

# **Enhertu**

Pronunciation: en-HER-too

**Generic name:** fam-trastuzumab deruxtecan [ FAM-tras-TOOZ-ue-mab-DER-ux-TEE-kan ]

Dosage form: intravenous infusion (100mg vial)

Drug class: HER2 inhibitors

Medically reviewed by Melisa Puckey, BPharm. Last updated on Feb 12, 2025.

### What is Enhertu?

Enhertu is a treatment for breast cancer, advanced stomach cancer, non-small cell lung cancer, and solid tumors with HER2 gene mutations in certain patients. Enhertu may help people with cancer live longer and delay the progression of their disease.

Enhertu is both a chemotherapy drug and a targeted therapy. Its active ingredient is fam-trastuzumab deruxtecan, which combines two cancer-fighting medicines joined together called an antibody-drug conjugate (ADC). The targeted therapy part is fam-trastuzumab which is linked to the chemotherapy part called deruxtecan (DXd).

Enhertu works by fam-trastuzumab targeting and attaching to HER2-positive cancer cells, preventing them from multiplying and slowing the cancer's growth. Then deruxtecan, the chemotherapy part, enters the cells and kills the cancer cell. Enhertu mechanism of action is as a HER2-directed antibody-drug conjugate.

Enhertu FDA approval was first granted on December 20, 2019, for breast cancer treatment in specific patients and then extended to cover other conditions. The most recent addition is (HR)-positive, HER2-low (IHC 1+ or IHC 2+/ISH-) or HER2-ultra low (IHC 0 with membrane staining) unresectable or metastatic breast cancer on January 28, 2025, after positive results from the DESTINY-Breast06 Phase III trial.

## What is the HER2 gene?

Some cancer cells have too many copies of the human epidermal growth factor receptor 2 (HER2) gene, which makes a protein called the HER2, these cancers are called HER2 positive. HER2 is a protein that controls cell growth, if your cancer is HER2 positive, it means it will more likely grow faster, spread, or come back. Some cancer cells that are HER2-negative still have several HER2 proteins on the surface of the cells, these cancer cells are called HER2-low. Cancer medicines like Enhertu block HER2 receptors to reduce the ability of the cancer to grow and spread.

### **Enhertu side effects**

#### **Common Enhertu side effects**

Common Enhertu side effects may include hair loss, nausea, vomiting, loss of appetite, diarrhea, constipation, cough, fever, tiredness (fatigue), muscle and joint pain, low blood cell counts, low potassium, and abnormal liver function tests.

These common side effects occurred in 20% or more of patients on Enhertu during clinical trials.

### Serious Enhertu side effects

Get emergency medical help if you have signs of an allergic reaction: hives; difficulty breathing; swelling other serious side effects. Call your doctor at once if you have:

- chest tightness, wheezing, cough, new or worsening shortness of breath;
- pounding heartbeats or fluttering in your chest;
- fever, tiredness, dizziness;
- swelling in your lower legs, sudden weight gain;
- a light-headed feeling, like you might pass out;
- low blood cell counts fever, chills, mouth sores, skin sores, easy bruising, unusual bleeding, pale skin, cold hands, and feet; or
- low potassium level leg cramps, constipation, irregular heartbeats, fluttering in your chest, increased thirst or urination, numbness or tingling, muscle weakness or limp feeling.

## Side effect management

You may be prescribed medicine to prevent nausea and vomiting.

You will need medical tests frequently to check blood counts.

Your cancer treatments may be delayed or permanently discontinued if you have certain side effects.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Enhertu side effects (more detail)

## Related/similar drugs

#### Verzenio

Verzenio is used to treat certain HRpositive and HER2-negative breast cancers in adults. It is an ...

#### **Reviews & ratings**

## **Trodelvy**

Trodelvy is a targeted anticancer medication used to treat types of breast cancer and bladder ...

FEATUR

#### Rybre

Rybreva non-sma has s

### What is Enhertu used for?

Enhertu is FDA-approved for use in adult patients who have:

- **HER2+ metastatic breast cancer.** Breast cancer that is (HER2)-positive that is not removable by surgery or has spread and has already had a specific anti-HER2-based regimen.
- **HER2-low metastatic breast cancer.** Breast cancer that is HER2-low (IHC 1+ or IHC 2+/ISH-) that is not removable by surgery or has spread to other parts of your body, and who have already had chemotherapy for cancer that has spread or cancer has returned within 6 months of finishing adjuvant chemotherapy.
- (HR)-positive, HER2-low (IHC 1+ or IHC 2+/ISH-) or HER2-ultra low (IHC 0 with membrane staining) unresectable or metastatic breast cancer that has been determined by an FDAapproved test. Cancer must have progressed on one or more endocrine therapies in the metastatic setting.
- HER2-positive (IHC 3+) metastatic solid tumors. Solid tumors that are HER2-positive (IHC 3+)cannot be removed by surgery or have spread to other parts of the body, and who have already had chemotherapy for cancer and have no satisfactory alternative treatment options. This approval is under the accelerated approval designation and continued approval may be contingent upon beneficial results being shown in clinical trials.
- HER2+ advanced stomach cancer. Gastric or gastroesophageal junction (GEJ) adenocarcinoma
  cancer that is HER2-positive and you have already had a trastuzumab-based regimen and cancer
  has spread to areas near your stomach (locally advanced) or has spread to other parts of your
  body (metastatic).
- HER2-mutant metastatic lung cancer. Non-small cell lung cancer (NSCLC) that has activating
  HER2 (ERBB2) mutations that cannot be removed by surgery or cancer that has spread to other
  parts of your body (metastatic), and you have already had systemic therapy. An FDA-approved
  test mustbe used to detect activating HER2 (ERBB2) mutations.

## **Warnings**

Enhertu can cause serious or life-threatening side effects on your heart or lungs. Call your doctor right away if you have a cough, tiredness, dizziness, chest tightness, wheezing, irregular heartbeats, new or worsening shortness of breath.

Enhertu can weaken (suppress) your immune system, and you may get an infection or bleed more easily. Tell your doctor if you have unusual bruising or bleeding or signs of infection (fever, chills,

weakness, cold or flu symptoms, frequent or recurring illness).

Both men and women using this medicine should use effective birth control to prevent pregnancy. Birth control should be continued for 7 months after the last dose of Enhertu in women and 4 months after in men.

Your doctor will perform blood tests to make sure you do not have conditions that would prevent you from safely using this medicine.

Enhertu (fam-trastuzumab deruxtecan) is **not** the same medicine as trastuzumab (Herceptin, Herzuma, Kanjinti, Ogivri, Ontruzant, Trazimera). These medicines contain **only** trastuzumab, they do not contain topoisomerase I inhibitor.

Enhertu (fam-trastuzumab deruxtecan-nxki) is **not** the same medicine as Kadcyla (ado-trastuzumab emtansine), which has a different antibody-drug conjugate.

## Before taking this medicine

Before starting this medicine, you should tell your healthcare provider about all of your medical conditions, especially if you:

- have any lung or breathing issues
- have symptoms or signs of infection
- have or have had in the past any heart problems

You may need to have a negative pregnancy test before starting this treatment.

### **Pregnancy**

Enhertu can harm an unborn baby if the mother or the father is using this medicine. You should not take Enhertu if you are pregnant or planning a pregnancy, as it can harm your unborn baby.

If you are a woman and you are able to become pregnant, your healthcare provider should do a pregnancy test before you start treatment with this medicine. Females who are able to become pregnant should use effective birth control (contraception) during treatment with this medicine and for at least 7 months after the last dose.

If you are a man who has a female partner that is able to become pregnant, you should use effective birth control (contraception) during treatment with Enhertu and for at least 4 months after the last dose.

This medicine may cause fertility problems in males, which may affect the ability to father children. Talk to your healthcare provider if you have concerns about fertility.

## **Breastfeeding**

#### Enhertu and breastfeeding:

- It is not known if Enhertu passes into your breast milk.
- Do not breastfeed during treatment with Enhertu and for 7 months after the last dose.
- 1 Enhertu pregnancy and breastfeeding warnings (more detail)

### How is Enhertu given?

Enhertu is given as an infusion into a vein by your healthcare provider.

Enhertu is usually given once every 3 weeks in a 21-day treatment cycle. The first infusion will take over 90 minutes, but your next infusions are usually given over 30 minutes.

The dose you will receive will depend on how much you weigh and your type of cancer.

During an infusion, it is possible to have an infusion-related reaction. If this happens, your healthcare provider may slow down or temporarily stop your infusion, if you have a severe infusion reaction, your healthcare provider may stop this treatment permanently.

Your doctor will determine how long to treat you with this medicine. If you develop side effects or your cancer progresses, your dose may be reduced, and treatment may be paused or even stopped.

Enhertu may make you feel sick, and you may vomit. Your doctor may prescribe a medicine to prevent nausea and vomiting.

You will need frequent medical tests.

## **Enhertu Dosing information**

Usual Adult Dose Unresectable Metastatic Breast Cancer or metastatic HER2-positive (IHC 3+) solid tumors:

• 5.4 mg/kg IV every 3 weeks (21-day cycle) given as an intravenous infusion until disease progression or unacceptable toxicity.

#### Usual Adult Dose for Unresectable or Metastatic HER2-Mutant NSCLC:

• 5.4 mg/kg IV every 3 weeks (21-day cycle) given as an intravenous infusion until disease progression or unacceptable toxicity.

#### **Usual Adult Dose for Locally Advanced or Metastatic Gastric Cancer:**

• 6.4 mg/kg given every 3 weeks (21-day cycle) as an intravenous infusion until disease progression or unacceptable toxicity.

#### **Comments:**

- Administer the first infusion over 90 minutes; administer subsequent infusions over 30 minutes if prior infusions were well tolerated.
- Slow or interrupt the infusion rate if the patient develops infusion-related symptoms.
- Permanently discontinue therapy for severe infusion reactions.
- Dose modifications should occur in renal or liver impairment and due to adverse reactions.

For more information on Enhertu dosing information click the link below.

1 Detailed Enhertu dosage information

## What happens if I miss a dose?

If you miss an appointment for your injection call your doctor to reschedule an appointment. Do not wait until the next planned treatment cycle.

## What happens if I overdose?

Since this medicine is given by a healthcare professional in a medical setting, an overdose is unlikely to occur.

## What should I avoid while receiving Enhertu?

Follow your doctor's instructions about any restrictions on food, beverages, or activity.

### **Interactions**

Some medications interact with Enhertu, so it is important to tell your doctor about any medicines that you are currently taking, or if you start or stop any medicine while you are having cancer treatment. Also tell your doctor about any vaccinations, over-the-counter medicines, vitamins, minerals or herbal products that you take.

1 Enhertu drug interactions (more detail)

### **Enhertu J code**

Enhertu J-code is J9358, 1 mg fam-trastuzumab deruxtecan-nxki.

J codes are used for medicines that are not taken orally and include injections, inhalations, and chemotherapies. J codes are important for accurate and consistent coding for billing and reimbursement purposes.

Your physician will need Enhertu J-code when filling out forms for your treatment.

### Enhertu Pl

https://www.drugs.com/enhertu.html

Review the Enhertu PI (Package Insert) contains more comprehensive information on Indications and Usage, Dosage and Administration, Clinical Pharmacology, Clinical Studies, Drug Interaction, and more. Refer to the Enhertu PI and discuss any medical questions you have with your doctor or other health care provider. This is not all the information you need to know about this medicine for safe and effective use, and it does not take the place of talking to your doctor about your treatment.

The Package Insert is sometimes called the Prescribing Information (PI) or The FDA label.

### **Storage**

- Store vials in a refrigerator at 2°C to 8°C (36°F to 46°F). Do not freeze.
- Store in the original carton to protect it from light until the time of reconstitution.
- Do not shake the reconstituted or diluted solution.

## Ingredients

Active Ingredient: fam-trastuzumab deruxtecan-nxki.

**Inactive Ingredients:** L-histidine, L-histidine hydrochloride monohydrate, polysorbate 80, and sucrose.

### Company

Enhertu is manufactured by: Daiichi Sankyo, Inc., Basking Ridge, NJ 07920 U.S. License No. 2128.

**Enhertu is marketed by:** Daiichi Sankyo, Inc., Basking Ridge, NJ 07920 and AstraZeneca Pharmaceuticals LP, Wilmington, DE 19850.

### **Enhertu Biosimilars**

Biosimilar and interchangeable products are biological products that are highly similar to and have no clinically meaningful differences from the reference product.

### Reference products

These are biological products that have already been approved by the FDA, against which biosimilar products are compared. There is 1 for Enhertu.

### Enhertu (fam-trastuzumab deruxtecan-nxki) - Daiichi Sankyo, Inc

Formulation type	Strength
Single-Dose Vial	100 mg

# **Popular FAQ**

Does Enhertu cause hair loss?	~
What is the success rate of Enhertu in metastatic breast cancer?	~
Is Enhertu a chemotherapy drug? What's Enhertu used for?	~

#### References

- 1. Enhertu Product Label
- 2. Shanu Modi, M.D., Cristina Saura, M.D., Ph.D., Toshinari Yamashita, M.D., et al. Trastuzumab Deruxtecan in Previously Treated HER2-Positive Breast Cancer.
- 3. Trastuzumab Deruxtecan after Endocrine Therapy in Metastatic Breast Cancer
- 4. Trastuzumab deruxtecan versus trastuzumab emtansine in patients with HER2-positive metastatic breast cancer: updated results from DESTINY-Breast03, a randomised, open-label, phase 3 trial

### **Further information**

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.