Patient Medication Information – Breast Cancer

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrTRAZIMERA®

trastuzumab for injection

BREAST CANCER

This Patient Medication Information is written for the person who will be taking **TRAZIMERA**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **TRAZIMERA**, talk to a healthcare professional.

TRAZIMERA is a biosimilar biologic drug (biosimilar) to the reference biologic drug HERCEPTIN®. A biosimilar is authorized based on its similarity to a reference biologic drug that was already authorized for sale.

Serious warnings and precautions box

- **Medication Errors**

There is a risk of medication errors between TRAZIMERA (trastuzumab) and trastuzumab emtansine or trastuzumab deruxtecan. Verify with the healthcare provider that the recommended TRAZIMERA (trastuzumab) dose and NOT trastuzumab emtansine or trastuzumab deruxtecan dose is used.

- **Cardiotoxicity (harm to the heart)**

TRAZIMERA can result in the development of heart problems including heart failure. The appearance of heart failure can be delayed and can occur after treatment with TRAZIMERA is completed. In early breast cancer, the incidence of cardiac dysfunction was higher in patients who received trastuzumab plus chemotherapy versus chemotherapy alone, with higher risk when trastuzumab was administered together with a taxane following an anthracycline and cyclophosphamide. In patients with breast cancer that has spread to other parts or organs of the body, the incidence and severity of cardiac dysfunction was particularly high in patients who received trastuzumab at the same time as anthracyclines and cyclophosphamide.

You should have your heart function evaluated by your doctor before and during treatment with TRAZIMERA.

- **Infusion Reactions; Lung Problems**

Some patients have had serious infusion reactions and lung problems; infusion reactions causing death have been reported. In most cases, these reactions occurred during or within 24 hours of receiving trastuzumab. Your TRAZIMERA infusion should be temporarily stopped if you have shortness of breath or very low blood pressure. Your doctor will monitor you until these symptoms go away. If you have a severe allergic reaction, swelling, lung problems, inflammation of the lung, or severe shortness of breath, your doctor may need to completely stop your TRAZIMERA treatment.

- **Toxicity to Fetus (Unborn Baby)**

TRAZIMERA can cause harm to the fetus (unborn baby), in some cases death of the fetus, when taken by a pregnant woman. Women who could become pregnant need to use effective birth control methods during TRAZIMERA treatment and for at least 7 months after treatment with TRAZIMERA. Nursing mothers treated with TRAZIMERA should discontinue nursing or discontinue TRAZIMERA.

What TRAZIMERA is used for:

- TRAZIMERA is a cancer medicine that must be prescribed by a doctor.
- Patients whose breast cancer tumour cells produce large amounts of the HER2 protein can use TRAZIMERA.
- TRAZIMERA is used for certain patients with early breast cancer following surgery and after chemotherapy OR following surgery and with taxane chemotherapy as well as for patients to whom breast cancer has spread to other parts or organs of the body.
- TRAZIMERA is used to slow down the growth of specific breast cancer cells that produce large amounts of HER2 protein. It is used only for patients whose tumours are growing more rapidly

than normal because of a genetic problem in the cells. This occurs in about 25 to 30% of breast cancer tumours.

- If your doctor has prescribed pertuzumab and the chemotherapy drug docetaxel in combination with TRAZIMERA, you should also read the leaflet for these medications.
- TRAZIMERA is also approved for the treatment of gastric cancer (a separate Patient Medication Information insert provides information on the use of TRAZIMERA in gastric cancer).

How TRAZIMERA works:

- Our bodies have a natural defence system against cancer cells. When cancer cells appear, our bodies respond by making special proteins called antibodies. The antibodies attach to other proteins on the growing tumour cells. Researchers studied this to learn how to create antibodies that help with cancer treatment.
- Antibodies are now made that can target tumours to try to control the growth of cancer.
- TRAZIMERA belongs to a family of medicines called monoclonal antibodies. It is an antibody that targets the HER2 gene to stop its activity. It attaches to the HER2 receptor on the cancer cell. When it is in place, it works to stop the growth of the cancer cells and may destroy them.

The ingredients in TRAZIMERA are:

Medicinal ingredient(s): trastuzumab

Non-medicinal ingredients: L histidine, L-histidine hydrochloride monohydrate, polysorbate 20, and sucrose.

The Bacteriostatic Water for Injection supplied with TRAZIMERA 440 mg contains benzyl alcohol.

TRAZIMERA comes in the following dosage form(s):

TRAZIMERA is a sterile, powder that will be reconstituted and given as an intravenous (IV) administration. Each vial of TRAZIMERA contains 440 mg or 150 mg trastuzumab.

Do not use TRAZIMERA if:

- you are allergic to trastuzumab, Chinese Hamster Ovary (CHO) cell proteins, or any component of this product (see “The ingredients in TRAZIMERA are”).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take TRAZIMERA. Talk about any health conditions or problems you may have, including if you:

- have ever had a bad reaction to TRAZIMERA, benzyl alcohol, or any of the inactive ingredients;
- are allergic to other medicines, food and dyes;
- are taking any other medicines, including those not prescribed by your doctor;
- have any other illness or diseases, such as heart problems, heart disease, breathing problems or lung disease; the risk of heart problems may be increased in geriatric patients in both early breast cancer and breast cancer that has spread to other parts or organs of the body; the risk of lung disease may increase if you have taken chemotherapy drugs which are toxic for the lungs;
- have already been treated with chemotherapy drugs (especially anthracyclines such as doxorubicin, epirubicin or related drugs such as mitoxantrone) or radiation therapy;

- are pregnant, plan to become pregnant or are breast-feeding a child. Please note that a reduction in the amount of [amniotic] fluid that surrounds the developing fetus within the amniotic sac has been observed in pregnant women receiving trastuzumab;
- have difficulty breathing at rest.

Other warnings you should know about:

- TRAZIMERA has a minor influence on the ability to drive and use machines. Dizziness and sleepiness may occur during treatment with TRAZIMERA. If you experience unwanted effects related to the infusion (such as itching, wheezing, dizziness, racing heart) you should not drive or operate machinery until symptoms resolve completely.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Formal drug interaction studies with TRAZIMERA have not been done in humans. Important interactions with other medications were not seen during clinical trials with trastuzumab.

How to take TRAZIMERA:

Your doctor has prescribed TRAZIMERA after carefully studying your condition. Other people may not benefit from taking this medicine, even though their problems may seem similar to yours.

Verify with the healthcare provider that the recommended TRAZIMERA (trastuzumab) dose and NOT trastuzumab emtansine or trastuzumab deruxtecan dose is used.

The hospital pharmacy will prepare TRAZIMERA so it can be used.

If you are sensitive to benzyl alcohol, the TRAZIMERA powder should be mixed with sterile water.

Usual dose:

The usual dose of TRAZIMERA depends on your body weight. Your doctor will calculate the dose for you.

How long you need to take TRAZIMERA will depend on your response to the treatment. Your doctor will check your response regularly and decide how many treatments you will receive.

A Registered Nurse in the hospital or outpatient clinic will give you TRAZIMERA at regular intervals determined by your physician. TRAZIMERA is not taken by mouth, but given through an intravenous line. An intravenous line, or IV, is a thin, plastic tube with a needle placed in a vein in your hand or arm. When TRAZIMERA is given intravenously, it is called an infusion.

Your first infusion of TRAZIMERA will take about 90 minutes. If you tolerate this infusion well, your next infusions may be given in less time, usually about 30 minutes.

Overdose:

If you think you, or a person you are caring for, have taken too much TRAZIMERA, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

For information on the risk of trastuzumab emtansine or trastuzumab deruxtecan overdose due to medication errors, see their respective Product Monographs.

Missed Dose:

If you miss a dose, your doctor will advise you on when your next administration of TRAZIMERA will be.

Possible side effects from using TRAZIMERA:

These are not all the possible side effects you may have when taking TRAZIMERA. If you experience any side effects not listed here, tell your healthcare professional.

Some unwanted effects happen during the first infusion or shortly after it is completed. The effects usually do not last long but may need treatment. The infusion may be stopped and may be restarted and/or given over a longer time.

These unwanted effects related to the infusion may include:

- Itching
- Wheezing
- Dizziness
- Racing heart

Giving certain medications before the next infusion of TRAZIMERA may prevent these unwanted effects.

In clinical studies, the most common unwanted effects were fever and chills, nausea, vomiting, diarrhea, pain, and headache. The symptoms can easily be treated. Giving certain medications before TRAZIMERA can prevent some unwanted effects.

Less common unwanted effects are:

- Shortness of breath and water retention, which are symptoms of heart problems. These are caused by an effect on the heart muscle that reduces the strength of the pumping action of the heart. This unwanted effect is more common in women who have previously had anthracycline chemotherapy (e.g. doxorubicin, epirubicin). Heart failure as a result of TRAZIMERA treatment can vary in severity and may require treatment with heart medications and/or TRAZIMERA treatment may need to be stopped.
- Shortness of breath, fatigue, or a racing heart, which are symptoms of anemia. This is caused by a temporary decrease in the number of red blood cells.
- A temporary decrease in the number of white blood cells may increase your risk of infection and diarrhea.

Difficulty breathing, fatigue and weight loss are commonly seen with lung disease.

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

- Shortness of breath;
- Increased cough;
- Swelling of the legs as a result of water retention;
- Diarrhea – if you have an extra four bowel movements each day or any diarrhea at night;
- Symptoms of infection that include:
  - fever: a temperature of 38°C or greater
  - sore throat

  - cough
  - any redness or swelling
  - pain when you pass urine
- Symptoms of an allergic reaction include:
  - closing of the throat
  - swelling of lips and tongue
  - hives
  - rash
  - dizziness
  - fast heartbeat

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Very common			
Diarrhea: Where you have an extra four bowel movements each day or any diarrhea at night		√	
Common			
Heart problems: shortness of breath, water retention (swelling of the lower legs)		√	
Anemia (reduced number of red blood cells of the blood):shortness of breath, racing heart, dizziness, light headedness		√	
Reduced number of white blood cells may lead to an increase chance of infection:fever (temperature above 38ºC or 101ºF), chills, sore throat, cough, any redness or swelling, pain when you pass your urine		√	
Lung problems: shortness of breath, wheezing or coughing		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- The hospital pharmacy will store TRAZIMERA in a refrigerator. TRAZIMERA can be at room temperature when the infusion is given.
- Keep out of reach and sight of children.

If you want more information about TRAZIMERA:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website: (Drug Product Database: Access the database); the manufacturer's website (www.pfizer.ca); or by calling 1-800-463-6001.

This leaflet was prepared by Pfizer Canada ULC.

Date of Authorization: 2025-12-23

Patient Medication Information – Gastric Cancer

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrTRAZIMERA®

trastuzumab for injection

GASTRIC CANCER

This Patient Medication Information is written for the person who will be taking **TRAZIMERA**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

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TRAZIMERA is a biosimilar biologic drug (biosimilar) to the reference biologic drug HERCEPTIN®. A biosimilar is authorized based on its similarity to a reference biologic drug that was already authorized for sale.

Serious warnings and precautions box

- **Medication Errors**

There is a risk of medication errors between TRAZIMERA (trastuzumab) and trastuzumab emtansine or trastuzumab deruxtecan. Verify with the healthcare provider that the recommended TRAZIMERA (trastuzumab) dose and NOT trastuzumab emtansine or trastuzumab deruxtecan dose is used.

- **Cardiotoxicity (harm to the heart)**

TRAZIMERA can result in the development of heart problems including heart failure. The appearance of heart failure can be delayed and can occur after treatment with TRAZIMERA is completed. In early breast cancer, the incidence of cardiac dysfunction was higher in patients who received trastuzumab plus chemotherapy versus chemotherapy alone, with higher risk when trastuzumab was administered together with a taxane following an anthracycline and cyclophosphamide. In patients with breast cancer that has spread to other parts or organs of the body, the incidence and severity of cardiac dysfunction was particularly high in patients who received trastuzumab at the same time as anthracyclines and cyclophosphamide.

You should have your heart function evaluated by your doctor before and during treatment with TRAZIMERA.

- **Infusion Reactions; Lung Problems**

Some patients have had serious infusion reactions and lung problems; infusion reactions causing death have been reported. In most cases, these reactions occurred during or within 24 hours of receiving trastuzumab. Your TRAZIMERA infusion should be temporarily stopped if you have shortness of breath or very low blood pressure. Your doctor will monitor you until these symptoms go away. If you have a severe allergic reaction, swelling, lung problems, inflammation of the lung, or severe shortness of breath, your doctor may need to completely stop your TRAZIMERA treatment.

- **Toxicity to Fetus (Unborn Baby)**

TRAZIMERA can cause harm to the fetus (unborn baby), in some cases death of the fetus, when taken by a pregnant woman. Women who could become pregnant need to use effective birth control methods during TRAZIMERA treatment and for at least 7 months after treatment with TRAZIMERA . Nursing mothers treated with TRAZIMERA should discontinue nursing or discontinue TRAZIMERA .

What TRAZIMERA is used for:

- TRAZIMERA is a cancer medicine that must be prescribed by a doctor.
- Patients whose gastric cancer tumour cells produce large amounts of the HER2 protein can use TRAZIMERA.
- TRAZIMERA is used for certain patients with gastric cancer that has spread to other parts or organs of the body to slow down the growth of specific gastric cancer cells that produce large amounts of HER2 protein.
- TRAZIMERA is used in combination with chemotherapy (capecitabine or intravenous 5-fluorouracil and in combination with cisplatin) for the treatment of gastric cancer that has spread to other parts or organs of the body in patients that have not received prior anti-cancer treatment for their disease.

- TRAZIMERA is also approved for the treatment of breast cancer (a separate Patient Medication Information insert provides information on the use of TRAZIMERA in breast cancer).

How TRAZIMERA works:

- Our bodies have a natural defence system against cancer cells. When cancer cells appear, our bodies respond by making special proteins called antibodies. The antibodies attach to other proteins on the growing tumour cells. Researchers studied this to learn how to create antibodies that help with cancer treatment.
- Antibodies are now made that can target tumours to try to control the growth of cancer.
- TRAZIMERA belongs to a family of medicines called monoclonal antibodies. It is an antibody that targets the HER2 gene to stop its activity. It attaches to the HER2 receptor on the cancer cell. When it is in place, it works to stop the growth of the cancer cells and may destroy them.

The ingredients in TRAZIMERA are:

Medicinal ingredients: trastuzumab

Non-medicinal ingredients: L histidine, L-histidine hydrochloride monohydrate, polysorbate 20, and sucrose.

The Bacteriostatic Water for Injection supplied with TRAZIMERA 440 mg contains benzyl alcohol.

TRAZIMERA comes in the following dosage form(s):

TRAZIMERA is a sterile, powder that will be reconstituted and given as an intravenous (IV) infusion. Each vial of TRAZIMERA contains 440 mg or 150 mg trastuzumab.

Do not use TRAZIMERA if:

- you are allergic to trastuzumab, Chinese Hamster Ovary (CHO) cell proteins, or any component of this product (see “The ingredients in TRAZIMERA are”).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take TRAZIMERA. Talk about any health conditions or problems you may have, including if you:

- have ever had a bad reaction to TRAZIMERA, benzyl alcohol, or any of the inactive ingredients;
- are allergic to other medicines, food and dyes;
- are taking any other medicines, including those not prescribed by your doctor;
- have any other illness or diseases, such as heart problems, heart disease, breathing problems or lung disease;
- are pregnant, plan to become pregnant or are breast-feeding a child. Please note that a reduction in the amount of [amniotic] fluid that surrounds the developing fetus within the amniotic sac has been observed in pregnant women receiving trastuzumab;
- have difficulty breathing at rest.

Other warnings you should know about:

- TRAZIMERA has a minor influence on the ability to drive and use machines. Dizziness and sleepiness may occur during treatment with TRAZIMERA. If you experience unwanted effects related to the infusion (such as itching, wheezing, dizziness, racing heart) you should not drive or operate machinery until symptoms resolve completely.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Formal drug interaction studies with TRAZIMERA have not been done in humans. Important interactions with other medications were not seen during clinical trials with trastuzumab.

How to take TRAZIMERA:

Your doctor has prescribed TRAZIMERA after carefully studying your condition. Other people may not benefit from taking this medicine, even though their problems may seem similar to yours.

Verify with the healthcare provider that the recommended TRAZIMERA (trastuzumab) dose and NOT trastuzumab emtansine or trastuzumab deruxtecan dose is used.

The hospital pharmacy will prepare TRAZIMERA so it can be used.

If you are sensitive to benzyl alcohol, the TRAZIMERA powder should be mixed with sterile water.

Usual dose:

The usual dose of TRAZIMERA depends on your body weight. Your doctor will calculate the dose for you.

How long you need to take TRAZIMERA will depend on your response to the treatment. Your doctor will check your response regularly and decide how many treatments you will receive.

A Registered Nurse in the hospital or outpatient clinic will give you TRAZIMERA at regular intervals (usually every 3 weeks) determined by your physician. TRAZIMERA is not taken by mouth but given through an intravenous line. An intravenous line, or IV, is a thin, plastic tube with a needle placed in a vein in your hand or arm. When TRAZIMERA is given intravenously, it is called an infusion.

Your first infusion of TRAZIMERA will take about 90 minutes. If you tolerate this infusion well, your next infusions may be given in less time, usually about 30 minutes.

Overdose:

If you think you, or a person you are caring for, have taken too much TRAZIMERA, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

For information on the risk of trastuzumab emtansine or trastuzumab deruxtecan overdose due to medication errors, see their respective Product Monographs.

Missed Dose:

If you miss a dose, your doctor will advise you on when your next administration of TRAZIMERA will be.

Possible side effects from using TRAZIMERA:

These are not all the possible side effects you may have when taking TRAZIMERA. If you experience any side effects not listed here, tell your healthcare professional.

Some unwanted effects happen during the first infusion or shortly after it is completed. The effects usually do not last long but may need treatment. The infusion may be stopped and may be restarted and/or given over a longer time.

These unwanted effects related to the infusion may include:

- Itching
- Wheezing
- Dizziness
- Racing heart

Giving certain medications before the next infusion of TRAZIMERA may prevent these unwanted effects.

In the main clinical study in gastric cancer, the most common unwanted effects which are known to be associated with both the chemotherapy drugs used in the study and with trastuzumab administration were:

- stomach disorders such as nausea, vomiting, diarrhea and constipation
- blood disorders such as neutropenia (reduced number of white blood cells) anemia (reduced number of red blood cells) and thrombocytopenia (reduced number of platelet cells (colorless blood cells that play an important role in blood clotting)).

Giving certain medications before TRAZIMERA can prevent some unwanted effects.

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

- Shortness of breath;
- Increased cough;
- Swelling of the legs as a result of water retention;
- Diarrhea – if you have an extra four bowel movements each day or any diarrhea at night;
- Symptoms of infection that include:
  - fever: a temperature of 38°C or greater
  - sore throat
  - cough
  - any redness or swelling
  - pain when you pass urine
- Symptoms of an allergic reaction include:
  - closing of the throat
  - swelling of lips and tongue
  - hives
  - rash
  - dizziness
  - fast heartbeat

In the main clinical study in gastric cancer, serious side effects that appeared with higher frequency in trastuzumab plus chemotherapy arm versus chemotherapy arm alone are listed in the table below.

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Common			
Stomach problems: Diarrhea, Vomiting, Difficulty swallowing		√	
Blood disorders:Reduced number of white blood cells leading to increased chance of infection; fever.		√	
Infections (Infection of the lungs (pneumonia)): symptoms of a cold followed by high fever.		√	
General Disorders: Fever		√	
Metabolism Disorders: Anorexia		√	
Kidney problems (Kidneys fail to function adequately): decreased or normal urine output, fluid retention, causing swelling in your legs, ankles or feet, drowsiness shortness of breath, fatigue.		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- The hospital pharmacy will store TRAZIMERA in a refrigerator. TRAZIMERA can be at room temperature when the infusion is given.
- Keep out of reach and sight of children.

If you want more information about TRAZIMERA:

- Talk to your healthcare professional
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This leaflet was prepared by Pfizer Canada ULC.

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