therapy can increase the chance of lung problems (interstitial lung disease).

Your doctor and pharmacist have more information on medicines to be careful with or avoid while receiving Herceptin SC.

It may take up to seven months for Herceptin SC to be removed from your body.

Tell your doctor or pharmacist that you have had Herceptin SC if you start any new medication in the seven months after stopping treatment.

4. How is Herceptin SC given?

Herceptin SC must be prepared by a healthcare professional and will be given in a hospital or clinic by a doctor or nurse.

- The recommended dose is 600 mg (in a solution of 5 mL). 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. The injection should not 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.

Follow all directions given to you by your doctor or nurse carefully. They may differ from the information contained in this leaflet.

Herceptin SC should not be mixed or diluted with other products.

Your doctor will decide how long you should receive Herceptin SC; this will depend on your response to Herceptin SC and the state of your disease.

If you miss a dose or your appointment to get Herceptin SC

As Herceptin SC 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 Herceptin SC, make another appointment as soon as possible. Your doctor will decide when your next dose of Herceptin SC will be.

If you are given too much Herceptin SC (overdose)

As Herceptin SC is given to you 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 Herceptin SC, tell your doctor immediately.

5. What should I know while receiving Herceptin SC?

Things you should do

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

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.

Your doctor may perform regular tests, including checking your heart function whilst you are being treated with Herceptin SC.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Tell your doctor if you feel that Herceptin SC is not helping your condition.

Things you should not do

Do not stop your Herceptin SC treatment 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 Herceptin SC affects you.

If you experience symptoms during your treatment with Herceptin SC you should not drive or operate machinery.

Looking after your medicine

Herceptin SC will be stored in the pharmacy or on the hospital ward in a refrigerator at a temperature between 2°C and 8°C. Herceptin SC should not be frozen.

The vial must be stored in the outer carton to protect it from light.

6. Are there any side effects?

Tell your doctor as soon as possible if you do not feel well while you are receiving Herceptin SC.

Herceptin SC helps most people with HER2 positive breast cancer but it may have some unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Because Herceptin SC 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 Herceptin SC or due to the other medicines.

For further information about the side effects of any other medicines you are receiving, please ask your doctor, nurse or pharmacist for the CMI leaflets for these medicines

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

Serious side effects

Serious side effects	What to do
<p>At the time of your injection</p> <ul style="list-style-type: none"> swelling of your face, lips, tongue or throat with difficulty breathing swelling of other parts of your body such as your hands or feet shortness of breath, wheezing or trouble breathing abnormal or irregular heartbeat rash, itching or hives on the skin feeling sick (nausea) or vomiting diarrhoea pain or discomfort (including stomach pain, back pain, chest or neck pain) fever or chills 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> <p>These may be serious side effects. You may require</p>

Serious side effects	What to do
<ul style="list-style-type: none"> headache fatigue or tiredness cough 	urgent medical attention.
<p>After your injection:</p> <ul style="list-style-type: none"> swelling of your face, lips, tongue or throat with difficulty breathing severe swelling of the hands, feet or legs severe shortness of breath, wheezing or trouble breathing severe chest pain spreading out to the arms, neck, shoulder and/or back abnormal or irregular beating of the heart rash, itching or hives on the skin fever or chills severe coughing 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> <p>These are serious side effects. You may require urgent medical attention.</p>

Less serious side effects

Less serious side effects	What to do
<p>After your injection:</p> <ul style="list-style-type: none"> pain or reaction at the site of your injection getting tired more easily after light physical activity, such as walking shortness of breath, especially when lying down or being woken from your sleep runny or blocked nose, or nosebleeds insomnia (difficulty sleeping) confusion weakness, soreness in muscles and/or joints increased cough feeling dizzy, tired, looking pale flu and/or cold like symptoms, frequent infections such as fever, severe chills, sore throat or mouth ulcers hot flushes diarrhoea changes in weight (gain or loss) decrease in or loss of appetite redness, dryness or peeling of the hands or feet (hand-foot syndrome) pain in hands or feet unusual hair loss or thinning nail problems eye problems such as producing more tears, swollen runny eyes or conjunctivitis (discharge with itching of the eyes and crusty eyelids) 	<p>Speak to your doctor or nurse as soon as possible if you have any of these side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell, even if it is not on this list.

This is not a complete list of all possible side effects. Your doctor or pharmacist has a more complete list. Others may occur in some people and there may be some side effects not yet known.

Ask your doctor or pharmacist if you don't understand anything on this list.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. 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

This medicine is only available with a doctor's prescription.

Herceptin SC fixed dose formulation is not for intravenous use and should be given as a subcutaneous injection only.

It is important to check the product labels to ensure that the correct formulation is being given as prescribed.

What Herceptin SC contains

Active ingredient (main ingredient)	Each vial of Herceptin SC contains 600 mg of the active ingredient trastuzumab The trastuzumab protein is made using Chinese hamster ovary cells
Other ingredients (inactive ingredients)	histidine hydrochloride monohydrate, histidine, methionine, polysorbate 20, trehalose dihydrate, vorhyaluronidase alfa, water for injections

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

What Herceptin SC looks like

Herceptin SC for injection is a colourless to yellowish, clear to opalescent solution.

Herceptin SC is supplied as a single vial pack and is available in one strength, 600 mg in 5 mL solution for subcutaneous injection. (Aust R 220402)

Who distributes Herceptin SC

Roche Products Pty Limited
ABN 70 000 132 865
Level 8, 30-34 Hickson Road
Sydney NSW 2000
AUSTRALIA

Medical enquiries: 1800 233 950

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