Understanding and managing potential side effects of ENHERTU

You can take steps to stay proactive—start by talking to your doctor and learning which steps are best for you.

What is ENHERTU?

Not an actual patient.

ENHERTU is a prescription medicine used to treat adults who have:

- Human epidermal growth factor receptor 2 (HER2)positive breast cancer that cannot be removed by
 surgery or that has spread to other parts of the body
 (metastatic), and who have received a prior anti-HER2
 breast cancer treatment:
 - for metastatic disease, or
 - have breast cancer that has come back during or within 6 months of completing treatment for their early-stage breast cancer.
- HER2-low breast cancer that cannot be removed by surgery or that has spread to other parts of the body (metastatic), and who have received a prior chemotherapy
 - 。for metastatic disease, or
 - whose disease has returned during or within 6 months of completing adjuvant chemotherapy (after surgery).

Your healthcare provider will perform a test to make sure ENHERTU is right for you.

- Hormone receptor (HR)-positive, HER2-low or HR-positive, HER2-ultralow, breast cancer that cannot be removed by surgery or that has spread to other parts of the body (metastatic), and who have received one or more endocrine treatments for metastatic disease. Your healthcare provider will perform a test to make sure ENHERTU is right for you.
- Non-small cell lung cancer (NSCLC) that has a certain mutation in the HER2 gene and cannot be removed

by surgery or has spread to other parts of your body (metastatic), and who have received a prior treatment. Your healthcare provider will perform a test to make sure ENHERTU is right for you.

- 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.
- Stomach cancer called gastric or GEJ adenocarcinoma that is HER2-positive and has spread to areas near your stomach (locally advanced) or that has spread to other parts of your body (metastatic), and who have received a prior trastuzumab-based regimen.
- Solid tumors that are HER2-positive (IHC 3+) and that cannot be removed by surgery or have spread to other parts of your body (metastatic), and who have received a prior treatment and have no other satisfactory treatment options. Your healthcare provider will perform a test to make sure ENHERTU is right for you.
 - . ENHERTU was FDA approved for this use based on clinical studies 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.

What is some of 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, low white blood cell counts that are common and sometimes severe, and problems with your heart pumping blood.



Side effects

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

ENHERTU can cause serious side effects. Some serious or life-threatening side effects may affect your lungs, heart, or white blood cell count, affecting your ability to fight infection.

Pay special attention to new or worsening symptoms as they may be related to:



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
- Trouble breathing or shortness of breath
- Fever
- Other new or worsening breathing symptoms (such as chest tightness, wheezing)



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.



Side effects (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

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.



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 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 4 months after the last dose

You are encouraged to report 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).





Common side effects

During treatment with ENHERTU, side effects may occur and you should notify your healthcare provider as early as possible

The most common side effects of ENHERTU, when used in people with metastatic breast cancer, HER2-mutant non-small cell lung cancer, and other HER2-positive solid tumors, include:

- Low white blood cell counts
- Nausea
- Low red blood cell counts
- Feeling tired
- Low platelet counts
- Increased liver function tests
- Vomiting

- Hair loss
- Constipation
- Low levels of blood potassium
- Decreased appetite
- Diarrhea
- Muscle or bone pain

The most common side effects of ENHERTU, when used in people with HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma, include:

- Low red blood cell counts
- Low white blood cell counts
- Low platelet counts
- Nausea
- Decreased appetite
- Increased liver function tests
- Feeling tired

- Diarrhea
- Low levels of blood potassium
- Vomiting
- Constipation
- Fever
- Hair loss

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.

The majority of side effects in people receiving ENHERTU were mild or moderate*; however, some people may have serious side effects that could lead to death. It is important to call your doctor for medical advice about side effects.

*Mild side effects are side effects you may have but they show no outward signs or medical intervention may not be needed. Moderate side effects may require some medical intervention or may affect you as you do day-to-day activities.

See the next page to explore steps you can take to help manage some potential side effects after speaking with your healthcare provider.

These are not all of the possible side effects of ENHERTU. Call your doctor for medical advice about side effects.



Useful tips

Steps you can take to **help manage** some potential side effects of ENHERTU

These tips are not a substitute for your healthcare team's advice.

Always talk to your healthcare provider about any side effects you're experiencing. By keeping your healthcare provider fully informed, you help ensure that they can provide prompt personalized treatment and care.



Stay hydrated

- Drink plenty of fluids each day to help manage tiredness and fatigue
- To help manage diarrhea, it's crucial to drink clear liquids to replace lost fluids. Check with your doctor on how much and what types of fluids are best for you



Listen to your body

- When your energy levels are higher, it is recommended to participate in exercise, such as a combination of aerobic and resistance training.
 Always check with your doctor beforehand
- Plan regular rest periods and avoid overexerting yourself to combat tiredness and fatigue. Let others help with daily tasks when possible
- Try relaxation techniques like meditation or tai chi to help reduce stress and promote relaxation, which can alleviate fatigue

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 of Trouble breathing or shortness of breath of Fever of Other new or worsening breathing symptoms (such as chest tightness, wheezing)



Useful tips (cont'd)



Mind your meals

- Eat 5 or 6 small meals and snacks each day instead of 3 large meals to help with nausea, vomiting, and diarrhea. Choose bland, easy-to-digest foods and avoid strong smells
 - —Talk to your doctor about nausea medication. You should receive medicines before your infusion to help prevent nausea and vomiting
- To help manage diarrhea, focus on eating low-fiber foods to ease symptoms



Care for your hair and scalp

- Be gentle when washing your hair to manage hair thinning or loss.
 Use a mild shampoo and avoid harsh hair treatments, such as dyes, perms, or relaxers
- Consider cutting your hair short to feel more in control of hair loss.
 Talk to your doctor about using cold caps or scalp cooling systems, which may reduce hair loss
- Wear a hat or head covering and apply sunscreen to protect your scalp if experiencing hair thinning or loss. Avoid exposing your scalp to extreme temperatures
- Sleep on a satin pillowcase for added comfort and to reduce friction



Breathe and get fresh air

- If you feel nauseous or like vomiting, try taking slow, deep breaths and getting fresh air to help alleviate symptoms
- Practicing breathing exercises or engaging in other anxiety-reducing activities can help prevent or lessen nausea and vomiting

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.



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
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- 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





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.

- 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 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 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.
- Your healthcare provider will give you medicines before your infusion to help prevent nausea and vomiting.
- 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.



Important Safety Information (cont'd)

What are the possible side effects of ENHERTU?

ENHERTU can cause serious side effects. See "What is the most important information I should know about ENHERTU?"

The most common side effects of ENHERTU, when used in people with metastatic breast cancer, HER2-mutant non-small cell lung cancer, and other HER2-positive solid tumors, include:

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- Nausea
- Low red blood cell counts
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- Increased liver function tests
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- Hair loss
- Constipation
- Low levels of blood potassium
- Decreased appetite
- Diarrhea
- Muscle or bone pain

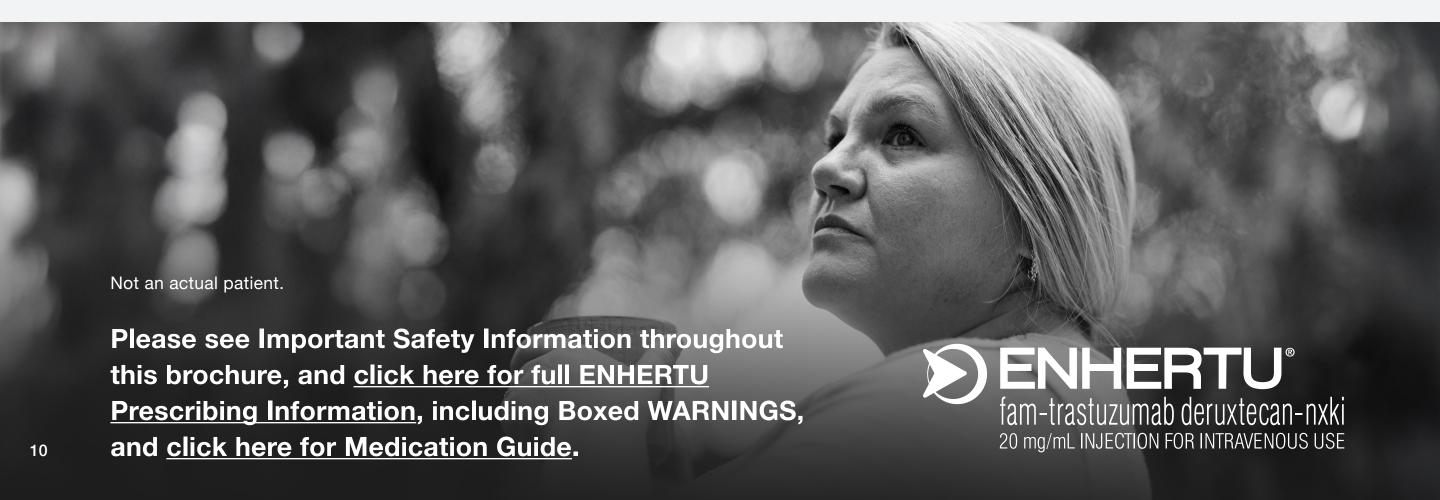
The most common side effects of ENHERTU, when used in people with HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma, include:

- Low red blood cell counts
- Low white blood cell counts
- Low platelet counts
- Nausea
- Decreased appetite
- Increased liver function tests
- Feeling tired

- Diarrhea
- Low levels of blood potassium
- Vomiting
- Constipation
- Fever
- Hair loss

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. Call your doctor for medical advice about side effects. You may report side effects to Daiichi Sankyo at 1-877-437-7763 or to FDA at 1-800-FDA-1088.



Important Safety Information (cont'd)

What is ENHERTU?

ENHERTU is a prescription medicine used to treat adults who have:

- Human epidermal growth factor receptor 2 (HER2)-positive breast cancer that cannot be removed by surgery or that has spread to other parts of the body (metastatic), and who have received a prior anti-HER2 breast cancer treatment:
 - o for metastatic disease, or
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