

CMI

Trastuzumab 150 mg, 440mg Powder for Injection for IV Infusion

## Consumer Medicine Information

# HERZUMA<sup>®</sup>

**Trastuzumab**

**150 mg and 440 mg powder for injection for intravenous infusion**

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### What is in this leaflet

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This leaflet answers some common questions about HERZUMA 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 HERZUMA against the benefits expected for you.

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

**Keep this leaflet with the medicine.**

You may need to read it again.

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### What HERZUMA is used for

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HERZUMA contains the active ingredient trastuzumab.

HERZUMA belongs to a group of medicines known as antineoplastic (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 tumours has tested positive to HER2.

HERZUMA may be used alone or 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 the chemotherapy medicines cisplatin and capecitabine (or 5FU).

For further information about other medicines you are receiving with HERZUMA, please ask your doctor, nurse or pharmacist for the Consumer medicine Information (CMI) leaflet.

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

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

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## Before you are given HERZUMA

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### *When you must not be given it*

#### Do not use HERZUMA if:

- **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 tire 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
- **you have had an allergic reaction to:**
    - **HERZUMA**
    - **benzyl alcohol**
    - **any proteins of Chinese hamster origin, or**
    - **any of the ingredients listed at the end of this leaflet**

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 HERZUMA, 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 plaque builds up inside the arteries)
  - **poorly controlled hypertension** (high blood pressure)
  - **heart failure** (where the heart can no longer pump normally)
  - **cardiac arrhythmia** (abnormal or rapid heart beat)
  - **angina** (chest pain)
- **you 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 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 pregnant or plan 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.
- **you are breast-feeding or plan to breast-feed**  
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 breast-feeding until 7 months after completing HERZUMA treatment.
- **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 related reactions).

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Your doctor or nurse will check for side effects during your infusion. See 'Side effects' for symptoms to look out for.

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

### *Taking other medicines*

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

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

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

**Tell your doctor or pharmacist that you have received HERZUMA therapy, if you start any new medication within seven months of stopping HERZUMA treatment.**

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

### *Use in children*

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

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## How HERZUMA is given

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

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

They may differ from the information contained in this leaflet.

HERZUMA must be prepared by a healthcare professional before treatment and will be given in a hospital or clinic by a doctor or nurse.

HERZUMA is given by "drip" into a vein (intravenous or 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.

For the treatment of breast cancer, HERZUMA may be 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 once every three weeks in combination with other medicines used to treat gastric cancer.

Your doctor will decide how long you should receive HERZUMA; this will depend on your response to HERZUMA and the state of your disease.

### *If you miss a dose*

As HERZUMA is given to you under the supervision of your doctor, you are unlikely to miss a dose. However, if you forget or miss an 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 are given too much (overdose)*

As HERZUMA is given to you under the supervision of your doctor it is unlikely that you will be given too much. However, if you experience any side effects after being given HERZUMA, tell your doctor or nurse immediately.

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## While you are receiving HERZUMA

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### *Things you must do*

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

**Tell your doctor or nurse immediately if you have any signs or symptoms of an allergic reaction or anaphylactic reaction.**

Some signs and symptoms 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

**Tell your doctor or nurse immediately if you have any signs and symptoms of heart problems.**

Some signs and symptoms of heart problems are:

- 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 these symptoms require medication.

**Tell your doctor if you become pregnant or plan to become pregnant while receiving HERZUMA or if you intend to start a family while receiving HERZUMA.**

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

Your doctor should perform regular tests.

### *Things you must not do*

**Do not stop your HERZUMA treatment without talking to your doctor first.**

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

**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 HERZUMA affects you.**

If you experience symptoms during your treatment with HERZUMA you should not drive or operate machinery.

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## Side effects

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**Tell your doctor as soon as possible if you do not feel well while you are receiving HERZUMA.**

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

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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 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.

### ***During an infusion***

**Tell your doctor or nurse immediately if you notice any of the following during, or soon after your infusion (particularly during the first infusion):**

- 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, difficulty breathing or wheezing
- abnormal or rapid beating of the heart
- hives, skin rashes or itching skin
- feeling sick (nausea) or vomiting, diarrhoea
- pain or discomfort (including stomach, back, chest or neck pain)
- fever or chills
- headache and/or dizziness
- weakness or fatigue
- cough

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

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

### ***After an infusion***

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

- 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.

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

**Tell your doctor or nurse as soon as possible if you notice any of the following:**

- any of the side effects listed above
- getting tired more easily after light physical activity, such as walking
- shortness of breath, especially when lying down or if it disturbs your sleep
- runny or blocked nose, or nose bleeds
- insomnia (difficulty sleeping), anxiety or depression
- weakness, soreness in muscles and/or joints
- increased cough
- feeling dizzy, tired, looking pale

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- 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)
- 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).

This is not a complete list of all possible side effects. Your doctor or pharmacist has a more complete list. Other side effects may occur in some people and there may be some 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.

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## Product description

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### *Storage*

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

### *Availability*

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

HERZUMA is available in one type (formulation);

- Powder for injection for intravenous infusion (drip into the vein). Supplied as a single dose vial and available in two strengths, 150 mg and 440mg.

### *What HERZUMA looks like*

HERZUMA is a white to pale yellow powder which is dissolved in sterile water before use. After dissolving, the

HERZUMA solution should appear as a clear colourless to yellow solution.

### *Ingredients*

Each vial of HERZUMA contains 150 mg or 440 mg of the active ingredient, trastuzumab. HERZUMA powder also contains histidine hydrochloride, histidine, trehalose dihydrate and polysorbate 20.

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

The trastuzumab protein is made using chinese hamster ovary cells.

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## Sponsor

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This leaflet was prepared in October 2020