

ENHERTU®

Trastuzumab deruxtecan, 100 mg; powder for concentrate for solution for infusion

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some of the common questions people ask about **ENHERTU**. It does not contain all the information that is known about **ENHERTU**.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking **ENHERTU** against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or nurse.

Keep this leaflet, you may need to read it again.

What ENHERTU is used for

ENHERTU contains the active ingredient trastuzumab deruxtecan. **ENHERTU** is made up of a monoclonal antibody connected to a medicine intended to kill cancer cells. The monoclonal antibody delivers the medicine to cancer cells that express HER2 proteins. Once **ENHERTU** enters the cell, the medicine becomes active and kills the cancer cells.

ENHERTU is used to treat adults who have:

- HER2-positive breast cancer that has spread to other parts of the body or cannot be taken out by surgery **and** who have also received prior treatment with trastuzumab and a taxane for metastatic disease, or have received one prior treatment for 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 your body (metastatic) **and** who have received prior chemotherapy for metastatic disease, **or** your disease has returned during or within 6 months of completing adjuvant chemotherapy (after surgery). If the breast cancer is also hormone receptor positive (HR+), you should have received hormonal therapy. A test will be performed to make sure **ENHERTU** is right for you.

This medicine is only available with a doctor's prescription.

Before you use ENHERTU

Before you start to use it

Check with your doctor if you:

- have or have had any lung problems, any kidney problems, any heart problems or any blood problems (low blood count).

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them (see Section "While you are receiving ENHERTU" and "Side effects").

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Pregnancy

- **ENHERTU** is not recommended if you are pregnant because this medicine may cause harm to the unborn baby.
- Tell your doctor before using **ENHERTU** if you are pregnant, think you may be pregnant or are planning to have a baby.
- Use effective contraception to avoid becoming pregnant while you are being treated with **ENHERTU**. Talk to your doctor about the best contraception for you.
- Females should continue to take contraception for at least 7 months after your last dose of **ENHERTU**. Talk to your doctor before stopping your contraception.

- Male patients with a female partner who could become pregnant should use effective contraception during treatment and for at least 4 months after the last dose of **ENHERTU**.
- If you do become pregnant during treatment with **ENHERTU**, tell your doctor right away.

Breastfeeding

- You should not breastfeed during treatment with **ENHERTU**.
- You should not breastfeed for at least 7 months after your last treatment of **ENHERTU**.
- It is not known whether the ingredients in **ENHERTU** pass into breast milk. Talk to your doctor about this.

Fertility

- Talk to your doctor about sperm storage before treatment with **ENHERTU** because the medicine may reduce your fertility. Do not freeze or donate sperm throughout the treatment period, and for at least 4 months after the final dose of **ENHERTU**.

Children and adolescents

ENHERTU is not recommended for anyone under the age of 18 years.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop. **Check with your doctor if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ENHERTU.**

How ENHERTU is given

How you are given ENHERTU

ENHERTU will be given to you in a hospital or clinic.

- The recommended dose of **ENHERTU** is 5.4 mg for every kilogram of your body weight, every 3 weeks.
- Your doctor or nurse will give you **ENHERTU** through an infusion into your vein (IV).
- Your first infusion will be given to you over 90 minutes. If you have no problems with the first infusion, the infusion on your next visits may be given over 30 minutes.
- Your doctor will decide how many treatments you need.
- Before each **ENHERTU** infusion, your doctor may give you medicines to help prevent nausea and vomiting.
- If you experience infusion-related symptoms, your doctor or nurse may slow, interrupt or stop your treatment.

If you miss an appointment to get ENHERTU

- Call your doctor right away to reschedule your appointment.
- It is very important that you do not miss a dose of this medicine.

If you stop receiving ENHERTU

- Do not stop treatment with **ENHERTU** unless you have discussed this with your doctor.
- If you have any further questions about your treatment, ask your doctor.

While you are receiving ENHERTU

Things you should do

- Remind any doctor, dentist or nurse you visit that you are receiving **ENHERTU**.
- Keep your appointments with your doctor, so that you do not miss a dose and progress is monitored.
- Tell your doctor or nurse if you are taking other medicines, vitamins or supplements.
- Tell your doctor if you experience any side effects, including those not listed in this leaflet.
- Use effective contraception to avoid becoming pregnant while being treated with ENHERTU (see “Contraception” section below).

Call your doctor straight away if you:

- have cough, shortness of breath, fever, or other new or worsening breathing problems. These may be symptoms of a serious and potentially fatal lung disease (interstitial lung disease [ILD] and/or pneumonitis). Patients with a history of this lung disease or kidney problems may have increased risk of developing interstitial lung disease. Your doctor may have to monitor your lungs while you are taking this medicine.
- have chills, fever, sores in your mouth, stomach pain or pain when urinating. These may be symptoms of an infection caused by low levels of a type of white blood cell called neutrophils (neutropenia).
- have new or worsening shortness of breath, cough, tiredness, swelling of your ankles or legs, irregular heartbeat, sudden weight gain, dizziness, or loss of consciousness. These may be symptoms of a problem with your heart's ability to pump blood (left ventricular ejection fraction [LVEF] decrease).
- become pregnant while using **ENHERTU**.
- experience any of the serious side effects listed in the "Side effects" section below.

Things you should not do

- Do not stop using **ENHERTU** suddenly, unless you have discussed this with your doctor.

Contraception

Use effective contraception to avoid becoming pregnant while being treated with **ENHERTU**. Females should continue to take contraception for at least 7 months after your last dose of **ENHERTU**. Men with a female partner who may become pregnant should use effective contraception:

- during treatment and
- for at least 4 months after the last dose of **ENHERTU**.

Talk to your doctor about the best contraception for you or before stopping your contraception.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how **ENHERTU** affects you. It is not expected that **ENHERTU** affects your ability to drive or use machines. Be careful if you feel tired, dizzy, or have a headache.

Side effects

All medicines can have side effects. If you do experience any side effects, some can be minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor if you have any further questions about side effects. Tell your doctor if you experience any side effects, including those not listed in this leaflet.

While you are taking ENHERTU

- Your doctor will carry out tests before and during your treatment with **ENHERTU**
- Depending on the side effects you experience, your doctor may decide to lower your dose, temporarily stop your treatment or permanently stop your treatment.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • cough, shortness of breath (dyspnoea), fever, or other new or worsening breathing problems as these may be symptoms of a lung problem (interstitial lung disease/pneumonitis). • chills, fever, sores in your mouth, stomach pain or pain when urinating as these may be symptoms of an infection caused by low levels of a type of white blood cell called neutrophils (neutropenia). • new onset or worsening shortness of breath, cough, tiredness, swelling of your ankles or legs, irregular heartbeat, sudden weight gain, dizziness, or loss of consciousness as these may be symptoms of a problem with your heart's ability to pump blood (left ventricular ejection fraction [LVEF] decrease). 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these symptoms because some of them may be signs of a serious or possibly fatal condition. Getting medical treatment right away may help keep these problems from becoming more serious.</p>

You may experience the following side effects:

Very common (may affect more than 1 in 10 people)	What to do
<ul style="list-style-type: none"> • Nausea • Feeling tired (fatigue) • Vomiting • Hair loss (alopecia) • Constipation • Feeling less hungry • Diarrhoea • Coughing • Stomach (abdominal) pain • Headache • Fever (pyrexia) • Infections of the nose, nasal passages, throat, voice box and vocal cords • Sores in or around your mouth (stomatitis) • Difficulty breathing (dyspnoea) • Indigestion (dyspepsia) • Severe nosebleeds (epistaxis) • Lung problems (interstitial lung disease/pneumonitis) • Rash • Dizziness • Pain in muscles and bone • Weight loss • Decrease in the number of red blood cells (anaemia) • Decrease in the number of neutrophils (neutropenia) • Decrease in the number of platelets (thrombocytopenia) • Decrease in the number of white blood cells (leukopenia) • Decrease in the number of lymphocytes (lymphopenia) • Blood tests showing increased level of liver enzymes such as transaminases (aspartate aminotransferase, alanine aminotransferase, gamma-glutamyltransferase). These are liver function tests that indicate abnormality. • Low potassium in the blood (hypokalaemia) 	<p>Speak to your doctor if you have any of these very common side effects and they worry you.</p>
Common (may affect up to 1 in 10 people)	What to do
<ul style="list-style-type: none"> • Reactions related to the infusion of the medicine • Itching (pruritus) • Darkening of the skin (skin hyperpigmentation) • Bad taste in mouth (dysgeusia) • Excessive gas in the stomach or intestine, bloating and breaking wind (abdominal distension and flatulence) • Inflammation of the stomach (gastritis) • Feeling thirsty, dry mouth (dehydration) • Blurry vision • Dry eye • Abnormal blood test (increased levels of blood bilirubin, blood creatinine or blood alkaline phosphatase) 	<p>Speak to your doctor if you have any of these common side effects and they worry you.</p>

Tell your doctor if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Looking after ENHERTU

Storage

ENHERTU will be stored by the healthcare professionals at the hospital or clinic where you receive treatment.

Product description

What ENHERTU looks like

ENHERTU is a white to yellowish-white freeze-dried powder supplied in a clear amber vial with a rubber stopper, aluminium seal and plastic flip-off cap.

Each carton contains 1 vial.

Ingredients

Active ingredient (main ingredient)	Trastuzumab deruxtecan
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• L histidine• L histidine hydrochloride monohydrate• sucrose• polysorbate 80

Marketed by:

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