

HERCEPTIN SC[®]

Subcutaneous injection

Contains the active ingredient trastuzumab (rch)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Herceptin SC. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given Herceptin SC against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

Herceptin is also available as an intravenous (IV) injection. For more information on Herceptin IV product please refer to the separate Consumer Medicine Information (CMI) for Herceptin IV or speak with your doctor or pharmacist.

What Herceptin SC is given for

Herceptin SC contains an active ingredient called 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 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 breast cancer whose tumour has tested positive to HER2.

Herceptin 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.

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

Before you are given Herceptin SC

When you must not be given it

Do not use Herceptin if:

- **you have had an allergic reaction to;**
 - **Herceptin,**
 - **any ingredient listed at the end of this leaflet or**
 - **any protein of Chinese hamster origin**

Some symptoms of an allergic reaction may include shortness of breath; wheezing or difficulty breathing; rash, itching or hives on the skin or swelling of the face, lips, tongue or other parts of the body.

- **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 build up
- abnormal or irregular heartbeat

If you are not sure if you should start receiving Herceptin SC, talk to your doctor.

Before you are given it

Tell your doctor if:

- **you have a history of 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

- **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.**

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.

- **if you have any breathing or lung problems**
- **you are allergic to any other medicines or any other substances such as foods, preservatives or dyes**
- **you are pregnant or intend to become pregnant**

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 "Side effects" for symptoms to look out for.

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.

- **you are breast-feeding or plan to breast-feed**

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.

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

Use in children

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

Taking other medicines

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

Herceptin SC treatment with 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.

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

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

How Herceptin SC is given

Follow all directions given to you by your doctor or nurse carefully.

They may differ from the information contained in this leaflet.

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 5mL). 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.

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

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, 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 (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.

While you are receiving Herceptin SC

Things you must 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 Herceptin SC.

Tell your doctor if you become pregnant or intend to start a family while receiving Herceptin SC or if

you intend to breast feed whilst receiving Herceptin SC.

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

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

Things you must not do

Do not stop your Herceptin SC treatment without talking to your doctor first.

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

Do not take any other medicines, whether they require a prescription or not, without first telling your doctor or consulting with a pharmacist.

Things to be careful of

Be careful driving or operating machinery until you know how Herceptin SC affects you.

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

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 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.

Ask your doctor or pharmacist to answer any questions you may have.

Because Herceptin SC may be used with other medicines that treat breast,

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

At time of injection

Tell your doctor or nurse immediately if you notice any of the following during, or soon after your injection:

- 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
- headache
- fatigue or tiredness
- cough

These may be serious side effects. You may require urgent medical attention.

Your doctor may prescribe medication to stop the side effects from occurring while receiving your Herceptin SC injection.

After your treatment

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

- swelling of your face, lips, tongue or throat with difficulty breathing
- severe shortness of breath, wheezing or trouble breathing

- severe chest pain spreading out to the arms, neck, shoulder and/or back
- rash, itching or hives on the skin
- fever or chills
- abnormal or irregular beating of the heart
- severe swelling of the hands, feet or legs
- severe coughing

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

Tell your doctor or nurse as soon as possible if you notice any of the following:

- any of the side effects listed above
- 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 with shortness of breath
- 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)

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.

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

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

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Product description

Storage

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.

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

Availability

Herceptin is available in two types (formulations);

- Solution for subcutaneous injection (under the skin). Supplied as a single vial pack and available in one strength, 600 mg in 5 mL solution.
- Powder for intravenous infusion (drip into the vein). Supplied as a single dose vial and available in two strengths, 60 mg and 150 mg.

It is important to check the product labels to ensure that the correct formulation is being given as prescribed. Herceptin SC fixed dose formulation is not for intravenous use and should be given as a subcutaneous injection only.

What Herceptin SC looks like

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

Ingredients

Each vial of Herceptin SC contains 600 mg of the active ingredient trastuzumab.

It also contains;

- Vorhyaluronidase alfa, an enzyme used to increase the dispersion and absorption of co-administered drugs when administered subcutaneously
- histidine hydrochloride monohydrate
- histidine
- trehalose dihydrate
- polysorbate 20
- methionine
- water for injections

The trastuzumab protein is made using Chinese hamster ovary cells.

Distributor

Herceptin SC is distributed by:

Roche Products Pty Limited

ABN 70 000 132 865

Level 8, 30 – 34 Hickson Road

Sydney NSW 2000

AUSTRALIA

Medical enquiries: 1800 233 950

Please check with your pharmacist for the latest Consumer Medicine Information (CMI)

Australian Registration Numbers:

Herceptin solution for subcutaneous injection:

AUST R 220402

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