

TRAZIMERA™

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 TRAZIMERA?

TRAZIMERA contains the active ingredient trastuzumab. TRAZIMERA is used to treat breast and gastric cancer. It is only used in patients whose tumour has tested positive to HER2.

For more information, see Section [1. Why am I using TRAZIMERA?](#) in the full CMI.

2. What should I know before I use TRAZIMERA?

Do not use if you have ever had an allergic reaction to any medicine containing trastuzumab, any protein of Chinese hamster origin or any of the ingredients listed at the end of the CMI.

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 TRAZIMERA?](#) in the full CMI.

3. What if I am taking other medicines?

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

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use TRAZIMERA?

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

TRAZIMERA is given by "drip" into a vein (intravenous (IV) infusion). The first TRAZIMERA 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, TRAZIMERA 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 TRAZIMERA is given every three weeks in combination with other medicines used to treat gastric cancer.

More instructions can be found in Section [4. How do I use TRAZIMERA?](#) in the full CMI.

5. What should I know while using TRAZIMERA?

Things you should do	<ul style="list-style-type: none">● Remind any doctor, dentist or pharmacist you visit that you are using TRAZIMERA.● Tell your doctor or nurse immediately if you have any signs and symptoms of an allergic or anaphylactic reaction.● Tell your doctor or nurse immediately if you have any signs and symptoms of heart problems.● Tell your doctor if you become pregnant or intend to start a family while receiving TRAZIMERA.● Keep all of your doctor's appointments so that your progress can be checked.
Things you should not do	<ul style="list-style-type: none">● Do not stop using this medicine without

	<p>checking with your doctor.</p> <ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Be careful driving or operating machinery until you know how TRAZIMERA affects you.

For more information, see Section [5. What should I know while using TRAZIMERA?](#) in the full CMI.

6. Are there any side effects?

TRAZIMERA may cause serious side effects, including: swelling of your face, lips, tongue or throat with difficulty breathing; severe chest pain spreading out to the arms, neck, shoulder and/or back; severe swelling of the hands, feet or legs.

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.

TRAZIMERA™

Active ingredient: *Trastuzumab*

Consumer Medicine Information (CMI)

This leaflet provides important information about using TRAZIMERA. **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 TRAZIMERA.**

Where to find information in this leaflet:

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

1. Why am I using TRAZIMERA?

TRAZIMERA contains the active ingredient trastuzumab.

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

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

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

TRAZIMERA 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 TRAZIMERA is used with chemotherapy medicines cisplatin and capecitabine (or 5FU).

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

2. What should I know before I use TRAZIMERA?

Warnings

Do not use TRAZIMERA if:

- 1. You are allergic to any medicine containing trastuzumab, any protein of Chinese hamster origin, or any of the ingredients listed at the end of this leaflet.** Some of the symptoms of an allergic reaction may include:
 - shortness of breath
 - wheezing or difficulty breathing
 - swelling of the face, lips, tongue or other part of the body
 - rash, itching or hives on the skin
- 2. 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 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

- abnormal or irregular heartbeat

If you are not sure whether you should start receiving this medicine, talk to your doctor.

Check with 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
- **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 TRAZIMERA**

Your doctor will monitor your heart function closely before and during your treatment with TRAZIMERA. Your heart function may also be monitored for years after ceasing TRAZIMERA treatment.

- **have any breathing or lung problems**
- **are allergic to any other medicines or any other substances such as foods, preservatives or dyes**

Allergic or anaphylactic reactions can occur with TRAZIMERA treatment (known as infusion or administration related reactions). Your doctor or nurse

will monitor you for side effects during treatment. See "side effects" for symptoms to look out for.

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**

TRAZIMERA may be harmful to an unborn baby. If there is

a need for TRAZIMERA 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 TRAZIMERA and

for 7 months after stopping treatment.

- **Talk to your doctor if you are breastfeeding or intend to breastfeed**

It is not known if TRAZIMERA passes into breast milk. It is recommended that you discontinue breast-feeding while you are being treated with TRAZIMERA and not

restart breast-feeding until 7 months after completing TRAZIMERA treatment.

If you have not told your doctor about any of the above, tell him/her before you start taking TRAZIMERA.

Use in children

The safety and effectiveness of TRAZIMERA 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.

TRAZIMERA treatment with gemcitabine, vinorelbine, a taxane 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 TRAZIMERA.

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

It may take up to seven months for TRAZIMERA 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 TRAZIMERA.

4. How do I use TRAZIMERA?

How TRAZIMERA is given

Follow all directions given to you by your doctor or nurse carefully.

They may differ from the information contained in this leaflet.

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

TRAZIMERA is given by "drip" into a vein (intravenous (IV) infusion).

The first TRAZIMERA 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, TRAZIMERA 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 TRAZIMERA is given every three weeks in combination with other medicines used to treat gastric cancer.

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

If you miss a dose

As TRAZIMERA 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 TRAZIMERA, make another appointment as soon as possible.

Your doctor will decide when and how much your next dose of TRAZIMERA will be.

If you are given too much

As TRAZIMERA 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 TRAZIMERA, tell your doctor immediately.

5. What should I know while using TRAZIMERA?

Things you should do

Tell your doctor or nurse straight away if you:

- **have any signs and symptoms of an allergic 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
- **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 doctors' instructions if any of these symptoms require medication.

Tell any other doctors, dentists, and pharmacists who treat you that you are receiving TRAZIMERA.

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

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may perform regular tests.

Things you should not do

- **Do not stop your TRAZIMERA treatment without checking with your doctor.**

Tell your doctor if you feel that TRAZIMERA 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.**

Driving or using machines

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

If you have experienced symptoms during your treatment with TRAZIMERA you should not drive or operate machinery.

6. Are there any side effects?

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

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

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 TRAZIMERA 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 TRAZIMERA or due to the other medicines.

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

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.

Side effects

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)	<p>Tell your doctor or nurse as soon as possible if you notice any of these side effects</p>

Side effects	What to do
<ul style="list-style-type: none"> ● 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) 	

Serious side effects

Serious side effects	What to do
<p>During an 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 	<p>Tell your doctor or nurse immediately if you notice any of these side effects while receiving an infusion (particularly during the first infusion)</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● 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>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 	<p>Tell your doctor immediately or go to Accident and Emergency at your nearest hospital</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● 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 	

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 TRAZIMERA contains

Active ingredient (main ingredient)	<ul style="list-style-type: none">● trastuzumab The trastuzumab protein is made using Chinese hamster ovary cells.
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">● histidine hydrochloride● histidine● polysorbate 20● sucrose

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

What TRAZIMERA looks like

TRAZIMERA is a white powder which is dissolved in sterile water before use.

After dissolving, the TRAZIMERA solution should appear as a clear, colourless to pale yellow-brown solution.

TRAZIMERA is available in two strengths, 60 mg and 150 mg.

60 mg: AUST R 304049

150 mg: AUST R 304050

Who distributes TRAZIMERA

TRAZIMERA is supplied in Australia by:

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free number: 1800 675 229

www.pfizermedinfo.com.au

This leaflet was prepared in May 2022.