



PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

Herceptin[®] SC 600 mg ; subcutaneous injection

The active substance is Trastuzumab

Sugar free

Read all of this leaflet carefully before you start being given Herceptin SC 600 mg

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- Herceptin SC 600 mg has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What Herceptin is and what it is used for
2. What you need to know before you are given Herceptin
3. How you are given Herceptin
4. Possible side effects
5. How to store Herceptin
6. Contents of the pack and other information

1. What Herceptin SC 600 mg is used for

Herceptin SC 600 mg contains the active substance trastuzumab, which is a humanised monoclonal antibody.

Herceptin SC 600 mg is used for the treatment of breast cancer if you have high levels of a protein called human epidermal growth factor receptor 2 (HER2).

- Herceptin SC 600 mg may be used with or without other products for breast cancer.
- Herceptin may be prescribed in combination with the chemotherapy medicine paclitaxel or docetaxel as first treatment for metastatic breast cancer or it may be prescribed alone if other treatments have proved unsuccessful.
- It is also used in combination with medicines called aromatase inhibitors with patients with high levels of HER2 and hormone receptor-positive metastatic breast cancer (cancer that is sensitive to the presence of female sex hormones).

2. What you need to know before you are given Herceptin SC 600 mg

You should not be given Herceptin SC 600 mg:

- If you are allergic to trastuzumab, to murine (mouse) proteins, or to any of the other ingredients in Herceptin SC 600 mg.
- If you have breathing problems at rest or if you need oxygen treatment.
- If you are pregnant or breastfeeding your baby.

Tell your doctor or healthcare professional before being given the Herceptin SC 600 mg injection:

Your doctor will closely supervise your therapy with Herceptin SC 600 mg. Treatment with Herceptin SC 600 mg may affect the heart. Therefore, your heart function will be checked

before and during the treatment with Herceptin SC 600 mg. If you develop any signs of heart failure (that is, inadequate pumping of blood by the heart), you may have to stop Herceptin SC 600 mg.

It may take up to 7 months for Herceptin SC 600 mg to be removed from the body. Therefore, you should tell your doctor or pharmacist that you have had Herceptin SC 600 mg if you start any new medication in the 7 months after stopping treatment.

- If you have or have had heart failure, coronary artery disease, heart valve disease (heart murmurs) or high blood pressure. This is because Herceptin SC 600 mg can cause heart failure.
- If you have ever had chemotherapy with a medicine called doxorubicin or a medicine related to doxorubicin (your doctor can advise you on this). Herceptin SC 600 mg and doxorubicin-like medicines can damage heart muscle and increase the risk of heart problems when being given Herceptin SC 600 mg.
- If you are breathless. Herceptin SC 600 mg can cause breathing difficulties. This could be more serious if you are already breathless.
- If you have ever had any other treatment for cancer.

Use in children and adolescents

Herceptin SC 600 mg is not recommended for anyone under the age of 18 years.

Taking other medicines with Herceptin SC 600 mg

Please tell your doctor or pharmacist that you have had Herceptin SC 600 mg if you start any medication in the 7 months after stopping treatment with Herceptin SC 600 mg.

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

Pregnancy and breastfeeding

You must not use Herceptin SC 600 mg if you are pregnant. Herceptin SC 600 mg can cause harm to the foetus (unborn baby), in some cases death to the foetus, when taken by a pregnant woman. Before starting treatment, you must tell your doctor if you are pregnant, if you think you are pregnant or if you intend to become pregnant.

If you are a woman or a man being given Herceptin SC 600 mg, you are advised to use a highly effective form of contraception, including a barrier method, while receiving Herceptin SC 600 mg and for at least 7 months after your last Herceptin SC 600 mg dose.

Do not breastfeed your baby during Herceptin SC 600 mg therapy and for 7 months after the last dose of Herceptin SC 600 mg.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before being given Herceptin SC 600 mg.

Driving and using machines

We do not know whether Herceptin SC 600 mg could affect your ability to drive a car or operate machinery. However, if you experience symptoms, such as chills or fever, during treatment with Herceptin SC 600 mg, you should not drive or use machines until these symptoms disappear.

3. How Herceptin SC 600 mg is administered

You will not be expected to give yourself Herceptin SC 600 mg. It will be given to you by a person who is qualified to do so, by an injection under the skin.

Dosage and frequency of administration

Before starting Herceptin SC 600 mg your doctor will determine the amount of HER2 receptors in your tumour. Only patients with a large amount of HER2 will be treated with Herceptin SC 600 mg. Herceptin SC 600 mg should only be administered by a doctor or a nurse.

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

The injection should be alternated between the left and right thigh. New injections should be given at least 2,5 cm from the previous site on healthy skin. No injection should be given into areas where the skin is red, bruised, tender or hard.

If other medicines for subcutaneous administration are used during the treatment course with Herceptin SC 600 mg, a different administration site should be used.

Herceptin SC 600 mg should not be diluted with other products.

If you missed a dose of Herceptin SC 600 mg

If you miss one dose, it is recommended to receive the next 600 mg dose (i.e. the missed dose) as soon as possible. The interval between subsequent Herceptin SC 600 mg doses should not be less than three weeks.

Effects when treatment with Herceptin SC 600 mg is stopped

Do not stop receiving Herceptin SC 600 mg without talking to your doctor first. All doses should be administered at the right time every three weeks. This helps Herceptin SC 600 mg work as well as it can.

4. Possible side effects

Herceptin SC 600 mg can cause side effects. Some of these side effects may be serious and may lead to hospitalisation or death.

Herceptin SC 600 mg administration can result in severe hypersensitivity reactions (including anaphylaxis, a rapidly progressing, life-threatening allergic reaction), administration reactions and pulmonary (lung/respiratory) events. These may cause death. In most cases, these symptoms occurred during or within 24 hours of administration of Herceptin SC 600 mg.

During treatment with Herceptin SC 600 mg, chills, fever and other flu-like symptoms may occur. These are very common. Other symptoms are: feeling sick (nausea), vomiting, pain, increased muscle tension and shaking, headache, dizziness, breathing difficulties, wheezing, high or low blood pressure, heart rhythm disturbances (palpitations, heart fluttering or irregular heart beat), swelling of the face and lips, rash and feeling tired. These symptoms can be serious and some patients have died.

You should tell your doctor immediately if you notice:

- breathlessness (including breathlessness at night)
- cough
- swelling of the lips, face, tongue or throat with difficulty in swallowing and breathing
- fluid retention (swelling) in the legs or arms or
- palpitations (heart fluttering or irregular heart beat)

Heart problems can occur and are serious. They include weakening of the heart muscle possibly leading to heart problems, and heart rhythm disturbances. Your doctor will monitor your heart regularly during treatment.

If you experience any of the above symptoms after treatment with Herceptin SC 600 mg has been stopped, you should consult your doctor and inform him/her that you have previously been treated with Herceptin SC 600 mg.



Taking Herceptin SC 600 mg can result in serious and potentially deadly lung problems, including:

- A severe shortness of breath
- Too little oxygen in the body
- Weakening of the heart valve between the heart and the lungs
- Swelling of the lungs
- Fluid in or around the lungs
- Scarring of the lungs

Problems like these may occur after administration of Herceptin SC 600 mg.

Very common side effects of Herceptin SC 600 mg are:

- Infections
- Diarrhoea
- Constipation
- heartburn (dyspepsia)
- fatigue
- skin rashes
- chest pain
- abdominal pain
- joint pain
- low counts of red blood cells and white blood cells (which help fight infection) sometimes with fever
- muscle pain
- conjunctivitis
- watery eyes
- nose bleeds



- runny nose
- hair loss
- tremor
- hot flush
- dizziness
- nail disorders
- weight loss
- loss of appetite
- inability to sleep (insomnia)
- altered taste
- low platelet count
- bruising
- numbness or tingling of the fingers and toes
- redness, swelling or sores in your mouth and/or throat
- pain, swelling, redness or tingling of hands and/or feet
- breathlessness
- headache
- cough
- vomiting
- nausea



Common side effects of Herceptin SC 600 mg are:

- allergic reactions
- throat infections
- bladder and skin infections
- inflammation of the breast
- inflammation of the liver
- kidney disorder
- increased muscle tone or tension (hypertonia)
- pain in the arms and/ or legs
- itchy rash
- sleepiness (somnolence)
- haemorrhoids
- itchiness
- dry mouth and skin
- Dry eyes
- Sweating
- Feeling weak and unwell
- Anxiety
- Depression
- Asthma
- Infection of lungs
- Lung disorder
- Back pain
- Neck pain
- Bone pain
- Acne
- Leg cramps

Uncommon side effects of Herceptin

- deafness
- bumpy rash
- wheezing
- inflammation or scarring of the lungs

Rare side effects of Herceptin

- jaundice
- anaphylactic reactions

Other side effects that have been reported with Herceptin use: frequency cannot be estimated from the available data

- Jaundice
- abnormal or impaired blood clotting
- high potassium levels
- swelling or bleeding at the back of the eyes
- shock
- abnormal heart rhythm
- respiratory distress
- respiratory failure
- acute accumulation of fluid in the lungs
- acute narrowing of the airways
- abnormally low oxygen levels in the blood
- difficulty in breathing when lying flat
- liver damage
- swelling of the face, lips and throat
- kidney failure
- abnormally low levels of fluid around baby in womb
- failure of the lungs of the baby to develop in the womb
- abnormal development of the kidneys of the baby in the womb

If you experience any of the side effects mentioned in this leaflet or notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist or other healthcare professional. Not all side effects reported for Herceptin SC 600 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Herceptin SC 600 mg, consult your doctor, pharmacist or other healthcare professional for advice.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions to SAHPRA via the “6.04 Adverse Drug Reaction Report Form”, found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>

5. How to store Herceptin SC 600 mg

Store out of reach of children.

Vials must be stored in a refrigerator between 2 °C - 8 °C.

Do not freeze.

Store in the original package in order to protect from light.

The vials should not be kept for more than 6 hours at ambient (room) temperature: do not store at or above 30 °C.

Do not use Herceptin SC 600 mg after the expiry date (EXP) stated on the outer carton and on the vial label.

Do not use Herceptin if you notice any particulate matter or discoloration prior to administration

Disposal of unused/expired medicine: The release of pharmaceuticals in the environment should be minimised. Medicines should not be disposed of via wastewater and disposal through household waste should be avoided. Use established collection systems, if available in your location.

6. Contents of the pack and other information

What Herceptin contains

Herceptin contains the excipients recombinant human hyaluronidase (rHuPH20), l-histadine, α,α-trehalose, l-methionine, polysorbate 20, water for injections



What Herceptin SC 600 mg looks like

Herceptin SC 600 mg is a sterile, colourless to yellowish, clear to opalescent liquid solution. Each carton contains one 6 ml colourless, type 1 glass vial, sealed with a grey rubber stopper (laminated with fluoro-resin) and crimped with an aluminum overseal fitted with a light blue plastic flip-off disk.

7. Holder of Certificate of Registration

Roche Products (Pty) Ltd

90 Bekker Road, Hertford Office Park

Building E, Vorna Valley, Midrand,

Johannesburg, 1686

South Africa

Roche Ethical Assistance Line (REAL) toll-free: 0800 21 21 25

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