

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using HERZUMA?

HERZUMA contains the active ingredient trastuzumab. HERZUMA is used to treat breast and gastric cancer. It is only used in patients whose tumour has tested positive to a protein called human epidermal growth factor receptor 2 (HER2). For more information, see Section [1. Why am I using HERZUMA?](#) in the full CMI.

2. What should I know before I use HERZUMA?

Do not use if you have ever had an allergic reaction to HERZUMA, any protein of Chinese hamster origin, or any of the ingredients listed at the end of the CMI. Do not use if you have breast cancer that has not spread (non-metastatic), and you have had a left ventricular ejection fraction (LVEF) test result (which measures how well your heart can pump blood) of less than 45%, or if you have symptoms of heart failure.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use HERZUMA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with HERZUMA and affect how it works. HERZUMA treatment with gemcitabine, vinorelbine, a taxane or radiation therapy can increase the chance of lung problems.

Tell your doctor or pharmacist that you have had HERZUMA if you start any new medicine in the seven months after stopping treatment. It may take up to seven months for HERZUMA to be removed from your body.

For more information, see Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How will I be given HERZUMA?

- HERZUMA must be prepared by a healthcare professional and will be given in a hospital or clinic by a doctor or nurse.
- HERZUMA is given by "drip" into a vein (intravenous (IV) infusion). For more information, see Section [4. How will I be given HERZUMA?](#) in the full CMI.

5. What should I know while being treated with HERZUMA?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using HERZUMA.• Tell your doctor or nurse immediately if you have any signs and symptoms of an allergic or anaphylactic reaction, such as swelling of your face, lips, tongue or throat with difficulty breathing.• Tell your doctor or nurse immediately if you have any signs and symptoms of heart problems, such as shortness of breath or getting tired easily after light physical activity.• Keep all of your appointments with your doctor so that your progress can be checked.
Things you should not do	<ul style="list-style-type: none">• Do not stop your HERZUMA treatment without talking to your doctor first.• Do not take any other medicines without first telling your doctor or consulting with a pharmacist.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how HERZUMA affects you.• HERZUMA may cause dizziness. If you experience symptoms such as dizziness you should not drive or operate machinery until your symptoms have completely gone away.

For more information, see Section [5. What should I know while being treated with HERZUMA?](#) in the full CMI.

6. Are there any side effects?

There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur. Common side effects include fever or chills, cough, feeling dizzy, fatigue or tiredness. Serious side effects include swelling of your face, lips, tongue or throat with difficulty breathing, rash, itching or hives of the skin, and irregular heartbeat. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

HERZUMA®

Active ingredient: *trastuzumab*

Consumer Medicine Information (CMI)

This leaflet provides important information about using HERZUMA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using HERZUMA.**

Where to find information in this leaflet:

- [1. Why am I using HERZUMA?](#)
- [2. What should I know before I use HERZUMA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use HERZUMA?](#)
- [5. What should I know while using HERZUMA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using HERZUMA?

HERZUMA contains the active ingredient trastuzumab.

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

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

HERZUMA is used to treat breast and gastric cancer. It is only used in patients whose tumour has tested positive to HER2.

HERZUMA may be used alone 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 the treatment of gastric cancer HERZUMA is used with chemotherapy medicine cisplatin and capecitabine (or 5FU).

2. What should I know before I use HERZUMA?

Warnings

Do not use HERZUMA if:

- you are allergic to trastuzumab, any protein of Chinese hamster origin, or any of the ingredients listed at the end of this leaflet.

- Always check the ingredients to make sure you can use this medicine.
- 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 tiring 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

Check with your doctor if you:

- have any other medical conditions, including:
- 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.
- have previously been treated with chemotherapy medicines known as anthracyclines (e.g. doxorubicin); these medicines can damage heart muscle and increase the risk of heart problems with HERZUMA
 - Your doctor will monitor your heart function closely HERZUMA before and during your treatment with HERZUMA. Your heart function may also be monitored for years after ceasing HERZUMA treatment.
- you have any breathing or lung problems
- you are allergic to any other medicines or any other substances such as foods, preservatives or dyes
 - Allergic or anaphylactic reactions can occur with HERZUMA treatment (known as infusion or administration related reactions). Your doctor or nurse will monitor you for side effects during treatment. See Section [6. Are there any side effects?](#) for symptoms to look out for.
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

HERZUMA may be harmful to an unborn baby.

If there is a need for HERZUMA 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 HERZUMA and for 7 months after stopping treatment.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not known if HERZUMA passes into breast milk.

It is recommended that you discontinue breast-feeding while you are being treated with HERZUMA and not restart breastfeeding until 7 months after completing HERZUMA treatment.

Use in children

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

3. What if I am taking other medicines?

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

Some medicines may interfere with HERZUMA and affect how it works.

HERZUMA treatment with gemcitabine, vinorelbine, a taxane or radiation therapy can increase the chance of lung problems (interstitial lung disease).

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

It may take up to seven months for HERZUMA to be removed from your body.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect HERZUMA.

4. How will I be given HERZUMA?

How much HERZUMA will be given

- HERZUMA must be prepared by a healthcare professional and will be given in a hospital or clinic by a doctor or nurse.
- HERZUMA is given by "drip" into a vein (intravenous (IV) infusion).
- The first HERZUMA infusion is given over 90 minutes. If the first infusion is well tolerated, your drip time may be shortened to 30 minutes.
- Follow the instructions provided and use HERZUMA until your doctor tells you to stop. Your doctor will decide how long you should receive HERZUMA. This

will depend on your response to the medicine and the state of your disease.

When you will be given HERZUMA

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

If you miss a dose of HERZUMA

As HERZUMA 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 HERZUMA, make another appointment as soon as possible. Your doctor will decide when and how much your next dose of HERZUMA will be.

If you use too much HERZUMA

As HERZUMA is given to you under the supervision of your doctor, it is unlikely that you will be given too much.

If you think that you have used too much HERZUMA, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while being treated with HERZUMA?

Things you should do

Call your doctor straight away if you:

- Have any signs and symptoms of an allergic or anaphylactic reaction. Some signs and symptoms of an allergic or anaphylactic reaction 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
- have any signs and symptoms of heart problems. Some signs and symptoms of heart problems include:
 - 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 doctor's instructions if any of the symptoms above require medication.
- Tell your doctor if you feel that HERZUMA is not helping your condition.
- Tell your doctor if you become pregnant or intend to start a family while receiving HERZUMA.
- Keep all of your appointments with your doctor so that your progress can be checked. Your doctor may perform regular tests.

Remind any doctor, dentist or pharmacist you visit that you are using HERZUMA.

Things you should not do

- Do not stop your HERZUMA treatment without talking to your doctor first.
- **Do not take any other medicines, whether they require a prescription or not, without first telling your doctor or consulting with a pharmacist.**

Driving or using machines

Be careful before you drive or use any machines or tools until you know how HERZUMA affects you.

HERZUMA may cause dizziness.

If you experience symptoms such as dizziness during your treatment with HERZUMA you should not drive or operate machinery until your symptoms have completely gone away.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

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

Follow the instructions in the carton on how to take care of your medicines properly.

Store it in a cool dry place away from moisture, heat or sunlight for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Because HERZUMA 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 HERZUMA 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 Consumer Medicine Information (CMI) leaflets for these medicines.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • 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) • 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) • 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) 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>During an infusion (particularly during the first infusion):</p> <ul style="list-style-type: none"> 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 	<p>Tell your doctor or nurse immediately.</p> <p>These may be serious effects. You may require urgent medical attention.</p> <p>Your doctor may prescribe medication to stop the side effects from occurring.</p>
<p>After an infusion:</p> <ul style="list-style-type: none"> 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 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> <p>These may be serious side effects. You may need urgent medical attention.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What HERZUMA contains

<p>Active ingredient (main ingredient)</p>	<ul style="list-style-type: none"> Trastuzumab <p>The trastuzumab protein is made using Chinese hamster ovary cells.</p>
<p>Other ingredients (inactive ingredients)</p>	<ul style="list-style-type: none"> Histidine hydrochloride Histidine Trehalose dihydrate Polysorbate 20 <p>The solvent vial (for use with the 440 mg vial only) also contains:</p> <ul style="list-style-type: none"> water for injections containing 1.1% benzyl alcohol (preservative)

Do not take this medicine if you are allergic to any of these ingredients.

What HERZUMA looks like

HERZUMA is a white to pale yellow powder which is dissolved in sterile water before use. It is supplied in a vial.

After dissolving, HERZUMA should appear as a clear, colourless to yellow solution.

HERZUMA is available in two strengths:

- 150 mg trastuzumab powder for injection for intravenous (IV) infusion (drip into the vein). Supplied as a single-dose vial for use in a single patient only. Pack size of 1x vial per carton (AUST R 289146).
- 440 mg trastuzumab powder for injection for intravenous (IV) infusion (drip into the vein). Supplied as a multi-dose vial for use in a single patient only. Pack size of 1x multi-dose vial and 1x vial (20 mL) of Bacteriostatic Water for Injection (BWI) containing 1.1% benzyl alcohol as a preservative (AUST R 318115).

Who distributes HERZUMA

Celltrion Healthcare Australia Pty. Ltd.

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Australia

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