

NOW APPROVED



ENHERTU[®]

fam-trastuzumab deruxtecan-nxki
20 mg/mL INJECTION FOR INTRAVENOUS USE

**For discussion with
your healthcare provider:**

Understanding and Managing Side Effects of ENHERTU

Visit **ENHERTU.com**
for more information.

Please see Important Safety Information throughout as well as on pages 13 to 17, and [click here for full Prescribing Information](#), including Boxed WARNING, and [click here for Medication Guide](#).

What is ENHERTU?

ENHERTU (fam-trastuzumab deruxtecan-nxki) is a prescription medicine used to treat adult patients with **H**uman **E**pidermal growth factor **R**eceptor **2** (HER2)-positive breast cancer that:

- Cannot be removed by surgery or that has spread to other parts of your body (known as metastatic), **and**
- Have received two or more prior anti-HER2 breast cancer treatments

ENHERTU was FDA approved for this use based on a clinical study that measured how many patients responded and how long they responded. ENHERTU is still being studied to confirm these results. It is not known if ENHERTU is safe and effective in children.

Find more information about ENHERTU by visiting www.ENHERTU.com.

Select Important Safety Information

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

ENHERTU can cause serious side effects, including:

Lung problems that may be severe, life-threatening or that may lead to death. If you develop lung problems your healthcare provider may treat you with corticosteroid medicines.

Tell your healthcare provider right away if you get any of the following signs and symptoms:

- Cough
- Fever
- Trouble breathing or shortness of breath
- Other new or worsening breathing symptoms (e.g., chest tightness, wheezing)

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How will I receive ENHERTU?

ENHERTU is given once every 3 weeks by intravenous (IV) infusion by your healthcare provider. Your healthcare provider will decide how many treatments you need.



- Your healthcare provider may slow down or temporarily stop your infusion of ENHERTU if you have an infusion-related reaction, or permanently stop ENHERTU if you have severe infusion reactions
- If you miss a planned dose of ENHERTU, call your healthcare provider right away to schedule an appointment. Do not wait until the next planned treatment cycle

How does ENHERTU work?

ENHERTU is made up of two cancer-fighting agents: an antibody attached to chemotherapy.^{1,2}

- ENHERTU works by attacking HER2+ cancer cells and delivering chemotherapy to them
- Although ENHERTU is designed to target HER2+ cancer cells it may still affect some healthy cells

Select Important Safety Information (cont'd)

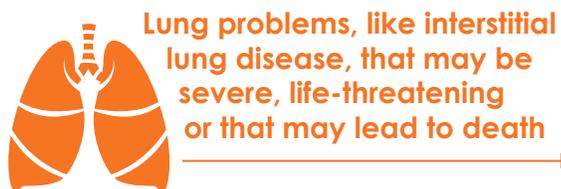
Low white blood cell count (neutropenia).

Low white blood cell counts are common with ENHERTU and can sometimes be severe. Your healthcare provider will check your white blood cell counts before starting ENHERTU and before starting each dose. Tell your healthcare provider right away if you develop any signs or symptoms of an infection or have fever or chills during treatment with ENHERTU.

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What is the most important information you should know about ENHERTU?

ENHERTU can cause serious side effects, including:



- Call or see your healthcare provider right away if you develop any of the following signs and symptoms or if these symptoms get worse:
 - Cough
 - Trouble breathing or shortness of breath
 - Fever
 - Other new or worsening breathing symptoms (e.g., chest tightness, wheezing)

If you develop lung problems your healthcare provider may treat you with corticosteroid medicines.

Call or see your healthcare provider right away if you develop any symptoms of these problems or if these symptoms get worse.

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Low white blood cell count (neutropenia)

Signs and symptoms may include:

- Low white blood cell counts are common with ENHERTU and can sometimes be severe
- Your healthcare provider will check your white blood cell counts before starting ENHERTU and before starting each dose
- Tell your healthcare provider right away if you develop any signs or symptoms of an infection or have fever or chills during treatment with ENHERTU



Heart problems that may affect your heart's ability to pump blood

- Your healthcare provider will check your heart function before starting treatment with ENHERTU

Signs and symptoms may include:

- New or worsening shortness of breath
- Coughing
- Feeling tired
- Swelling of your ankles or legs
- Irregular heartbeat
- Sudden weight gain
- Dizziness or feeling light-headed
- Loss of consciousness

Getting medical treatment right away may help keep these problems from becoming more serious.

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What are the possible side effects of ENHERTU?

ENHERTU can cause serious side effects. Please see pages 4-5 and 13-17 for more information.

The most common side effects of ENHERTU include:

- Nausea
- Feeling tired
- Vomiting
- Hair loss
- Constipation
- Decreased appetite
- Low red blood cell counts
- Low white blood cell counts
- Diarrhea
- Cough
- Low platelet counts

ENHERTU 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.

These are not all of the possible side effects of ENHERTU. Tell your healthcare provider if you experience any side effects, including those not listed in this guide.

Call your healthcare provider for medical advice about side effects.

You are encouraged to report negative side effects of ENHERTU by calling **1-877-437-7763**.

If you prefer to report these to the FDA, visit **www.FDA.gov/medwatch** or call **1-800-FDA-1088 (1-800-332-1088)**.

Let your healthcare provider know right away if you are experiencing any side effects³

Your healthcare provider may take steps to help manage your side effects, including:

- Changing your dose of ENHERTU
- Prescribing other medicines to help lessen side effects
- Recommending lifestyle changes
- Interrupting or stopping treatment



Talk to your healthcare provider before taking any medications or making changes to your diet or daily activities.

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Tips that may help with side effects³

Nausea and vomiting

- Eat 5 or 6 small meals and snacks instead of 3 large meals each day
- Eat bland, easy-to-digest food and drinks
 - Avoid food and drinks that are too hot or too cold
- Avoid strong smells
- Suck on small bites of popsicles or fruit ices
- If you feel like vomiting, take deep, slow breaths and if possible get fresh air



Diarrhea

- Eat 5 or 6 small meals and snacks instead of 3 large meals each day
- Eat foods low in fiber
- Drink clear liquids to replace lost fluids. Check with your healthcare provider how much fluid you should drink and what types of fluid might be best for you



Talk to your healthcare provider about these tips and before taking any medicine for nausea or diarrhea.

Select Important Safety Information (cont'd)

Heart problems that may affect your heart's ability to pump blood. Your healthcare provider will check your heart function before starting treatment with ENHERTU. Tell your healthcare provider right away if you get any of the following signs and symptoms:

- New or worsening shortness of breath
- Coughing
- Feeling tired
- Swelling of your ankles or legs
- Irregular heartbeat
- Sudden weight gain
- Dizziness or feeling light-headed
- Loss of consciousness

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Select Important Safety Information (cont'd)

Your healthcare provider will check you for these side effects during your treatment with ENHERTU. Your healthcare provider may reduce your dose, delay treatment or completely stop treatment with ENHERTU if you have severe side effects.

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Tips that may help with side effects (cont'd)³

Fatigue (tiredness)

- Meditation may help you relax and decrease stress
- Plan time to rest and try not to do too much
- Get regular exercise (according to your healthcare provider's approval) and plan activities when you have the most energy
- Let other people help!



Talk to your healthcare provider to help determine the cause of why you may be feeling tired.

Select Important Safety Information (cont'd)

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

- If you are able to become pregnant, your healthcare provider should do a pregnancy test before you start treatment with ENHERTU.
- **Females** who are able to become pregnant should use effective birth control (contraception) during treatment with ENHERTU and for at least 7 months after the last dose.
- **Males** who have female partners that are able to become pregnant should use effective birth control (contraception) during treatment with ENHERTU and for at least 4 months after the last dose.

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Hair loss (alopecia)

Before hair loss:

- Talk with your healthcare provider about the possibility of hair loss
- Consider cutting your hair short to feel more in control of hair loss
- Be gentle when you wash your hair. Use a mild shampoo, such as baby shampoo
- Avoid items such as electric hair dryers, hairspray, hair dyes, products to perm or relax your hair, hair bands, and clips that can hurt your scalp
- Ask your healthcare provider about other therapies that may help minimize hair loss⁴

During and after hair loss:

- Protect your scalp
- Cover your head to help stay warm. You may feel colder once you lose your hair
- Sleep on a satin pillow case. Satin creates less friction and may be more comfortable

If you are concerned about hair loss, you might want to talk with a member of your healthcare team, a friend or family member, or another person like you undergoing treatment.

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What should I tell my healthcare provider before starting ENHERTU?

Let your healthcare provider know 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 ENHERTU passes into your breast milk. Do not breastfeed during treatment with ENHERTU and for 7 months after the last dose

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

Important Safety Information

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- Cough
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- Fever
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- **Males** who have female partners that are able to become pregnant should use effective birth control (contraception) during treatment with ENHERTU and for at least 4 months after the last dose.

Before you receive ENHERTU, 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 ENHERTU passes into your breast milk. Do not breastfeed during treatment with ENHERTU and for 7 months after the last dose.

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

How will I receive ENHERTU?

- You will receive ENHERTU into your vein through an intravenous (IV) line by your healthcare provider.
- ENHERTU is given 1 time every three weeks (21-day treatment cycle).
- Your healthcare provider will decide how many treatments you need.

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Important Safety Information (cont'd)

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What are the possible side effects of ENHERTU?

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What is ENHERTU?

ENHERTU is a prescription medicine used in adults to treat human epidermal growth factor receptor 2 (HER2) positive breast cancer that cannot be removed by surgery or that has spread to other parts of your body (metastatic), and who have received two or more prior anti-HER2 breast cancer treatments.

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References: **1.** Ogitani Y, Aida T, Hagihara K, et al. DS-8201a, a novel HER2-targeting ADC with a novel DNA topoisomerase I inhibitor, demonstrates a promising antitumor efficacy with differentiation from T-DM1. *Clin Cancer Res.* 2016;22(20):5097-5108.

2. Nakada T, Sugihara K, Jikoh T, Abe Y, Agatsuma T. The latest research and development into the antibody-drug conjugate, [fam-] trastuzumab deruxtecan (DS-8201a), for HER2 cancer therapy. *Chem Pharm Bull.* 2019;67(3):173-185. **3.** Chemotherapy and you: support for people with cancer. National Cancer Institute website. <https://www.cancer.gov/publications/patient-education/chemotherapy-and-you.pdf>. Accessed November 22, 2019.

4. Dunnill CJ, Al-Tameemi W, Collett A, Haslam IS, Georgopoulos NT. A clinical and biological guide for understanding chemotherapy-induced alopecia and its prevention. *Oncologist.* 2018;23(1):84-96.

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