

A Guide to ENHERTU

For adults who received a prior treatment for unresectable or metastatic* non-small cell lung cancer (NSCLC), and who have a certain mutation in the HER2 gene

*Unresectable is defined as cancer that cannot be removed by surgery.
Metastatic is defined as cancer that has spread to other parts of the body.
HER2, human epidermal growth factor receptor 2.
Not an actual patient.

What is ENHERTU?

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

It is not known if ENHERTU is safe and effective in children.

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
 - trouble breathing or shortness of breath
 - fever
 - other new or worsening breathing symptoms (such as chest tightness, wheezing)

Please see additional Important Safety Information throughout and on pages 17-19, and [click here for full Prescribing Information, including Boxed WARNINGS, and click here for Medication Guide.](#)

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20 mg/mL INJECTION FOR INTRAVENOUS USE

Your guide to ENHERTU

Whether you have already started on or are considering treatment with ENHERTU, this brochure is designed to provide you with:

- Information about ENHERTU and HER2 mutations
- Clinical trial results
- Possible side effects, including serious ones
- Details about how you will receive ENHERTU
- Resources to help you access and afford treatment

It may be helpful for you to review this brochure with your healthcare team, who can answer any further questions you may have.

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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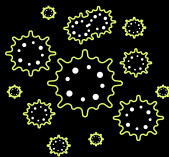
What is HER2-mutant NSCLC?



HER2 is a protein that lives on a cell's surface and can be used as a target for certain cancer medicines.



HER2 can be present on normal cells; however, mutations can develop, which most commonly occur at the base of the HER2 protein inside the cell.



HER2 mutations can cause abnormal cell activity, promoting the growth of cancer cells.



2-4% of people with NSCLC have HER2 mutations. If test results show that your NSCLC has a certain HER2 mutation, ENHERTU might be right for you.

HER2 mutations can occur in a range of people with NSCLC, and the cause of these mutations is unknown.

**Learn more about HER2-mutant NSCLC
and ask your doctor about ENHERTU.**

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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Results with ENHERTU

How was ENHERTU studied?

ENHERTU was studied in a clinical trial of 101 adults who received a 5.4 mg/kg dose and:

- Had HER2-mutant NSCLC that had spread to other parts of their body (metastatic) or could not be removed by surgery (unresectable)
- Had their disease return after a prior treatment for lung cancer

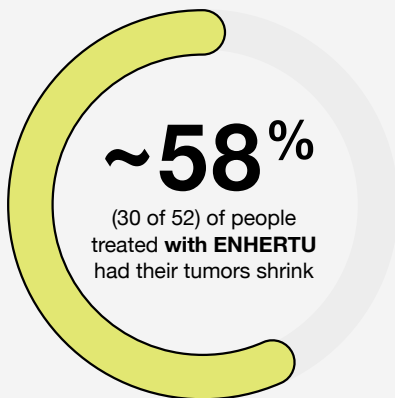
The study included many types of adults, including those with different ages, races, genders, and smoking histories.

This study only evaluated ENHERTU. There was not a comparison of results to another treatment option for HER2-mutant metastatic NSCLC.

What were the results of the ENHERTU study?

Overall response rate

In a clinical study, about 58% of people treated with ENHERTU had their tumors shrink



~56% (29 of 52)

of people achieved what is known as a partial response, meaning their tumor shrank by at least 30%

~2% (1 of 52)

of people achieved what is known as a complete response, meaning their tumor could not be seen on imaging tests

This is called overall response rate. Overall response rate is the proportion of patients who have a partial or complete response to therapy.

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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Median duration of response



Half of the people who responded to ENHERTU were **still responding** after nearly 9 months

This is called median duration of response.*

ENHERTU is still being studied to confirm these results.

*A median is the middle number in a set of numbers. Median duration of response is the length of time half of the people in the trial continued to respond after the first response was seen.

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.

Response to ENHERTU was studied in adults with HER2-mutant unresectable or metastatic NSCLC, including those of different ages, genders, races, smoking histories, and prior treatments.

ENHERTU is also approved for other uses beyond HER2-mutant NSCLC, including metastatic solid tumors with HER2 overexpression (IHC 3+).

A healthcare provider will determine eligibility for ENHERTU based on HER2 mutation via next-generation sequencing (NGS) testing or HER2 overexpression via immunohistochemistry (IHC) testing. Further details about benefits and risks of ENHERTU, including other approved uses, can be found at [ENHERTU.com/lung](https://www.enhertu.com/lung).

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 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.

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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, like interstitial lung disease/ pneumonitis, that may be severe, life-threatening, or that may lead to death

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 (such as chest tightness, wheezing)

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



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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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.

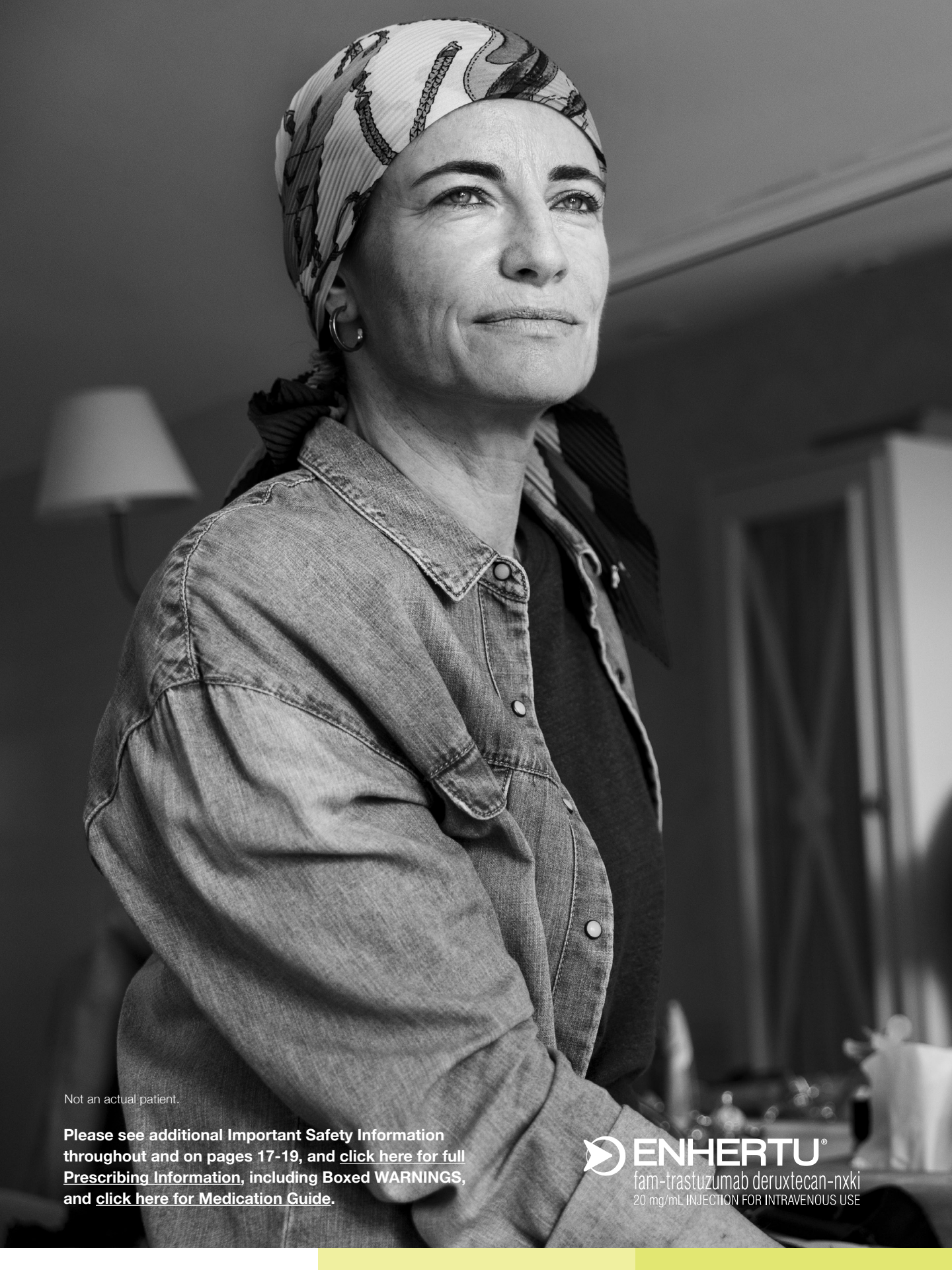


- If you are able to become pregnant, your healthcare provider should do a pregnancy test before you start treatment with ENHERTU
- **Females** who are able to become pregnant should use effective birth control (contraception) during treatment with ENHERTU and for 7 months after the last dose
- **Males**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

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

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What are the possible side effects of ENHERTU?

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

ENHERTU can cause serious, potentially fatal side effects. See pages 6-7 for the most important information you should know about ENHERTU.

The most common side effects of ENHERTU, when used alone at the 5.4 mg/kg dose in people with 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 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.

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 of ENHERTU to Daiichi Sankyo at 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).

**Find details about how you will receive ENHERTU
on page 13 of this brochure.**

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What to tell your healthcare provider

Before you receive ENHERTU, tell your healthcare provider about all of your medical conditions, including if you:

- Have lung or breathing problems
- Have kidney problems. Your healthcare provider may follow you more closely. In clinical trials, more serious lung problems were seen in patients with certain kidney problems
- Have liver problems. Your healthcare provider may follow you more closely
- 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.

Remember to call your healthcare provider right away for medical advice if you experience any side effects. It is important to manage any side effects you may have with your healthcare provider.

IMPORTANT SAFETY INFORMATION (cont'd)

Before you receive ENHERTU, tell your healthcare provider about all of your medical conditions, including if you:

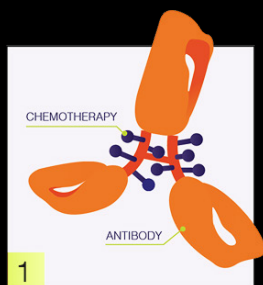
- have lung or breathing problems
- have signs or symptoms of an infection
- have or have had any heart problems
- are breastfeeding or plan to breastfeed. It is not known if ENHERTU passes into your breast milk. Do not breastfeed during treatment with ENHERTU and for 7 months after the last dose.

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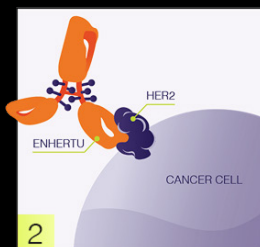
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How is ENHERTU thought to work?

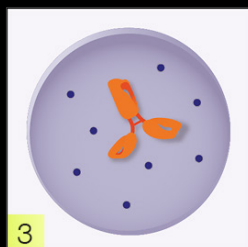
As a targeted treatment called an antibody-drug conjugate (ADC), ENHERTU is designed to work differently than traditional chemotherapies.



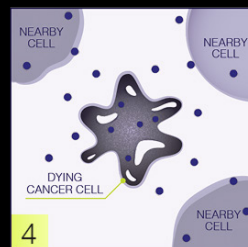
ENHERTU is made up of an antibody with the chemotherapy attached



The antibody part of ENHERTU targets and attaches to HER2 on the cancer cell



ENHERTU enters the cancer cell and the chemotherapy is released



The chemotherapy part of ENHERTU helps destroy the cancer cell as well as other cells nearby

Although ENHERTU is designed to target HER2 on cancer cells, it may affect some healthy cells. ENHERTU may not work for everyone.

IMPORTANT SAFETY INFORMATION (cont'd)

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

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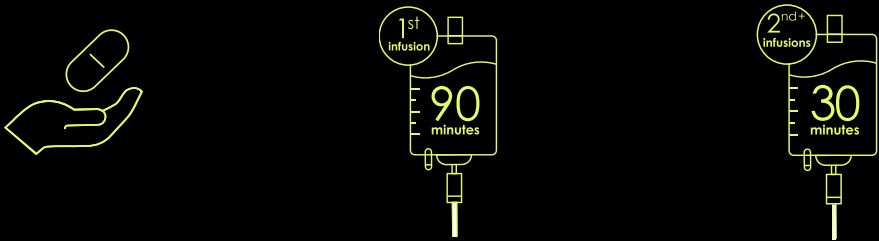
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How will I receive ENHERTU?

ENHERTU is given as an intravenous (IV) infusion

You will receive an ENHERTU infusion once every 3 weeks, either at your oncologist's office or at a nearby infusion center.



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

The first ENHERTU infusion will take about 90 minutes so the healthcare provider can monitor any potential reactions

Future ENHERTU infusions should take about 30 minutes if your first infusion was well tolerated

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.

If you experience side effects, your doctor may treat the side effect, delay your dose, reduce your dose, or stop ENHERTU.

IMPORTANT SAFETY INFORMATION (cont'd)

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.

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Support & resources

ENHERTU4U may be able to help you access and afford treatment with **ENHERTU** after it has been prescribed

The ENHERTU4U program is designed to help you access and afford your prescribed ENHERTU treatment, including benefits reviews, prior authorization and/or claims appeal information, and paying for your prescription.*



ACCESS

ENHERTU4U is here to help your healthcare provider understand your insurance company's requirements for access to treatment with ENHERTU.



FINANCIAL ASSISTANCE

We have multiple options to help you afford your treatment.* Your healthcare provider can provide more information about how ENHERTU4U may be able to help.

*For eligible patients. Terms and conditions apply.

For more information about ENHERTU4U, please call 1-833-ENHERTU (1-833-364-3788) or scan the QR code to visit [ENHERTU4U.com](https://www.enherthu4u.com).

ENHERTU4U does not guarantee access or cost savings for patients prescribed ENHERTU.



Connect with helpful resources



American Lung Association
[lung.org](https://www.lung.org)



LUNGEvity Foundation
[lungcancer.org](https://www.lungcancer.org)



American Cancer Society
[cancer.org](https://www.cancer.org)
The American Cancer Society does not endorse any product or service.



Lung Cancer Research Foundation
[lcrf.org](https://www.lcrf.org)



GO2 Foundation for Lung Cancer
[go2foundation.org](https://www.go2foundation.org)

This is not an all-inclusive list of resources.

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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
 - 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.
- **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.
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Important Safety Information (cont'd)

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- 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.

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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 alone at the 5.4 mg/kg dose in people with 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

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Important Safety Information (cont'd)

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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 FDA at 1-800-FDA-1088.

What is ENHERTU?

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

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It is not known if ENHERTU is safe and effective in children.

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Find out more about ENHERTU by speaking to your healthcare provider and by visiting [ENHERTU.com/lung](https://www.enherthu.com/lung)

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