

HERCESSI IS HERE

TARGETING THE HER2+ CANCER CELL



**A Guide to Getting Started on
HERCESSI (trastuzumab-strf)**

 **accord™**

HERCESSI MAY CAUSE SERIOUS SIDE EFFECTS, INCLUDING:¹

- Heart problems
- Infusion reactions
- Harm to your unborn baby
- Severe lung problems

Please see Important Safety Information throughout this brochure and Full Prescribing Information for complete BOXED WARNING for HERCESSI to discuss with your doctor.

Understanding HER2+ Cancer

Breast Cancer



Breast cancer is the most common cancer in the US with HER2+ cases accounting for approximately **20%** of cases (~297,790 women, ~2,800 men in 2023).²



About 1 in 5

Breast Cancers are Human Epidermal Growth Factor Receptor 2-positive (HER2+)²

Breast Cancer Symptoms May Include:³

- A lump or thickening in the breast or underarm area
- Changes in size, shape, or appearance of the breast
- Nipple discharge or pain
- Skin changes, such as redness, dimpling, or peeling

Normal cells also have HER2 (lesser amount), so HER2-targeted therapies can also affect normal cells and can cause side effects. See Important Safety Information throughout this brochure.

IMPORTANT SAFETY INFORMATION

HERCESSI is a prescription medicine that may cause serious side effects, including heart failure, severe infusion reactions, lung complications, and harm to your unborn baby. It can increase the risk of heart problems, especially with anthracycline-based chemotherapy. Lung problems, some fatal, have been reported. If you are pregnant or could become pregnant, discuss contraception with your doctor. Read the Important Safety Information on pages 12-15 and the enclosed Full Prescribing Information, including Boxed Warnings, and talk to your doctor about any concerns.

Understanding HER2+ Cancer

When cells have a more than normal level of a protein called HER2, it is considered positive (HER2+). In HER2+ breast cancer, the cancer cells grow faster because there is too much HER2. HERCESSI was created to target the HER2 receptors to block growth signals that slow or stop the cancer from growing.

HERCESSI is a prescription medicine used for the treatment of:¹

Early Breast Cancer

HERCESSI is approved to treat early-stage breast cancer in adults with HER2+ breast cancer that may or may not have spread into the lymph nodes. Also, 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. See the full indication on page 12 to see how HERCESSI can be used in early-stage breast cancer.

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

Metastatic Breast Cancer (Cancer that has spread to other parts of the body)

HERCESSI has two approved uses in metastatic breast cancer:

- In combination with paclitaxel for first-line treatment of HER2+ metastatic breast cancer
- HERCESSI used alone is approved for the treatment of HER2+ 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.

Gastric Cancer

HER2+ cancer cells in the stomach may have too many HER2 receptors, which send signals telling the cells to grow and divide too quickly, causing tumors to form.



For 2025, ~ **30,300** new cases of stomach cancer (also known as gastric cancer) are estimated in the United States.⁴

Gastric Cancer Symptoms:⁶

- Persistent stomach pain or discomfort
- Difficulty swallowing
- Fatigue
- Loss of appetite
- Unexplained weight loss
- Nausea or vomiting

HERCESSI is a prescription medicine used for the treatment of:¹

Metastatic Gastric Cancer

HERCESSI is indicated in adults, in combination with cisplatin and capecitabine or 5-fluorouracil, for the treatment of patients with HER2+ metastatic gastric (stomach) cancer or gastroesophageal junction (where esophagus meets stomach) adenocarcinoma who have not received prior treatment for metastatic disease.

HERCESSI (trastuzumab-strf) is an FDA-approved biosimilar to Herceptin (trastuzumab), designed for targeted therapy in HER2+ cancers. It attaches to HER2 receptors, which are overexpressed.

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

What is HERCESSI?

HERCESSI is a biosimilar⁷



Biosimilars are biological medicines that closely resemble an approved original biological product. Biologic products are made from natural sources making biosimilars hard to duplicate. While not identical, they undergo rigorous evaluation to ensure there are no clinically meaningful differences in efficacy, safety, or function.

A similar protein structure: HERCESSI is a trastuzumab biosimilar with an amino acid (protein) structure identical to that of Herceptin.⁸

Similar efficacy: Clinical studies show HERCESSI is just as effective as Herceptin in treating HER2+ breast and gastric cancers.

Similar safety: HERCESSI has a similar safety profile to Herceptin.¹

Can I switch to HERCESSI if I've already started with Herceptin Treatment?

Your doctor can change your medicine to HERCESSI, as it offers highly similar efficacy and safety as Herceptin.¹



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Medisafe: Medication Management App



Ranked #1 by pharmacists and physicians, this free app fulfills critical needs including disease education, dosing reminders, and coaching for caregivers throughout your treatment journey.

500K User Reviews

13M Patients and Caregivers

- **Medication Management:** Delivers personalized and real-time dosing reminders to help you stay on track.
- **Access & Education:** Provides helpful health information tailored to your condition or medication.
- **Caregiver Support:** Allows your care network to stay connected throughout your treatment journey.

SCAN THE QR CODE TO
DOWNLOAD THE APP



How Will I Receive HERCESSI?¹

HERCESSI is administered as an intravenous (IV) infusion with the supervision of a healthcare professional. The dosage and schedule depend on the condition being treated:

Adjuvant HER2+ Breast Cancer: Initial infusion of **over 90 minutes**, followed by **weekly infusions for 12–18 weeks** with chemotherapy. After this phase, an **infusion every 3 weeks** is given for a total duration of **52 weeks**.

Metastatic HER2+ Breast Cancer: Initial infusion of **over 90 minutes**, followed by **a weekly infusion**, either alone or in combination with paclitaxel, until disease progression.

Metastatic HER2+ Gastric Cancer: Initial infusion over **90 minutes**, followed by an infusion **every 3 weeks**, continued until disease progression.

Potential HERCESSI Side Effects

The following side effects were reported by patients receiving trastuzumab products in clinical trials:¹

Breast Cancer Patients

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

Stomach Cancer Patients

Low white blood cell count	Upper respiratory tract infections
Diarrhea	Fever
Feeling tired	Low platelet count
Low red blood cell count	Swelling of the mucous membranes
Swelling of the mouth lining	Nasal congestion
Weight loss	Change in taste



**IF YOU FEEL UNWELL DURING YOUR TREATMENT,
PLEASE TELL YOUR HEALTHCARE TEAM**

IMPORTANT SAFETY INFORMATION

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Accord BioPharma

Backed by the 50-year heritage of Intas Pharmaceuticals, Accord BioPharma is at the forefront of biosimilar transformation. Learn more about our mission to make quality, life-altering therapies more affordable and more accessible to more patients around the world.

GET TO KNOW US
SCAN HERE



Accord BioPharma is built on 3 foundational pillars⁸

EXTENSIVE EXPERIENCE

Backed by Intas, a biopharma leader for nearly 50 years

Developing one of the largest biosimilar pipelines

CUSTOMER-FOCUSED APPROACH

Providing eligible patients with co-pay and financial assistance from AccordCares[®]

ONCOLOGY BIOSIMILARS

Committed to making FDA-approved therapies more affordable and accessible

Currently developing numerous oncology biosimilars

RESOURCES FOR YOU

WELCOME TO ACCORDCARES®

The AccordCares® program offers financial assistance for HERCESSI™ out-of-pocket expenses. The program partners with your existing commercial insurance to help cover eligible costs, including co-payments, co-insurance, and deductibles.



Out-of-Pocket Cost Reduction:

Eligible patients can significantly reduce their out-of-pocket expenses, potentially paying as little as \$0 for their HERCESSI treatment.

Coverage Details:

The program covers prescription-related costs, including deductibles, co-pays, or co-insurance, up to a maximum allowable benefit of \$25,000 per calendar year.

Key Benefits:

Submitting Reimbursement Requests:

If you have already paid for drug co-pays, co-insurance, or deductibles, you can submit receipts for reimbursement within 120 days from the date of service.

No Income Eligibility Requirement:

There is no income requirement to apply for assistance.

CONTACT ACCORDCARES®

Phone: 1-866-258-7151 | **Hours:** Mon-Fri, 8 AM-8 PM EST

For more details, visit the <https://www.hercessihcp.com/patient-support/>

HERCESSI (trastuzumab-strf) IMPORTANT SAFETY INFORMATION¹

HERCESSI™ (trastuzumab-strf) is biosimilar to HERCEPTIN® (trastuzumab)

WHAT is HERCESSI?

HERCESSI is a prescription medicine used in adult patients selected for therapy based on an FDA-approved test for a trastuzumab for the treatment of:

Adjuvant Breast Cancer

HERCESSI is used for the treatment of early-stage breast cancer that is **H**uman **E**pidermal growth factor **R**eceptor **2**-positive (**HER2+**) and that 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. HERCESSI can be used in 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 chemotherapies, including an anthracycline (doxorubicin) based therapy

Metastatic Breast Cancer

HERCESSI has two approved uses in metastatic breast cancer:

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

Metastatic Gastric Cancer

HERCESSI is used in combination with chemotherapy (cisplatin and either capecitabine or 5-fluorouracil), for the treatment of HER2-positive 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.

HERCESSI (trastuzumab-strf) IMPORTANT SAFETY INFORMATION¹

IMPORTANT SAFETY INFORMATION

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

HERCESSI may cause serious side effects including:

Heart problems that may affect your heart's ability to pump blood and may be with or without symptoms. The risk for and seriousness of these heart problems were highest in people who received both a trastuzumab product, like HERCESSI, and a certain type of chemotherapy (anthracycline). Your healthcare provider will check your heart function before starting, during and after treatment with HERCESSI.

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
- Lack of energy and strength

These symptoms usually happen within 24 hours after receiving HERCESSI.

Harm to your unborn baby. Tell your healthcare provider right away if you become pregnant or think you might be pregnant during treatment with HERCESSI.

- HERCESSI may result in the death of an unborn baby or birth defects
- If you are able to become pregnant, your healthcare provider should do a pregnancy test before you start treatment with HERCESSI
- Females who are able to become pregnant should use effective birth control (contraception) during treatment with HERCESSI and for 7 months after the last dose

Severe lung problems that may be life-threatening or that may lead to death. Your healthcare provider may check for signs of severe lung problems. Signs of these lung problems may include:

- Trouble breathing or shortness of breath
- Fluid in or around the lungs

HERCESSI (trastuzumab-strf) IMPORTANT SAFETY INFORMATION¹

- Weakening of the valve between the heart and the lungs
- Not enough oxygen in the body
- Swelling of the lungs
- Scarring of the lungs

Low white blood cell count 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 healthcare provider will check your white blood cell counts.

Before starting HERCESSI, tell your healthcare provider about all of your medical conditions, including if you:

- Have lung or breathing problems
- Have signs or symptoms of an infection
- Have or have had any heart problems
- Are breastfeeding or plan to breastfeed. It is not known if HERCESSI passes into your breast milk

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

The most common side effects of HERCESSI in breast cancer are:

- 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 count
- Muscle aches and pain

HERCESSI (trastuzumab-strf) IMPORTANT SAFETY INFORMATION¹

The most common side effects of HERCESSI in metastatic gastric cancer are:

- Low white blood cell count
- Diarrhea
- Feeling tired
- Low red blood cell count
- Swelling of the mouth lining
- Weight loss
- Upper respiratory tract infections
- Fever
- Low platelet count
- Swelling of the mucous membranes
- Nasal congestion
- Change in taste

These are not all the possible side effects of HERCESSI. Tell your healthcare provider about any side effects that you experience. For additional information, see the full prescribing information or ask your healthcare provider or pharmacist.

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

HERCESSI™ (trastuzumab-strf) for injection is available as a single-dose vial for the 150 mg/vial strength and as a multiple-dose vial for the 420 mg/vial strength.

For more information, please see the enclosed full Prescribing Information, including Boxed Warnings or go to www.HERCESSI.com

References: **1.** Accord BioPharma HERCESSI™ (trastuzumab-strf) Prescribing Information [PI]. Raleigh, NC: Accord BioPharma. **2.** Breast Cancer Research Foundation. HER2-Positive Breast Cancer: Treatment and Research [Internet]. 2023 [cited 2025 Feb 7]. Available from: <https://www.bcrf.org/blog/her2-positive-breast-cancer-treatment-research>. **3.** Penn Medicine. Breast cancer [Internet]. Philadelphia, PA: Penn Medicine; [cited 2025 Feb 1]. Available from: <https://www.pennmedicine.org/cancer/types-of-cancer/breast-cancer> **4.** American Cancer Society. Key statistics for stomach cancer [Internet]. American Cancer Society; [date unknown] [cited 2025 Feb 18]. Available from: <https://www.cancer.org/cancer/types/stomach-cancer/about/key-statistics.html> **5.** Curea FG, Hebbar M, Ilie SM, Bacinschi XE, Trifanescu OG, Botnariuc I, Anghel RM. Current targeted therapies in HER2-positive gastric adenocarcinoma. *Cancer Biotherapy & Radiopharmaceuticals*. 2017 Dec 1;32(10):351-63. **6.** Moffitt Cancer Center. What are the most common metastatic stomach cancer symptoms? [Internet]. Tampa, FL: Moffitt Cancer Center; [cited 2025 Feb 7]. Available from: <https://www.moffitt.org/cancers/stomach-gastric-cancer/faqs/what-are-the-most-common-metastatic-stomach-cancer-symptoms/> **7.** U.S. Food and Drug Administration (FDA). Scientific Considerations in Demonstrating Biosimilarity to a Reference Product: Guidance for Industry. Available at: <https://www.fda.gov/media/82647/download> **8.** Data on file. Accord BioPharma; 2023.



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