

contains the active ingredient trastuzumab (rch)

Consumer Medicine Information

the growth and spread of the cancer cells.

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

What is in this leaflet

This leaflet answers some common questions about HERCEPTIN. 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 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.

You may need to read it again.

What HERCEPTIN is given for

HERCEPTIN contains an active ingredient called trastuzumab.

HERCEPTIN belongs to a group of medicines known as anti-neoplastic (or anti-cancer) agents. There are many different classes of anti-neoplastic agents. HERCEPTIN 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 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

HERCEPTIN is used to treat breast and gastric cancer in patients who have tested positive to HER2.

Your doctor may have prescribed HERCEPTIN for another reason.

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

Do not use HERCEPTIN if:

- **you have had an allergic reaction to HERCEPTIN 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**
- **you have localised (early) breast cancer with symptomatic heart failure; unless you have results of more than 45% for a test called LVEF which measures how well your heart can pump blood.**

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.

Some signs of symptomatic heart failure include shortness of breath and swelling of the feet or legs due to fluid build-up.

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**

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

HERCEPTIN may increase the risk of heart disorders.

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

HERCEPTIN may be harmful to an unborn baby. 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. It is recommended that you discontinue breast-feeding while you are being treated with HERCEPTIN and not restart breast-feeding until 6 months after completing HERCEPTIN treatment.

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

Use in children

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

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.

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).

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

How HERCEPTIN 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 must be prepared by a healthcare professional.

After preparation, HERCEPTIN is given by slow infusion into a vein

(intravenous "drip") 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 is given either once a week or once every three weeks. It may be given alone or in combination with other medicines used to treat breast cancer.

For the treatment of gastric cancer HERCEPTIN is given every three weeks in combination with other medicines used to treat gastric cancer.

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

While you are receiving HERCEPTIN

Things you must do

Tell your doctor immediately if you have any signs and symptoms of heart disease, chest pain or difficulty in breathing.

Some signs and symptoms of heart disease are shortness of breath or difficulty breathing, cough, swelling of the hands or feet and an 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.

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 may perform regular tests.

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.

HERCEPTIN does not generally cause any problems with your ability to drive 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 and gastric 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.

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.

The following is a list of the more common side effects.

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 pain, back pain, chest or neck pain)
- weakness, soreness in muscles and/or joints
- feeling tired
- headache and/or dizziness
- hives or itchy skin rash
- cough

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

Your doctor may prescribe medication to stop 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***”
- insomnia (difficulty sleeping)
- increased cough
- runny or blocked nose
- flu and/or cold like symptoms
- diarrhoea
- weight loss
- feeling of numbness or tingling in hands or feet

- redness, dryness or peeling of the hands or feet (hand-foot syndrome)

These are mild side effects of this medicine.

Tell your doctor immediately if you notice any of the following:

- shortness of breath and/or difficulty in breathing (sometimes occurring suddenly at night)
- sore throat, chills and fever which does not get better

These may be serious side effects. You may need medical attention.

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

- severe shortness of breath and/or severe difficulty in breathing
- severe coughing
- severe swelling of the feet or legs
- severe chest pain spreading out to the arms, neck, shoulder and/or back
- abnormal or irregular beating of the heart
- 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. 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 in this list.

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

You may not experience any of them.

After receiving HERCEPTIN

Storage

HERCEPTIN will be stored in the pharmacy or on the hospital ward in a refrigerator at a temperature between 2°C and 8°C.

Product description

Availability

HERCEPTIN is supplied as a pack of one single dose vial and is available in two strengths, 60 mg and 150 mg,

What HERCEPTIN looks like

HERCEPTIN is a white to pale yellow powder which is dissolved before you receive it.

After dissolving, the HERCEPTIN solution should appear as a clear colourless to yellow solution. The solution will then be diluted in a saline (salt) solution bag before being given to you as an intravenous drip.

Ingredients

Active ingredient – trastuzumab

Each vial of HERCEPTIN powder contains 60 mg or 150 mg trastuzumab.

Trastuzumab is made using chinese hamster ovary cells.

Inactive ingredients

HERCEPTIN powder also contains:

- histidine hydrochloride
- histidine
- trehalose dihydrate
- polysorbate 20

Distributor

HERCEPTIN is distributed by:

Roche Products Pty Limited
ABN 70 000 132 865
4-10 Inman Road
Dee Why NSW 2099
AUSTRALIA

Customer enquires: 1800 233 950

Please check with your pharmacist for
the latest Consumer Medicine
Information

Australian Registration Numbers:

- 60 mg: AUST R 171014
- 150 mg: AUST R 73229

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