

SELECTED SAFETY INFORMATION

Possible Serious Side Effects With TRAZIMERA

Not all people have serious side effects, but side effects with trastuzumab-product therapy are common.

Although some people may have a life-threatening side effect, most do not.

Your doctor will stop treatment if any serious side effects occur.

TRAZIMERA is not for everyone. Be sure to contact your doctor if you are experiencing any of the following:

HEART PROBLEMS

These include heart problems—such as congestive heart failure or reduced heart function—with or without symptoms. The risk for and seriousness of these heart problems were highest in people who received both trastuzumab and a certain type of chemotherapy (anthracycline). In a study of adjuvant (early) breast cancer, one patient died of significantly weakened heart muscle. Your doctor will check for signs of heart problems before, during, and after treatment with TRAZIMERA.





What is TRAZIMERA?

TRAZIMERA (trastuzumab-qyyp) is an FDA-approved biosimilar* to Herceptin® (trastuzumab), which is used for the treatment of certain kinds of breast cancer and stomach cancer.

TRAZIMERA is FDA approved to help treat*:



Adjuvant Breast Cancer

TRAZIMERA is approved for the treatment of early-stage breast cancer that is Human Epidermal growth factor Receptor 2-positive (HER2+) and

- has spread into the lymph nodes, **OR**
- has <u>not</u> spread into the lymph nodes

If it has **not** spread into the lymph nodes,

- the cancer needs to be estrogen receptor/ progesterone receptor (ER/PR) negative <u>OR</u>
- have one high-risk feature[‡]

TRAZIMERA can be used in several different ways:

- As part of a treatment course that includes the chemotherapy drugs doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
- With the chemotherapy drugs docetaxel and carboplatin
- Alone after treatment with multiple other therapies, including an anthracycline-based therapy (like doxorubicin)



Metastatic Breast Cancer

TRAZIMERA has 2 approved uses in metastatic breast cancer:

- TRAZIMERA, in combination with the chemotherapy drug paclitaxel, is approved for the first-line treatment of HER2+ metastatic breast cancer
- TRAZIMERA alone is approved for the treatment of HER2+ breast cancer in patients who have received one or more chemotherapy courses for metastatic disease



Metastatic Gastric Cancer

TRAZIMERA is approved, in combination with chemotherapy (cisplatin and either capecitabine or 5-fluorouracil), for the treatment of HER2+ metastatic cancer of the stomach or gastroesophageal junction (where the esophagus meets the stomach) in patients who have not received prior treatment for their metastatic disease.

Please see Important Safety Information on pages 7 and 8 and full Prescribing Information, including BOXED WARNINGS, at TRAZIMERA.com.

What are biosimilars?

Biosimilars are highly similar to the original biologics. Although it is impossible to produce an identical copy of a biologic medicine, a biosimilar must be proven to show no clinically meaningful differences from a reference product.

Do biosimilars have the same side effects and safety profile as the reference products?

Biosimilars must demonstrate that they have no clinically meaningful differences from their reference products in terms of safety and effectiveness. They are expected to work the same way as the original medicines.

How long have biosimilars been available?

The first biosimilar was approved in the United States in 2015.

How will I receive TRAZIMERA?

Your healthcare provider will give you TRAZIMERA treatments through intravenous infusions. That means you get TRAZIMERA through a needle in your vein.

Before each TRAZIMERA treatment, your healthcare provider or nurse will ask you questions about your general health. Tell your healthcare provider or nurse about any new symptoms.

*Biosimilar means that the biological product is approved based on data demonstrating that it is highly similar to an FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar and the reference product.

†Patients are selected for therapy based on an FDA-approved test for trastuzumab products.

"High risk is defined as ER/PR positive with one of the following features: tumor size >2 cm, age <35 years, or tumor grade 2 or 3.

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HEART PROBLEMS

Contact your doctor immediately for any of the following: new onset or worsening shortness of breath, cough, swelling of the ankles/legs, swelling of the face, palpitations, weight gain of more than 5 pounds in 24 hours, dizziness, or loss of consciousness.

INFUSION REACTIONS, including:

- Fever and chills
- Feeling sick to your stomach (nausea)
- Headache
- Dizziness
- Shortness of breath
- Throwing up (vomiting)
- Pain (in some cases at tumor sites)

These signs usually happen within 24 hours after receiving trastuzumab products.





What is the most important information I should know about TRAZIMERA?

Although some people may have a life-threatening side effect, most do not.

Your doctor will stop treatment if any serious side effects occur.

TRAZIMERA is not for everyone. Be sure to contact your doctor if you are experiencing any of the following:



Heart problems

These include heart problems—such as congestive heart failure or reduced heart function—with or without symptoms. The risk for and seriousness of these heart problems were highest in people who received both trastuzumab and a certain type of chemotherapy (anthracycline). In an adjuvant (early) breast cancer study, one patient died of significantly weakened heart muscle. Your doctor will check for signs of heart problems before, during, and after treatment with TRAZIMERA.

Contact your doctor immediately for any of the following: new onset or worsening shortness of breath, cough, swelling of the ankles/legs, swelling of the face, palpitations, weight gain of more than 5 pounds in 24 hours, dizziness, or loss of consciousness.



Infusion reactions, including:

- Fever and chills
- Feeling sick to your stomach (nausea)
- Throwing up (vomiting)
- Pain (in some cases at tumor sites)
- Headache
- Dizziness
- Shortness of breath
- Low blood pressure
- Rash
- Weakness

These signs usually happen within 24 hours after receiving trastuzumab products.

Be sure to contact your doctor if you:



Are a woman who could become pregnant, or may be pregnant

Use of trastuzumab products may result in the death of an unborn baby or birth defects. Contraception should be used while receiving TRAZIMERA and for 7 months after your last dose of TRAZIMERA.



Have any signs of severe lung problems, including:

- Severe shortness of breath
- Fluid in or around the lungs
- Weakening of the valve between the heart and the lungs
- Not enough oxygen in the body
- Swelling of the lungs
- Scarring of the lungs

Your doctor may check for signs of severe lung problems when he or she examines you.



Have low white blood cell counts

Low white blood cell counts can be life threatening. Low white blood cell counts were seen more often in patients receiving trastuzumab plus chemotherapy than in patients receiving chemotherapy alone.

Your doctor may check for signs of low white blood cell counts when he or she examines you.

See "What are the side effects seen most often with TRAZIMERA?" on the next page for more information about side effects.





What are the side effects seen most often with TRAZIMERA?

Some patients receiving trastuzumab had the side effects listed below. You should contact your doctor immediately if you have any of these side effects.

Some patients receiving trastuzumab for breast cancer had the following side effects:



- Fever
- Feeling sick to your stomach (nausea)
- Throwing up (vomiting)
- Infusion reactions
- Diarrhea
- Infections
- Increased cough
- Headache
- Feeling tired
- Shortness of breath
- Rash
- Low white and red blood cell counts
- Muscle pain

Some patients receiving trastuzumab for metastatic stomach cancer had the following side effects:



- Low white blood cell counts
- Diarrhea
- Feeling tired
- Low red blood cell counts
- Swelling of the mouth lining
- Weight loss
- Upper respiratory tract infections
- Fever
- Low platelet counts
- Swelling of the mucous membranes
- Swelling of the nose and throat
- Change in taste



Trazimera° trastuzumab-qyyp ≥pfizer

What financial support may be available for my TRAZIMERA prescription?

At Pfizer Oncology Together™, we treat your individual needs as a priority. We'll help you identify financial assistance options so you can get your prescribed TRAZIMERA, regardless of your insurance coverage: commercial, Medicare/government issued, or uninsured.

Eligible patients may pay as little as per treatment

- Pfizer Oncology Together Co-Pay Savings Program for Injectables
 - Eligible,* commercially insured patients†
 may pay as little as \$0 per treatment for
 TRAZIMERA, regardless of income.† Limits,
 terms, and conditions apply

FOR LIVE, PERSONALIZED SUPPORT

Call 1-877-744-5675 (Monday–Friday 8 AM–8 PM ET) or Visit PfizerOncologyTogether.com

*Terms and Conditions: By using this program, you acknowledge that you currently meet the eligibility criteria and will comply with the terms and conditions below:

The Pfizer Oncology Together Co-Pay Savings Program for Injectables for TRAZIMERA® is not valid for patients who are enrolled in a state or federally funded insurance program, including but not limited to Medicare, Medicaid, TRICARE, Veterans Affairs health care, a state prescription drug assistance program, or the Government Health Insurance Plan available in Puerto Rico (formerly known as "La Reforma de Salud"). Program offer is not valid for cash-paying patients. With this program, eligible patients may pay as little as \$0 co-pay per TRAZIMERA treatment, subject to a maximum benefit of \$25,000 per calendar year for outof-pocket expenses for TRAZIMERA including co-pays or coinsurances. The amount of any benefit is the difference between your co-pay and \$0. After the maximum of \$25,000 you will be responsible for the remaining monthly out-of-pocket costs. Patient must have private insurance with coverage of TRAZIMERA. This offer is not valid when the entire cost of your prescription drug is eligible to be reimbursed by your private insurance plans or other private health or pharmacy benefit programs. You must deduct the value of this assistance from any reimbursement request submitted to your private insurance plan, either directly by you or on your behalf. You are responsible for reporting use of the program to any private insurer, health plan, or other third party who pays for or reimburses any part of the prescription filled using the program, as may be required. You should not use the program if your insurer or health plan prohibits use of manufacturer co-pay assistance programs. This program is not valid where prohibited by law. This program cannot be combined with any other savings, free trial or similar offer for the specified prescription. Co-pay card will be accepted only at participating pharmacies. This program is not health insurance. This program is good only in the U.S. and Puerto Rico. This program is limited to 1 per person

This program is good only in the U.S. and Puerto Rico. This program is limited to 1 per person during this offering period and is not transferable. No other purchase is necessary. Data related to your redemption of the program assistance may be collected, analyzed, and shared with Pfizer, for market research and other purposes related to assessing Pfizer's programs. Data shared with Pfizer will be aggregated and de-identified; it will be combined with data related to other assistance redemptions and will not identify you. Pfizer reserves the right to rescind, revoke or amend this program without notice. This program may not be available to patients in all states. For more information about Pfizer, visit www.pfizer.com. For more information about the Pfizer Oncology Together Co-Pay Savings Program for Injectables, visit pfizeroncologytogether.com, call 1-877-744-5675, or write to Pfizer Oncology Together Co-Pay Savings Program for Injectables, P.O. Box 220366, Charlotte, NC 28222. Program terms and offer will expire at the end of each calendar year. Before the calendar year ends, you will receive information and eligibility requirements for continued participation.

Are any other patient support resources available?

At Pfizer Oncology Together, our Care Champions, who have social work experience, can provide you resources that may help with some of your day-to-day challenges[§]:



Connections to emotional support resources

Connections to independent organizations that help eligible patients find free rides and lodging for treatment-related appointments





Educational information about physical and mental health, nutrition, and TRAZIMERA

Information to help you prepare for leaving or returning to work



[†]For patients to be eligible for the Injectables Co-Pay Program for TRAZIMERA, they must have commercial insurance that covers TRAZIMERA and they cannot be enrolled in a state or federally funded insurance program. Whether a co-pay expense is eligible for the Injectables Co-Pay Program for TRAZIMERA benefit will be determined at the time the benefit is paid. Co-pay expenses must be in connection with a separately paid claim for TRAZIMERA administered in the outpatient setting.

The Injectables Co-Pay Program for TRAZIMERA will pay the co-pay for TRAZIMERA up to the annual assistance limit of \$25,000 per calendar year per patient.

^{\$}Some services are provided through third-party organizations that operate independently and are not controlled by Pfizer. Availability of services and eligibility requirements are determined solely by these organizations.





Is there a digital resource that can help me keep track of my cancer care?

A free app designed to help manage life with cancer

Whether you're living with cancer or want to support someone who is, **LivingWith™**, a free app developed by Pfizer Oncology, may help you stay connected and organized, all in one place.

Visit <u>ThisIsLivingWithCancer.com</u> to learn more. Available in English and Spanish. Download LivingWith for free.



to TRAZIMERA.





Motos



The free resources offered through **This Is Living With Cancer™** and **LivingWith™** are available to anyone living with cancer and their loved ones, and are not specific

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Notes	





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- Headache
- Dizziness
- Shortness of breath

These signs usually happen within 24 hours after receiving trastuzumab products.

Be sure to contact your doctor if you:

Are a woman who could become pregnant, or may be pregnant

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Use of trastuzumab products may result in the death of an unborn baby or birth defects. Contraception should be used while receiving TRAZIMERA and for 7 months after your last dose of TRAZIMERA.

Have any signs of **SEVERE LUNG PROBLEMS**, including:

- Severe shortness of breath
- Fluid in or around the lungs
- Weakening of the valve between the heart and the lungs
- Not enough oxygen in the body
- Swelling of the lungs
- Scarring of the lungs

Your doctor may check for signs of severe lung problems when he or she examines you.

Have LOW WHITE BLOOD CELL COUNTS

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Side Effects Seen Most Often With Trastuzumab Products

Some patients receiving trastuzumab for breast cancer had the following side effects:

- Fever
- Feeling sick to your stomach (nausea)
- Throwing up (vomiting)
- Infusion reactions
- Diarrhea
- Infections
- Increased cough
- Headache
- Feeling tired
- Shortness of breath
- Rash
- Low white and red blood cell counts
- Muscle pain





IMPORTANT SAFETY INFORMATION AND INDICATIONS (CONTINUED)

Side Effects Seen Most Often With Trastuzumab Products (continued)

Some patients receiving trastuzumab for metastatic stomach cancer had the following side effects:

- Low white blood cell counts
- Diarrhea
- · Feeling tired
- · Low red blood cell counts
- Swelling of the mouth lining
- Weight loss
- · Upper respiratory tract infections
- Fever
- Low platelet counts
- Swelling of the mucous membranes
- Swelling of the nose and throat
- Change in taste

You should contact your doctor immediately if you have any of the side effects listed above.

INDICATIONS

Adjuvant Breast Cancer

TRAZIMERA is approved for the treatment of early-stage breast cancer that is Human Epidermal growth factor Receptor 2-positive (HER2+) and has spread into the lymph nodes, or is HER2+ and has not spread into the lymph nodes. If it has not spread into the lymph nodes, the cancer needs to be estrogen receptor/progesterone receptor (ER/PR)-negative or have one high-risk feature.* TRAZIMERA can be used in several different ways:

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Your introduction to



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The health information contained herein is provided for educational purposes only and is not intended to replace discussions with a healthcare provider. All decisions regarding patient care must be made with a healthcare provider, considering the unique characteristics of the patient.

The product information provided in this brochure is intended only for residents of the United States. The products discussed herein may have different product labeling in different countries.

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