Herceptin® 600 mg solution for injection in vial

(trastuzumab) UK510008P98A-2.0

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

This product is called Herceptin 600 mg solution for injection in vial but will be referred to as Herceptin throughout the leaflet.

What is in this leaflet:

1. What Herceptin is and what it is used for

Herceptin contains the active substance trastuzumab, which is a monoclonal antibody. Monoclonal antibodies attach to specific proteins or antigens. Trastuzumab is designed to bind selectively to an antigen called human epidermal growth factor receptor 2 (HER2).
HER2 is found in large amounts on the surface of some cancer cells where it stimulates their growth. When Herceptin binds to HER2 it stops the growth of such cells and causes them to die.

Your doctor may prescribe Herceptin for the treatment of breast cancer when:
- You have early breast cancer, with high levels of a protein called HER2.
- You have metastatic breast cancer (breast cancer that has spread beyond the original tumour) with high levels of HER2. Herceptin may be prescribed in combination with the chemotherapy medicines 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

Do not use Herceptin if:
- you are allergic to trastuzumab (the active substance of Herceptin), murine (mouse) proteins, or any of the other ingredients of this medicine (listed in section 6).
- you have severe breathing problems at rest due to your cancer or if you need oxygen treatment.

Warnings and precautions
Your doctor will closely supervise your therapy.

Heart checks
Treatment with Herceptin alone or with a taxane may affect the heart, especially if you have ever used an anthracycline (taxanes and anthracyclines are two other kinds of medicine used to treat cancer). The effects may be moderate to severe and could cause death. Therefore, your heart function will be checked before, during (every three months) and after (up to two to five years) treatment with Herceptin. If you develop any signs of heart failure (i.e. inadequate pumping of blood by the heart), your heart function may be checked more frequently (every six to eight weeks), you may receive treatment for heart failure or you may have to stop Herceptin treatment.

Talk to your doctor, pharmacist or nurse before you are given Herceptin if:
- you have had heart failure, coronary artery disease, heart valve disease (heart murmurs), high blood pressure, taken any high blood pressure medicine or are currently taking any high blood pressure medicine.
- you have ever had or are currently using a medicine called doxorubicin or epirubicin (medicines used to treat cancer). These medicines (or any other anthracyclines) can damage heart muscle and increase the risk of heart problems with Herceptin.
- you suffer from breathlessness, especially if you are currently using a taxane. Herceptin can cause breathing difficulties, especially when it is first given. This could be more serious if you are already breathless. Very rarely, patients with severe breathing difficulties before treatment have died when they were given Herceptin.
- you have ever had any other treatment for cancer.

If you receive Herceptin with any other medicine to treat cancer, such as paclitaxel, docetaxel, an aromatase inhibitor, carboplatin or cisplatin you should also read the patient information leaflets for these products.

Children and adolescents
Herceptin is not recommended for anyone under the age of 18 years.

Other medicines and Herceptin
Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines.

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

Pregnancy and breast-feeding
- If you are pregnant, think you may be pregnant or are planning to have a baby, you must tell your doctor, pharmacist or nurse before taking this medicine.
- You should use effective contraception during treatment with Herceptin and for at least 7 months after treatment has ended.

Your doctor will advise you of the risks and benefits of taking Herceptin during pregnancy.
In rare cases, a reduction in the amount of (amniotic) fluid that surrounds the developing baby within the womb has been observed in pregnant women receiving Herceptin. This condition may be harmful to your baby in the womb and has been associated with the lungs not developing fully resulting in foetal death.

Do not breast-feed your baby during Herceptin therapy and for 7 months after the last dose of Herceptin as Herceptin may pass to your baby through your breast milk.

Ask your doctor, pharmacist or nurse for advice before taking any medicine.

Driving and using machines
Herceptin may affect your ability to drive a car or operate machines. If during treatment, you experience symptoms, such as dizziness, sleepiness, chills or fever, you should not drive or use machines until these symptoms disappear.

Herceptin contains sodium
Herceptin contains less than 1 mmol of sodium (23 mg) per dose, that is to say essentially sodium-free.

Herceptin contains polysorbate
Herceptin contains 2.0 mg of polysorbate 20 in each 600 mg/5 mL vial, which is equivalent to 0.4 mg/mL. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

3. How Herceptin is given

Before starting the treatment your doctor will determine the amount of HER2 in your tumour. Only patients with a large amount of HER2 will be treated with Herceptin.
Herceptin should only be given by a doctor or nurse.

Two different types (formulations) of Herceptin exist:
- one is given as an infusion into a vein (intravenous infusion)
- the other is given as an injection under the skin (subcutaneous injection).

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

Your doctor may consider switching your Herceptin intravenous treatment to Herceptin subcutaneous treatment (and vice versa) if considered appropriate for you.

In order to prevent medication errors it is also important to check the vial labels to ensure that the medicine being prepared and given is Herceptin (trastuzumab) and not another trastuzumab-containing product (e.g. trastuzumab emtansine or trastuzumab deruxtecan).

The recommended dose is 600 mg. Herceptin 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, a different injection site should be used. Herceptin should not be mixed or diluted with other products.

If you stop using Herceptin
Do not stop using this medicine without talking to your doctor first. All doses should be taken at the right time every three weeks. This helps your medicine work as well as it can.

It may take up to 7 months for Herceptin to be removed from your body. Therefore your doctor may decide to continue to check your heart functions, even after you finish treatment.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Some of these side effects may be serious and may lead to hospitalisation.
During treatment with Herceptin, chills, fever and other flu like symptoms may occur.
These are very common (may affect more than 1 in 10 people). Other symptoms are: feeling sick (nausea), vomiting, pain, increased muscle tension and shaking, headache, dizziness, breathing difficulties, 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. Some of these symptoms can be serious and some patients have died (see the section “Warnings and precautions”).

Your doctor or nurse will check for side effects during the administration and for 30 minutes after the first administration and for 15 minutes after other administrations.

Serious side effects

Other side effects can occur at any time during treatment with Herceptin. **Tell a doctor or nurse straight away, if you notice any of the following side effects:**

- Heart problems can sometimes occur during treatment and occasionally after treatment has stopped and can be serious. They include weakening of the heart muscle possibly leading to heart failure, inflammation of the lining around the heart and heart rhythm disturbances. This can lead to symptoms such as breathlessness (including breathlessness at night), cough, fluid retention (swelling) in the legs or arms, palpitations (heart fluttering or irregular heart beat) (see section 2. Heart checks).

Your doctor will monitor your heart regularly during and after treatment but you should tell your doctor immediately if you notice any of the above symptoms.

- Tumour lysis syndrome (a group of metabolic complications occurring after cancer treatment characterised by high blood levels of potassium and phosphate, and low blood levels of calcium). Symptoms may include kidney problems (weakness, shortness of breath, fatigue and confusion), heart problems (fluttering of the heart or a faster or slower heartbeat), seizures, vomiting or diarrhoea and tingling in the mouth, hands or feet.

If you experience any of the above symptoms when your treatment with Herceptin has finished, you should see your doctor and tell them that you have previously been treated with Herceptin.

Two different types (formulations) of Herceptin exist:
- one is given as an infusion into a vein over 30 to 90 minutes
- the other is given as a subcutaneous injection over 2 to 5 minutes.

In the clinical study comparing these two formulations, infections and cardiac events leading to hospitalisation were more frequent with the subcutaneous formulation. There were also more local reactions at the site of injection and more increases in blood pressure. Other side effects were similar.

Very common side effects of Herceptin: may affect more than 1 in 10 people

- 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, which occasionally may extend to the rest of the limb
- 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: may affect up to 1 in 10 people

- allergic reactions
- throat infections
- bladder and skin infections
- inflammation of the breast
- inflammation of the liver
- kidney disorders
- 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 disorders
- back pain
- neck pain
- bone pain
- acne
- leg cramps

Uncommon side effects of Herceptin: may affect up to 1 in 100 people

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

Rare side effects of Herceptin: may affect up to 1 in 1,000 people

- jaundice
- anaphylactic reactions

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

- 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

Some of the side effects you experience may be due to your underlying breast cancer.
If you receive Herceptin in combination with chemotherapy, some of them may also be due to the chemotherapy.

If you get any side effects, talk to your doctor, pharmacist or nurse.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Herceptin

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the outer carton and on the vial label after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C).

Keep the vial in the outer carton to protect from light.

Do not freeze.

Upon opening of the vial, the solution should be used immediately.

Do not use this medicine if you notice any particulate matter or discoloration prior to administration.

If the medicine becomes discolored or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Herceptin contains

- The active substance is trastuzumab. One vial of 5 mL contains 600 mg of trastuzumab.
- The other ingredients are recombinant human hyaluronidase (rHuPH20), L-histidine, L-histidine hydrochloride monohydrate, α,α-trehalose dihydrate, L-methionine, polysorbate 20 (E432), water for injections (see section 2 “Herceptin contains polysorbate”).

What Herceptin looks like and contents of the pack
6 mL clear glass type I vial with butyl rubber stopper containing 5 mL of solution.
The solution is clear to opalescent and colourless to yellowish.

Each carton contains one vial.

Manufacturer
Roche Pharma AG
Emil-Barell-Strasse 1
79639 Grenzach-Wyhlen
Germany

Procured from within the EU and repackaged for the PL Holder: Abacus Medicine Ltd., Abbey House, 282 Farnborough Road, Farnborough, GU14 7NA, United Kingdom

Herceptin 600 mg solution for injection in vial
PL 45763/0009

POM

For any information about this medicine, please contact the local representative of the Product Licence Holder:
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