# POWER FOR THE HER2+ BREAST CANCER Fight

Not an actual patient.

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

ONTRUZANT is indicated for adjuvant treatment of HER2-overexpressing node-positive or node-negative (ER/PR-negative or with one high-risk feature) breast cancer:

- As part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
- As part of a treatment regimen with docetaxel and carboplatin
- As a single agent following multi-modality anthracycline-based therapy

Select patients for therapy based on an FDA-approved companion diagnostic for a trastuzumab product.

ER, estrogen receptor; FDA, US Food and Drug Administration; HER2, human epidermal growth factor receptor 2; HER2+, HER2-positive; PR, progesterone receptor.

Get started

## SELECTED SAFETY INFORMATION

**Serious and sometimes fatal side effects have been reported with trastuzumab products. Subclinical and clinical cardiac failure have been reported. The incidence and severity was highest in patients receiving trastuzumab with anthracycline-containing regimens. Discontinue ONTRUZANT treatment for cardiomyopathy. Administration of ONTRUZANT can result in serious and fatal infusion reactions and pulmonary toxicity. Symptoms usually occur during or within 24 hours of administration. Interrupt ONTRUZANT infusion for dyspnea or clinically significant hypotension. Discontinue ONTRUZANT for anaphylaxis, angioedema, interstitial pneumonitis, or acute respiratory distress syndrome. Exposure to ONTRUZANT during pregnancy can result in oligohydramnios, in some cases complicated by pulmonary hypoplasia, skeletal abnormalities, and neonatal death. Exacerbation of chemotherapy-induced neutropenia can also occur. Detection of HER2 protein overexpression is necessary for selection of patients appropriate for ONTRUZANT therapy.**

**Before prescribing ONTRUZANT, please read the accompanying Prescribing Information, including the Boxed Warning about cardiomyopathy, infusion reactions (pulmonary toxicity), and embryo-fetal toxicity.**

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# ONTRUZANT: Indications and Usage

## Adjuvant Breast Cancer

ONTRUZANT is indicated for adjuvant treatment of HER2-overexpressing node-positive or node-negative (ER/PR-negative or with one high-risk feature) breast cancer:

- As part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
- As part of a treatment regimen with docetaxel and carboplatin
- As a single agent following multi-modality anthracycline-based therapy

Select patients for therapy based on an FDA-approved companion diagnostic for a trastuzumab product.

## Metastatic Breast Cancer

ONTRUZANT is indicated:

- In combination with paclitaxel for the first-line treatment of HER2-overexpressing metastatic breast cancer
- As a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease

Select patients for therapy based on an FDA-approved companion diagnostic for a trastuzumab product.

## Metastatic Gastric Cancer

ONTRUZANT is indicated, in combination with cisplatin and capecitabine or 5-fluorouracil, for the treatment of patients with HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma who have not received prior treatment for metastatic disease.

Select patients for therapy based on an FDA-approved companion diagnostic for a trastuzumab product.

ER, estrogen receptor; FDA, US Food and Drug Administration; HER2, human epidermal growth factor receptor 2; PR, progesterone receptor.

Go to the overview ›

## SELECTED SAFETY INFORMATION

### CARDIOMYOPATHY

- **Administration of trastuzumab products can result in subclinical and clinical cardiac failure. The incidence and severity was highest in patients receiving a trastuzumab product with anthracycline-containing chemotherapy regimens.**
- **Evaluate left ventricular function in all patients prior to and during treatment with ONTRUZANT. Discontinue ONTRUZANT treatment in patients receiving adjuvant therapy and withhold ONTRUZANT in patients with metastatic disease for clinically significant decrease in left ventricular function.**

**Before prescribing ONTRUZANT, please read the accompanying Prescribing Information, including the Boxed Warning about cardiomyopathy, infusion reactions (pulmonary toxicity), and embryo-fetal toxicity.**

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# Today we will explore the following considerations for utilizing ONTRUZANT:

- NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) include FDA-approved trastuzumab biosimilars[1,2,a]
- ONTRUZANT was developed in accordance with rigorous FDA standards
- How might ONTRUZANT help benefit your practice or institution?
- Getting started can be simple with the right support

[a]The NCCN Guidelines support the use of an FDA-approved trastuzumab biosimilar as an appropriate substitute for trastuzumab (*Herceptin*). NCCN makes no warranties of any kind whatsoever regarding their content, use, or application and disclaims any responsibility for their application or use in any way.

FDA, US Food and Drug Administration; NCCN, National Comprehensive Cancer Network®.

Discover ONTRUZANT

## SELECTED SAFETY INFORMATION *(continued)*

### INFUSION REACTIONS; PULMONARY TOXICITY

- **Administration of trastuzumab products can result in serious and fatal infusion reactions and pulmonary toxicity. Symptoms usually occur during or within 24 hours of administration. Interrupt ONTRUZANT infusion for dyspnea or clinically significant hypotension. Monitor patients until symptoms completely resolve. Discontinue ONTRUZANT for anaphylaxis, angioedema, interstitial pneumonitis, or acute respiratory distress syndrome.**

### EMBRYO-FETAL TOXICITY

- **Exposure to trastuzumab products during pregnancy can result in oligohydramnios and oligohydramnios sequence manifesting as pulmonary hypoplasia, skeletal abnormalities, and neonatal death. Advise patients of these risks and the need for effective contraception.**

**Before prescribing ONTRUZANT, please read the accompanying Prescribing Information, including the Boxed Warning about cardiomyopathy, infusion reactions (pulmonary toxicity), and embryo-fetal toxicity.**

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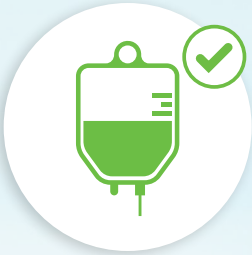
# NCCN Guidelines® support using a biosimilar such as trastuzumab-dttb (ONTRUZANT®) as an appropriate substitute for trastuzumab[1,2,a]

**ONTRUZANT was FDA-approved as biosimilar to *Herceptin* (trastuzumab) with *THE SAME*:**

Indications and usage

Mechanism of action



Dosing and administration

No additional staff training is needed for dosing and administration.

The FDA approved ONTRUZANT with **no clinically meaningful differences in safety, purity, and potency from *Herceptin*.**[3,4]

**Diluent included for multiple-dose vial**

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FDA, US Food and Drug Administration; NCCN, National Comprehensive Cancer Network®.

Discover the data >

## SELECTED SAFETY INFORMATION *(continued)*

### WARNINGS AND PRECAUTIONS

**CARDIOMYOPATHY**

- **Administration of trastuzumab products can result in subclinical and clinical cardiac failure. The incidence and severity was highest in patients receiving trastuzumab with anthracycline-containing chemotherapy regimens. In a pivotal adjuvant breast cancer trial, one patient who developed congestive heart failure (CHF) died of cardiomyopathy.**
- Trastuzumab products can cause left ventricular cardiac dysfunction, arrhythmias, hypertension, disabling cardiac failure, cardiomyopathy, and cardiac death.
- Trastuzumab products can also cause asymptomatic decline in left ventricular ejection fraction (LVEF).

**Before prescribing ONTRUZANT, please read the accompanying Prescribing Information, including the Boxed Warning about cardiomyopathy, infusion reactions (pulmonary toxicity), and embryo-fetal toxicity.**

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# How was ONTRUZANT FDA-approved as biosimilar?

ONTRUZANT was evaluated in **65 structural and functional tests** as well as **the largest clinical trial among biosimilars.**[3,5,6]

## STRUCTURAL

**46 structural and physiochemical analysis methods** played a critical role in supporting overall biosimilarity.[5]

## FUNCTIONAL

**19 functional analysis methods** showed ONTRUZANT and *Herceptin* (trastuzumab) have the same MOA.[5]

## CLINICAL

**Head-to-head pharmacokinetic (PK)[a] and comparative-equivalence clinical[b] studies** helped support the approval of ONTRUZANT.[3,7]

[a]EU-sourced and US-sourced *Herceptin* were used for the purposes of this study.

[b]EU-sourced *Herceptin* was used for the purposes of this study.

The rigorous evaluation of the "totality of evidence" led to the **FDA approval of ONTRUZANT as biosimilar to *Herceptin*.**[3–5]

Explore biosimilar data in more detail

EU, European Union; FDA, US Food and Drug Administration; MOA, mechanism of action.

Learn what ONTRUZANT can offer your office

## SELECTED SAFETY INFORMATION *(continued)*

### WARNINGS AND PRECAUTIONS *(continued)*

**CARDIOMYOPATHY *(continued)***

- **Discontinue ONTRUZANT treatment in patients receiving adjuvant breast cancer therapy and withhold ONTRUZANT in patients with metastatic disease for clinically significant decrease in left ventricular function.**

**CARDIAC MONITORING**

- **Evaluate cardiac function prior to and during treatment. For adjuvant breast cancer therapy, also evaluate cardiac function after completion of ONTRUZANT.**
- Conduct a thorough cardiac assessment, including history, physical examination, and determination of LVEF by echocardiogram or MUGA scan.

**Before prescribing ONTRUZANT, please read the accompanying Prescribing Information, including the Boxed Warning about cardiomyopathy, infusion reactions (pulmonary toxicity), and embryo-fetal toxicity.**

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# What should your practice or institution expect when adding ONTRUZANT?

We aim to provide a personalized biosimilar experience by understanding the logistics of biosimilar adoption and committing to high industry standards.

**This starts with a dedication to:**

### Manufacturing and supply

Our manufacturers[a] work to help ensure a continuous supply of product

### Resources and support

Equipping you, your office, and your patients with the right information and resources at every step

### Your biosimilar goals

Connecting you with additional educational tools and resources from Organon Biosimilars

Ask your ONTRUZANT representative **how we can help** guide you to information and resources that may help you achieve your biosimilar goals.

**Explore support that makes a difference**

[a]Samsung Bioepis and their associated contract manufacturing organizations.

## SELECTED SAFETY INFORMATION *(continued)*

### WARNINGS AND PRECAUTIONS *(continued)*

**CARDIAC MONITORING *(continued)***

- Monitor frequently for decreased left ventricular function during and after ONTRUZANT treatment.
- Monitor more frequently if ONTRUZANT is withheld for significant left ventricular cardiac dysfunction.

**INFUSION REACTIONS**

- **Administration of trastuzumab products can result in serious and fatal infusion reactions.**
- **Symptoms usually occur during or within 24 hours of ONTRUZANT administration.**
- **Interrupt ONTRUZANT infusion for dyspnea or clinically significant hypotension.**

**Before prescribing ONTRUZANT, please read the accompanying Prescribing Information, including the Boxed Warning about cardiomyopathy, infusion reactions (pulmonary toxicity), and embryo-fetal toxicity.**

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# Coverage and reimbursement support for ONTRUZANT

## THE ORGANON ACCESS PROGRAM can help answer questions about:

- **Billing and coding:** Provides information regarding billing for ONTRUZANT and its administration.
- **Benefit investigations:** Can contact insurers to request patient-specific coverage and benefits information for ONTRUZANT.
- **The prior authorization and appeals process:** May be able to help with prior authorizations, including whether a prior authorization is required. May be able to provide information regarding the appeals process for denied claims.
- **Co-pay assistance for eligible, privately insured patients:** Offers assistance to eligible patients who need help affording ONTRUZANT.
- **Referral to the Organon Patient Assistance Program for eligibility determination (provided through the Organon Patient Assistance Program, Inc):** The Organon Patient Assistance Program provides certain Organon medicines free of charge to eligible patients.

Contact The Organon Access Program at **844-326-2986**, Monday through Friday, 8 AM to 5 PM ET, or **learn more on the website**.

## SELECTED SAFETY INFORMATION *(continued)*

### WARNINGS AND PRECAUTIONS *(continued)*

**INFUSION REACTIONS *(continued)***

- **Monitor patients until symptoms completely resolve.**
- **Discontinue ONTRUZANT for infusion reactions manifesting as anaphylaxis, angioedema, interstitial pneumonitis, or acute respiratory distress syndrome. Strongly consider permanent discontinuation in all patients with severe infusion reactions.**
- Infusion reactions consist of a symptom complex characterized by fever and chills, and on occasion include nausea, vomiting, pain (in some cases at tumor sites), headache, dizziness, dyspnea, hypotension, rash, and asthenia.

**Before prescribing ONTRUZANT, please read the accompanying Prescribing Information, including the Boxed Warning about cardiomyopathy, infusion reactions (pulmonary toxicity), and embryo-fetal toxicity.**

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# Coverage and reimbursement support for ONTRUZANT

If a prior authorization is required, or for assistance in understanding if a prior authorization is required, The Organon Access Program may be able to help.

## Getting started is simple. For patient-specific prior authorization questions:

**Download and complete** the appropriate sections of the enrollment form, OR use the **electronic enrollment form**.

**Submit** electronically, or print and fax the completed downloadable form to 800-538-5812.

A program representative will contact your patient and your office.

If your patient is eligible and interested in co-pay assistance or the Organon Patient Assistance Program, please have them complete the appropriate sections on the form.

Contact The Organon Access Program at **844-326-2986**, Monday through Friday, 8 AM to 5 PM ET, or **learn more on the website.**

## SELECTED SAFETY INFORMATION *(continued)*

### WARNINGS AND PRECAUTIONS *(continued)*

**EMBRYO-FETAL TOXICITY**

- **Exposure to trastuzumab products during pregnancy can result in oligohydramnios and oligohydramnios sequence manifesting as pulmonary hypoplasia, skeletal abnormalities, and neonatal death. Advise patients of these risks and the need for effective contraception.**
- Verify the pregnancy status of females of reproductive potential prior to the initiation of ONTRUZANT.
- Advise pregnant women and females of reproductive potential that exposure to ONTRUZANT during pregnancy or within 7 months prior to conception can result in fetal harm.

**Before prescribing ONTRUZANT, please read the accompanying Prescribing Information, including the Boxed Warning about cardiomyopathy, infusion reactions (pulmonary toxicity), and embryo-fetal toxicity.**

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# Patient support resources for ONTRUZANT

**The Organon Co-pay Assistance Program offers assistance to eligible patients who may need help with their out-of-pocket costs for ONTRUZANT.**

Once enrolled, eligible, privately insured patients pay the first $5 of their co-pay per infusion.

Maximum co-pay assistance program benefit is $25,000 per patient, per calendar year.

Co-pay assistance from the Organon Co-pay Assistance Program is not insurance. Restrictions apply. See Terms and Conditions.

**The Organon Co-pay Assistance Program is not valid for patients covered under a Government Program, as that term is defined in the Terms and Conditions. The Organon Co-pay Assistance Program is not valid for uninsured patients.**

Patient and health care professional must submit all required information. Please see the enrollment form for details.

**Enroll now using the printed form, or sign and submit electronically**

## SELECTED SAFETY INFORMATION *(continued)*

Review the summary

### WARNINGS AND PRECAUTIONS *(continued)*

**EMBRYO-FETAL TOXICITY *(continued)***

- Advise females of reproductive potential to use effective contraception during treatment and for at least 7 months following the last dose of ONTRUZANT.
- Consider the developmental and health benefits of breastfeeding along with the mother's clinical need for ONTRUZANT treatment and any potential adverse effects on the breastfed child from ONTRUZANT or from the underlying maternal condition.

**Before prescribing ONTRUZANT, please read the accompanying Prescribing Information, including the Boxed Warning about cardiomyopathy, infusion reactions (pulmonary toxicity), and embryo-fetal toxicity.**

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# Consider trying ONTRUZANT with appropriate patients

## In summary:

**NCCN Guidelines® support using a biosimilar** such as trastuzumab-dttb (ONTRUZANT®) as an appropriate substitute for trastuzumab[1,2,a]

**The FDA approval of ONTRUZANT was based on a rigorous evaluation** of the "totality of evidence," which included structural, functional, and clinical data[3–5]

**With ONTRUZANT comes our commitment to prioritizing the needs of your practice or institution** when navigating biosimilar adoption

**Comprehensive support services are always available** to help on your biosimilars journey

If you have **any additional questions about ONTRUZANT,** ask your representative or use our Rep on Demand service.

**Rep on Demand**

Representatives are available Monday through Friday, 8 AM to 5 PM ET, excluding US holidays.

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FDA, US Food and Drug Administration; NCCN, National Comprehensive Cancer Network®.

See Selected Safety Information >

## SELECTED SAFETY INFORMATION *(continued)*

### WARNINGS AND PRECAUTIONS *(continued)*

#### PULMONARY TOXICITY

- **Administration of trastuzumab products can result in serious and fatal pulmonary toxicity,** which includes dyspnea, interstitial pneumonitis, pulmonary infiltrates, pleural effusions, noncardiogenic pulmonary edema, pulmonary insufficiency and hypoxia, acute respiratory distress syndrome, and pulmonary fibrosis. Such events can occur as sequelae of infusion reactions.
- Patients with symptomatic intrinsic lung disease or with extensive tumor involvement of the lungs, resulting in dyspnea at rest, appear to have more severe toxicity.

**Before prescribing ONTRUZANT, please read the accompanying Prescribing Information, including the Boxed Warning about cardiomyopathy, infusion reactions (pulmonary toxicity), and embryo-fetal toxicity.**

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# Selected Safety Information

## CARDIOMYOPATHY

- **Administration of trastuzumab products can result in subclinical and clinical cardiac failure. The incidence and severity was highest in patients receiving a trastuzumab product with anthracycline-containing chemotherapy regimens.**
- **Evaluate left ventricular function in all patients prior to and during treatment with ONTRUZANT. Discontinue ONTRUZANT treatment in patients receiving adjuvant therapy and withhold ONTRUZANT in patients with metastatic disease for clinically significant decrease in left ventricular function.**

## INFUSION REACTIONS; PULMONARY TOXICITY

- **Administration of trastuzumab products can result in serious and fatal infusion reactions and pulmonary toxicity. Symptoms usually occur during or within 24 hours of administration. Interrupt ONTRUZANT infusion for dyspnea or clinically significant hypotension. Monitor patients until symptoms completely resolve. Discontinue ONTRUZANT for anaphylaxis, angioedema, interstitial pneumonitis, or acute respiratory distress syndrome.**

## EMBRYO-FETAL TOXICITY

- **Exposure to trastuzumab products during pregnancy can result in oligohydramnios and oligohydramnios sequence manifesting as pulmonary hypoplasia, skeletal abnormalities, and neonatal death. Advise patients of these risks and the need for effective contraception.**

## WARNINGS AND PRECAUTIONS

### CARDIOMYOPATHY

- **Administration of trastuzumab products can result in subclinical and clinical cardiac failure. The incidence and severity was highest in patients receiving trastuzumab with anthracycline-containing chemotherapy regimens. In a pivotal adjuvant breast cancer trial, one patient who developed congestive heart failure (CHF) died of cardiomyopathy.**
- Trastuzumab products can cause left ventricular cardiac dysfunction, arrhythmias, hypertension, disabling cardiac failure, cardiomyopathy, and cardiac death.
- Trastuzumab products can also cause asymptomatic decline in left ventricular ejection fraction (LVEF).
- **Discontinue ONTRUZANT treatment in patients receiving adjuvant breast cancer therapy and withhold ONTRUZANT in patients with metastatic disease for clinically significant decrease in left ventricular function.**

### CARDIAC MONITORING

- **Evaluate cardiac function prior to and during treatment. For adjuvant breast cancer therapy, also evaluate cardiac function after completion of ONTRUZANT.**
- Conduct a thorough cardiac assessment, including history, physical examination, and determination of LVEF by echocardiogram or MUGA scan.
- Monitor frequently for decreased left ventricular function during and after ONTRUZANT treatment.
- Monitor more frequently if ONTRUZANT is withheld for significant left ventricular cardiac dysfunction.

# Selected Safety Information *(continued)*

## INFUSION REACTIONS

- **Administration of trastuzumab products can result in serious and fatal infusion reactions.**
- **Symptoms usually occur during or within 24 hours of ONTRUZANT administration.**
- **Interrupt ONTRUZANT infusion for dyspnea or clinically significant hypotension.**
- **Monitor patients until symptoms completely resolve.**
- **Discontinue ONTRUZANT for infusion reactions manifesting as anaphylaxis, angioedema, interstitial pneumonitis, or acute respiratory distress syndrome. Strongly consider permanent discontinuation in all patients with severe infusion reactions.**
- Infusion reactions consist of a symptom complex characterized by fever and chills, and on occasion include nausea, vomiting, pain (in some cases at tumor sites), headache, dizziness, dyspnea, hypotension, rash, and asthenia.

## EMBRYO-FETAL TOXICITY

- **Exposure to trastuzumab products during pregnancy can result in oligohydramnios and oligohydramnios sequence manifesting as pulmonary hypoplasia, skeletal abnormalities, and neonatal death. Advise patients of these risks and the need for effective contraception.**
- Verify the pregnancy status of females of reproductive potential prior to the initiation of ONTRUZANT.
- Advise pregnant women and females of reproductive potential that exposure to ONTRUZANT during pregnancy or within 7 months prior to conception can result in fetal harm.
- Advise females of reproductive potential to use effective contraception during treatment and for at least 7 months following the last dose of ONTRUZANT.
- Consider the developmental and health benefits of breastfeeding along with the mother's clinical need for ONTRUZANT treatment and any potential adverse effects on the breastfed child from ONTRUZANT or from the underlying maternal condition.

## PULMONARY TOXICITY

- **Administration of trastuzumab products can result in serious and fatal pulmonary toxicity,** which includes dyspnea, interstitial pneumonitis, pulmonary infiltrates, pleural effusions, noncardiogenic pulmonary edema, pulmonary insufficiency and hypoxia, acute respiratory distress syndrome, and pulmonary fibrosis. Such events can occur as sequelae of infusion reactions.
- Patients with symptomatic intrinsic lung disease or with extensive tumor involvement of the lungs, resulting in dyspnea at rest, appear to have more severe toxicity.
- Discontinue ONTRUZANT in patients experiencing pulmonary toxicity.

## EXACERBATION OF CHEMOTHERAPY-INDUCED NEUTROPENIA

- In randomized, controlled clinical trials, the per-patient incidences of NCI-CTC grade 3-4 neutropenia and of febrile neutropenia were higher in patients receiving trastuzumab in combination with myelosuppressive chemotherapy as compared to those who received chemotherapy alone. The incidence of septic death was similar among patients who received trastuzumab and those who did not.

# Selected Safety Information *(continued)*

## DRUG INTERACTIONS

- Patients who receive anthracycline after stopping trastuzumab products may be at increased risk of cardiac dysfunction because of trastuzumab's long washout period based on population PK analysis. If possible, physicians should avoid anthracycline-based therapy for up to 7 months after stopping trastuzumab products. If anthracyclines are used, the patient's cardiac function should be monitored carefully.

## ADVERSE REACTIONS

- The most common adverse reactions associated with trastuzumab products in the adjuvant and metastatic breast cancer setting are fever, nausea, vomiting, infusion reactions, diarrhea, infections, increased cough, headache, fatigue, dyspnea, rash, neutropenia, anemia, and myalgia.
- The most common adverse reactions associated with trastuzumab products in the gastric cancer setting were neutropenia, diarrhea, fatigue, anemia, stomatitis, weight loss, upper respiratory tract infections, fever, thrombocytopenia, mucosal inflammation, nasopharyngitis, and dysgeusia.

**Before prescribing ONTRUZANT, please read the accompanying Prescribing Information, including the Boxed Warning about cardiomyopathy, infusion reactions (pulmonary toxicity), and embryo-fetal toxicity.**

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**References: 1.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer. V.4.2021. © National Comprehensive Cancer Network, Inc. 2021. All rights reserved. Accessed June 7, 2021. To view the most recent and complete version of the guideline, go online to NCCN.org. **2.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Gastric Cancer. V.2.2021. © National Comprehensive Cancer Network, Inc. 2021. All rights reserved. Accessed May 14, 2021. To view the most recent and complete version of the guideline, go online to NCCN.org. **3.** Pivot X, Bondarenko I, Nowecki Z, et al. Phase III, randomized, double-blind study comparing the efficacy, safety, and immunogenicity of SB3 (trastuzumab biosimilar) and reference trastuzumab in patients treated with neoadjuvant therapy for human epidermal growth factor receptor 2–positive early breast cancer. *J Clin Oncol*. 2018;36(10):968–974. doi:10.1200/JCO.2017.74.0126 **4.** Scientific considerations in demonstrating biosimilarity to a reference product. FDA Website. Accessed May 13, 2021. www.fda.gov/downloads/drugs/guidances/ucm291128.pdf **5.** Data available on request from Merck & Co., Inc., Professional Services-DAP, WP1-27, PO Box 4, West Point, PA 19486-0004. Please specify information package US-SBF-00343. **6.** Data available on request from Merck & Co., Inc., Professional Services-DAP, WP1-27, PO Box 4, West Point, PA 19486-0004. Please specify information package US-SBF-00344. **7.** Pivot X, Curtit E, Lee YJ, et al. A randomized phase I pharmacokinetic study comparing biosimilar candidate SB3 and trastuzumab in healthy male subjects. *Clin Ther*. 2016;38(7):1665–1673.e3. doi:10.1016/j.clinthera.2016.06.002

## SELECTED SAFETY INFORMATION *(continued)*

### WARNINGS AND PRECAUTIONS *(continued)*

#### PULMONARY TOXICITY *(continued)*

- Discontinue ONTRUZANT in patients experiencing pulmonary toxicity.

#### EXACERBATION OF CHEMOTHERAPY-INDUCED NEUTROPENIA

- In randomized, controlled clinical trials, the per-patient incidences of NCI-CTC grade 3-4 neutropenia and of febrile neutropenia were higher in patients receiving trastuzumab in combination with myelosuppressive chemotherapy as compared to those who received chemotherapy alone. The incidence of septic death was similar among patients who received trastuzumab and those who did not.

### DRUG INTERACTIONS

- Patients who receive anthracycline after stopping trastuzumab products may be at increased risk of cardiac dysfunction because of trastuzumab's long washout period based on population PK analysis. If possible, physicians should avoid anthracycline-based therapy for up to 7 months after stopping trastuzumab products. If anthracyclines are used, the patient's cardiac function should be monitored carefully.

### ADVERSE REACTIONS

- The most common adverse reactions associated with trastuzumab products in the adjuvant and metastatic breast cancer setting are fever, nausea, vomiting, infusion reactions, diarrhea, infections, increased cough, headache, fatigue, dyspnea, rash, neutropenia, anemia, and myalgia.
- The most common adverse reactions associated with trastuzumab products in the gastric cancer setting were neutropenia, diarrhea, fatigue, anemia, stomatitis, weight loss, upper respiratory tract infections, fever, thrombocytopenia, mucosal inflammation, nasopharyngitis, and dysgeusia.

**Before prescribing ONTRUZANT, please read the accompanying Prescribing Information, including the Boxed Warning about cardiomyopathy, infusion reactions (pulmonary toxicity), and embryo-fetal toxicity.**

Not an actual patient.



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