



Not an actual patient.



Ontruzant[®]
trastuzumab-dttb
for injection, for intravenous use 21 mg/mL

THE POWER TO HELP YOU FIGHT

A guide for patients getting started on ONTRUZANT

ONTRUZANT is approved in adults 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-positive 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. ONTRUZANT can be used in several different ways:

- As part of a treatment course including the chemotherapy drugs doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel. This treatment course is known as “AC→TH”
- With the chemotherapy drugs docetaxel and carboplatin. This treatment course is known as “TCH”
- Alone after treatment with multiple other therapies, including an anthracycline (doxorubicin)-based therapy (a type of chemotherapy)

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

*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.

Please see full Indications and Usage for ONTRUZANT on page 6 of this brochure.

IMPORTANT SAFETY INFORMATION

Treatment with trastuzumab products (ONTRUZANT) can result in heart problems. Serious and sometimes fatal events have occurred. Some patients have had serious and fatal infusion reactions and lung problems. Symptoms usually occur during or within 24 hours of administration. Trastuzumab products (ONTRUZANT) can cause harm to an unborn baby, in some cases death of the unborn baby, when taken by a pregnant woman. Treatment with trastuzumab products (ONTRUZANT) may lead to a worsening of low white blood cell count. To learn more about these and other serious risks, please read the Important Safety Information on pages 6 and 7, and the physician [Prescribing Information](#), and talk with your doctor.



Dare to move forward.
Our commitment is all in.

What Is ONTRUZANT?

What to Expect From
Treatment With
ONTRUZANT

Indications and Usage
& Important Safety
Information

How Is ONTRUZANT
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READY TO FIGHT



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HER2+ Breast Cancer

What is breast cancer?

Breast cancer is a tumor that starts in the breast. This happens when cells in the breast grow out of control. The tumor can be felt as a lump, which should be checked out by your doctor immediately if it has not been already. Your doctor will perform tests to determine whether or not the tumor is cancerous.

How will I know if my cancer is HER2+?

If you are diagnosed with breast cancer, your doctor will want to know more details in order to help choose the best course of treatment. They will order tests, including one to determine HER2 status. If this test identifies your breast cancer as HER2-positive, or HER2+, your doctor will know to treat your breast cancer with drugs that target the HER2 protein.

What makes breast cancer HER2+?

HER2 receptors are proteins found on the surfaces of cells. In a healthy breast cell, HER2 receptors send signals telling cells to grow and divide. However, HER2-positive breast cancer cells have a higher-than-normal number of HER2 receptors. Having too many HER2 receptors may make the cancer grow and divide faster.



1 out of every **4**
breast cancers
is **HER2+**



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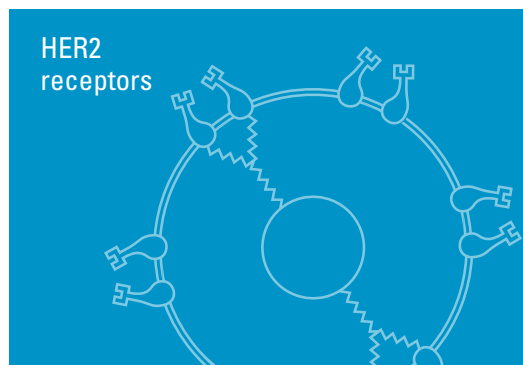
ONTRUZANT® (trastuzumab-dttb)

Ready to Fight HER2+ Breast Cancer

The following information will help you get to know your medicine and answer important questions you may have.

What is ONTRUZANT?

ONTRUZANT is a biological prescription medicine that can help you fight your breast cancer. Your doctor chose it for you because it treats the type of cancer you have: HER2+ breast cancer.



How is it thought to work?

- ONTRUZANT is a targeted therapy designed to interrupt tumor cell growth in HER2+ breast cancer.
- ONTRUZANT may stop the HER2 receptors from signaling cancer cells to grow.
- ONTRUZANT may also be able to identify tumor cells to be destroyed by the immune system.
- Because normal cells have HER2 receptors, ONTRUZANT can also prevent their growth and cause serious side effects.

Biological medicines are medicines made from living cells.

IMPORTANT SAFETY INFORMATION CAN BE FOUND ON PAGES 6 AND 7.

Please read the physician [Prescribing Information](#), including the information about heart problems, infusion reactions (lung problems), and harm to an unborn baby, and discuss it with your doctor.



ONTRUZANT® (trastuzumab-dttb) Is a Biosimilar of HERCEPTIN (trastuzumab)

What is a biosimilar?

A biosimilar is a type of biological medicine. Biosimilars are approved by the US Food and Drug Administration, or FDA, as being highly similar to an already approved biological medicine. Thus the name “biosimilar.” ONTRUZANT is an FDA-approved biosimilar of the drug HERCEPTIN.

Are biosimilars like generic medicines?

No, they are not. Biosimilars are made from living cells and are more complex than generics, which are made from a simpler chemical process. Therefore, the approval standards for biosimilars and generics are different, but each has its own set of rigorous standards that it needs to meet.



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What to Expect From Treatment With ONTRUZANT

ONTRUZANT is an FDA-approved biosimilar of HERCEPTIN for the treatment of HER2+ breast cancer.

ONTRUZANT and HERCEPTIN both:

- Work the same way in the body
- Have the same dosage
- Are given the same way

Similar in effectiveness and safety

This means you can also **expect similar treatment benefits from ONTRUZANT, and similar potential side effects**, as you would expect from HERCEPTIN.

What should I know about HERCEPTIN?

HERCEPTIN has been used to treat HER2+ breast cancer for over 20 years. It has been studied in more than 10,000 women with HER2+ breast cancer.

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Indications and Usage

What conditions is ONTRUZANT used to treat?

ONTRUZANT is a prescription medication used to treat:

Early Breast Cancer

ONTRUZANT is approved in adults for the treatment of early-stage breast cancer that is **H**uman **E**pidermal growth factor **R**eceptor **2**-positive (**HER2+**) and has spread into the lymph nodes, or is HER2-positive 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. ONTRUZANT can be used in several different ways:

- As part of a treatment course including the chemotherapy drugs doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel. This treatment course is known as “AC→TH”
- With the chemotherapy drugs docetaxel and carboplatin. This treatment course is known as “TCH”
- Alone after treatment with multiple other therapies, including an anthracycline (doxorubicin)-based therapy (a type of chemotherapy)

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

*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.

Metastatic Breast Cancer

ONTRUZANT has 2 approved uses in adults in metastatic breast cancer:

- ONTRUZANT in combination with the chemotherapy drug paclitaxel is approved for the first-line treatment of **H**uman **E**pidermal growth factor **R**eceptor **2**-positive (**HER2+**) metastatic breast cancer
- ONTRUZANT alone is approved for the treatment of HER2-positive breast cancer in patients who have received one or more chemotherapy courses for metastatic disease

Patients are selected for therapy based on an FDA-approved test for a trastuzumab product.



IMPORTANT SAFETY INFORMATION

Possible Serious Side Effects With ONTRUZANT

Not all people have serious side effects, but side effects with ONTRUZANT 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.

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

HEART PROBLEMS

These may include serious and fatal 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 ONTRUZANT. Your doctor will also evaluate your heart function every 6 months for at least 2 years following completion of ONTRUZANT as a component of adjuvant therapy.

Contact your doctor immediately if you experience any of the following:

- New or worsening shortness of breath
- Cough
- Swelling of the ankles or legs
- Swelling of the face
- Heart palpitations
- Weight gain of more than 5 pounds in 24 hours
- Dizziness
- Loss of consciousness

INFUSION REACTIONS

Trastuzumab products (ONTRUZANT) can result in serious and fatal infusion reactions and lung problems. Symptoms of infusion reactions include:

- 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
- Physical weakness or lack of energy

IMPORTANT SAFETY INFORMATION (*continued*)

These symptoms usually occur during or within 24 hours of administration.

What should I tell my doctor before I take ONTRUZANT?

Be sure to contact your doctor if you:

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

Trastuzumab products (ONTRUZANT) may result in the death of an unborn baby or birth defects. Women who can become pregnant will be checked by their doctor to verify pregnancy status before starting treatment with ONTRUZANT. In pregnant women and women who can become pregnant, exposure to ONTRUZANT during pregnancy or within 7 months prior to conception can result in fetal harm. Contraception should be used while receiving ONTRUZANT and for 7 months after your last dose of ONTRUZANT.

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

Trastuzumab products (ONTRUZANT) can result in serious and fatal lung problems. 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 a trastuzumab product 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.

What should I watch for and talk to my doctor about before or while taking ONTRUZANT?

Side effects seen most often with ONTRUZANT

Some patients receiving a trastuzumab product 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

Because everyone is different, it is not possible to predict what side effects any one person will have. If you have questions or concerns about side effects, you should talk to your doctor.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please read the physician [Prescribing Information](#), including the information about heart problems, infusion reactions (lung problems), and harm to an unborn baby, and discuss it with your doctor.

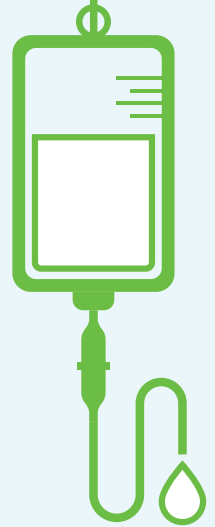


How Is ONTRUZANT® (trastuzumab-dttb) Given?

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ONTRUZANT is given through an intravenous (IV) infusion. A needle will be inserted into a vein so the medicine can be delivered into the bloodstream. How often you get ONTRUZANT depends on the stage of your disease and the way your doctor prescribes treatment.



How to Prepare for Your IV Infusion

You will be receiving infusions of ONTRUZANT at an infusion center on a regular basis. Each infusion can range from 30 to 90 minutes, and you can spend this time doing a number of things.

You could keep yourself busy during treatment with various activities or take the time to relax and sleep. Keep in mind that the treatment room may be cold, so you might want to bring something to keep you warm.

Here are some items you may wish to bring with you when sitting for treatment:

- Blanket
- Clothing with zippers for IV access
- Phone
- Laptop
- Headphones
- Books
- Pillow
- Sleep mask
- Hot or cold pack
- Slippers
- Snacks
- Drinks



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Where Can I Find Patient Support for ONTRUZANT® (trastuzumab-dttb)?



The Organon Access Program for ONTRUZANT

To learn more about The Organon Access Program, ask your doctor or health care professional, or visit www.organonaccessprogram.com or call **866-809-9515**.

Do you have questions about insurance or co-pay assistance?

The Organon Access Program for ONTRUZANT may be able to answer your questions about insurance coverage, co-pay assistance for eligible patients, or eligibility determination. There are several options available to you:



- Speak to a representative by calling **866-809-9515**.



- Learn about options for co-pay assistance for eligible patients.



- Find out about insurance coverage for ONTRUZANT costs, including any out-of-pocket costs.

www.organonaccessprogram.com

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THE POWER TO HELP YOU FIGHT

- FDA approved as a biosimilar of HERCEPTIN (trastuzumab) for the treatment of HER2+ breast cancer
- Patient education and support provided by Organon

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HER2+ Fight

BREAST
CANCER

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