

Consumer Medicine Information

HERCEPTIN[®]

Trastuzumab

150 mg and 440 mg powder for concentrate for solution for infusion

What is in this leaflet

This leaflet answers some common questions about HERCEPTIN infusion.

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 against the benefits expected for you.

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

Keep this leaflet.

You may need to read it again.

What HERCEPTIN is used for

HERCEPTIN contains the active ingredient trastuzumab.

HERCEPTIN belongs to a group of medicines known as antineoplastic (or anti-cancer) agents. There are many different classes of antineoplastic agents. HERCEPTIN belongs to a class called monoclonal antibodies.

HERCEPTIN 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 binds to HER2 it stops the growth and spread of the cancer cells.

HERCEPTIN is used to treat the following cancers in patients whose tumours have tested positive for HER2 receptors:

- Metastatic (spreading) breast cancer
- Early breast cancer in women with normal heart function
- Gastric (stomach) cancer

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

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

Before you are given HERCEPTIN

When you must not be given it

You should not have HERCEPTIN if:

- **you have had an allergic reaction to HERCEPTIN, benzyl alcohol or any of the ingredients listed at the end of this leaflet**

- **you have had an allergic reaction to any proteins that are 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.

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

Before you are given it

Tell your doctor if:

- **you have a history of:**
 - **coronary artery disease** (also known as CAD, a condition where the arteries carrying blood to your heart are blocked or narrowed)
 - **poorly controlled hypertension** (high blood pressure)
 - **heart failure** (where the heart can no longer pump blood strongly enough for the body's needs; symptoms include shortness of breath and swelling of the feet or legs due to fluid build-up)
 - **arrhythmia** (abnormal or rapid heart beat)
 - **angina** (a feeling of pain, tightness, pressure or heaviness in the chest)
 - **any other type of heart disease**

Your doctor will check your heart function before starting HERCEPTIN and will monitor your heart function closely during your treatment with HERCEPTIN.

HERCEPTIN may increase the risk of heart disorders.

- **lung disease or tumours in the lung**
- **if you have any breathing or lung problems**
- **you have been previously treated with other medications used to treat cancer such as anthracycline and cyclophosphamide**
- **you are pregnant or plan to become pregnant**

HERCEPTIN may be harmful to an unborn baby when taken by a pregnant woman. There have been cases of decreased fluid surrounding the baby (amniotic fluid). If there is a need to take HERCEPTIN when you are pregnant your doctor will discuss the risks and benefits to you and the unborn baby.
- **you are breast-feeding or plan to breast-feed**

It is not known if HERCEPTIN passes into breast milk. Breast-feeding is not recommended if you are being treated with HERCEPTIN and you should not restart breast-feeding until 6 months after completing HERCEPTIN treatment.
- **you are allergic to any other medicines or any other substances such as foods, preservatives or dyes.**

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

Taking other medicines

Tell your doctor if you are taking any other cancer medications.

Taking HERCEPTIN with taxanes, gemcitabine, vinorelbine or radiation therapy can increase the chance of lung problems (interstitial lung disease).

Tell your doctor if you are taking any other medicines, including any that you have bought from a pharmacy, supermarket or health food shop.

Your doctor and pharmacist may have information on medicines to be careful with or avoid while undergoing treatment with HERCEPTIN.

Use in children

The safety and effectiveness of HERCEPTIN in children have not been established.

How HERCEPTIN is given

Your doctor will perform a test to check that your cancer is HER2 positive before starting treatment with HERCEPTIN.

Follow all directions given to you by your healthcare professional (doctor, nurse or pharmacist).

They may differ from the information contained in this leaflet.

HERCEPTIN must be prepared by a healthcare professional before treatment.

After preparation, HERCEPTIN is given by slow infusion into a vein (intravenous infusion) by a healthcare professional.

The first infusion is given over 90 minutes. If the first infusion is well tolerated, following infusions may be given over 30 minutes.

Your doctor will decide the dose and treatment regimen that is right for your condition.

For the treatment of breast cancer, HERCEPTIN may be given either once a week or once every three weeks.

For the treatment of gastric cancer, HERCEPTIN is given once every three weeks.

Your doctor will decide how long you should receive HERCEPTIN depending on your response to the medicine and the state of your disease.

Once weekly dose schedule

The first dose is usually 4 milligrams (mg) per kilogram (kg) bodyweight given over at least 90 minutes. Following doses are usually 2 mg per kg bodyweight given over at least 30 minutes, once each week.

Three weekly dose schedule

The first dose is usually 8 mg per kg bodyweight given over at least 90 minutes. Following doses are usually 6 mg per kg bodyweight given over at least 30 minutes, once every three weeks.

HERCEPTIN may be used by itself or it may be used in combination with other medicines that treat cancer.

While you are receiving HERCEPTIN

Things you must do

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

Tell your doctor immediately if you have any chest pain, abnormal or rapid heart beat, difficulty breathing, shortness of breath and/or swelling of the feet and hands while you are receiving HERCEPTIN.

Please follow all your doctors instructions if any of these symptoms require medication.

Tell your doctor if you become pregnant while receiving HERCEPTIN.

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

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

Your doctor should perform regular tests, including checking your heart function, while you are being treated with HERCEPTIN.

Things you must not do

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 affects you.

However, HERCEPTIN is not expected to affect your ability to drive a car or operate machinery.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are receiving HERCEPTIN.

HERCEPTIN helps most people with HER2 positive breast cancer and gastric cancer, but it may have some unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious. 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 may be used with other medicines that treat breast and gastric cancer, it may be difficult for your doctor to tell whether the side effects are due to HERCEPTIN or due to the other medicines.

During an infusion

Tell your doctor if you notice any of the following *while receiving an infusion (particularly during the first infusion)* and they worry you:

- chills and/or shivering

- fever
- nausea and/or vomiting
- pain or discomfort (including stomach, back, chest or neck pain)
- stiffness or shaking
- weakness, soreness in muscles and/or joints
- headache and/or dizziness
- cough
- hives, skin rashes or itching skin
- weakness or fatigue
- shortness of breath, difficulty breathing or wheezing
- abnormal or rapid beating of the heart
- feeling faint

These side effects are usually mild to moderate and occur less frequently with subsequent infusions.

Your doctor will monitor your heart function closely during your treatment with HERCEPTIN.

Your doctor may prescribe medication to prevent the side effects from occurring while receiving your HERCEPTIN infusion.

Tell your doctor immediately if you notice any of the following while receiving an infusion (*particularly during the first infusion*):

- difficulty in breathing or shortness of breath
- wheezing

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

After an infusion

Tell your doctor if you notice any of the following *after an infusion* and they worry you:

- any of the side effects listed above under “*During an infusion*”
- swelling of the feet or legs
- insomnia (difficulty sleeping), anxiety or depression
- worsening cough
- runny or blocked nose
- nose bleeds
- flu and/or cold-like symptoms
- chest infection
- pain on urination, or increased frequency of urination
- diarrhoea
- weight loss
- hair loss
- problems with your nails
- soreness in muscles and/or joints
- sweating
- sore throat
- acne
- bone pain
- loss of appetite, change in sense of taste, constipation, indigestion
- tingling or numbness of the hands or feet
- redness, dryness or peeling of the hands or feet (hand-foot syndrome)
- mouth ulcers, cold sores
- discharge with itching of the eyes and crusty eyelids

These are mild side effects of this medicine.

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

- high temperature or fever
- shortness of breath and/or difficulty in breathing (sometimes occurring suddenly at night)
- sore throat, chills and fever which does not get better
- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing
- severe coughing
- chest pain spreading out to the arms, neck, shoulder and/or back
- abnormal or rapid beating of the heart
- severe diarrhoea or vomiting
- feeling faint
- severe skin infections, including a bright red rash on the face or legs
- shortness of breath, especially when lying down or being woken from your sleep with shortness of breath

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

This is not a complete list of all possible side effects. 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 in this list.

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

Product description

Availability

Both HERCEPTIN 150 mg and 440 mg vials are supplied in single packs.

What HERCEPTIN looks like

HERCEPTIN is a white to pale yellow powder which is dissolved before use.

Ingredients

Active ingredient – trastuzumab

Each vial of HERCEPTIN 150 mg powder contains 150 mg trastuzumab

Each vial of HERCEPTIN 440 mg powder contains 440 mg trastuzumab

Inactive ingredients

HERCEPTIN powder also contains L-histidine hydrochloride, L-histidine, α,α -trehalose dihydrate and polysorbate 20.

The solvent vial (for use with the 440 mg vial only) also contains water for injections and 1.1% benzyl alcohol.



Distributor

HERCEPTIN is distributed by:

Roche Products (New Zealand) Limited
P O Box 12492
Penrose
AUCKLAND

Telephone: (09) 635 1500

Toll Free: 0800 656 464

This leaflet was prepared on 24 September 2010.