

Consumer Medicine Information (CMI) summary

The [full CMI](#) on Page 2 has more details. If you are worried about using this medicine, speak to your doctor or nurse.



This medicine is new or being used differently. Please report side effects. See the [full CMI](#) (page 2) for further details.

1. Why am I using ENHERTU?

ENHERTU contains the active ingredient trastuzumab deruxtecan. ENHERTU is used to treat several kinds of cancers.

For more information, see Section 1 in the [full CMI](#).

2. What should I know before I use ENHERTU?

Before you are given ENHERTU, tell your doctor if you have or have had any lung problems, any kidney problems, any heart problems or any blood problems (low blood count). **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section 2 in the [full CMI](#).

3. What if I am taking other medicines?

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines. See Section 3 in the [full CMI](#).

4. How is ENHERTU given to me?

ENHERTU will be given to you in a hospital or clinic by a doctor or nurse. See Section 4 in the [full CMI](#).

5. What should I know while 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. - Use effective contraception to avoid becoming pregnant while being treated with ENHERTU.
Things you should not do	Do not stop using ENHERTU suddenly, unless you have discussed this with your doctor.
Driving or using machines	Be careful before you drive or use any machines or tools until you know how ENHERTU affects you.
Call your doctor straight away	- If you experience any of the serious side effects listed in Section 6 in the full CMI. - If you have cough, shortness of breath, fever, or other new or worsening breathing problems. - If you become pregnant while using ENHERTU.
Looking after your medicine	ENHERTU will be stored by the healthcare professionals at the hospital or clinic where you receive treatment.

For more information, see Section 5 in the [full CMI](#).

6. Are there any 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 be serious and possibly fatal, therefore will need immediate medical attention. See Section 6 in the [full CMI](#) 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.

For more information, including what to do if you have any side effects, see Section 6 in the [full CMI](#).

▼ This medicine is subject to additional monitoring due to approval of an extension of indications. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

ENHERTU®

Active ingredient: trastuzumab deruxtecan

ENHERTU has **provisional approval** to treat HER2-positive stomach cancer called gastric or gastroesophageal junction (GEJ) adenocarcinoma that has spread to areas near the stomach (locally advanced) or that has spread to other parts of the body (metastatic) and a prior treatment has been received, including one that targeted HER2-positive stomach cancer. The decision to approve the new use of this medicine has been made on the basis of promising results from preliminary studies. More evidence is required to be submitted when available to fully confirm the benefit and safety of the medicine for this use.

ENHERTU also has **provisional approval** for other HER2-positive solid tumours that have spread to other parts of the body (metastatic) or cannot be taken out by surgery in patients who have received prior treatment and who have no other treatment options. The decision to approve these new uses of the medicine has been made on the basis of promising results from preliminary studies. More evidence is required to be submitted when available to fully confirm the benefit and safety of the medicine for this use.

ENHERTU also has **provisional approval** for non-small cell lung cancer that has a certain mutation in the HER2 gene and where the cancer has spread to other parts of the body (metastatic) or cannot be taken out by surgery and a prior treatment has been received. The decision to approve the new use of this medicine has been made on the basis of promising results from preliminary studies. More evidence is required to be submitted when available to fully confirm the benefit and safety of the medicine for this use.

Consumer Medicine Information (CMI)

This leaflet provides important information about using ENHERTU. **You should also speak to your doctor or nurse if you would like further information or if you have any concerns or questions about using ENHERTU.**

Where to find information in this leaflet:

1. [Why am I using ENHERTU?](#)
2. [What should I know before I use ENHERTU?](#)
3. [What if I am taking other medicines?](#)
4. [How is ENHERTU given to me?](#)
5. [What should I know while receiving ENHERTU?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using ENHERTU?

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 human epidermal growth factor receptor 2 (HER2) proteins or have a certain mutation in the HER2 gene. 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 the 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 may be performed to make sure ENHERTU is right for you.
- Hormone receptor (HR)-positive and either HER2-low or HER2-ultralow breast cancer that cannot be removed by surgery or that has spread to other parts of the body (metastatic), who have received at least one endocrine treatment for metastatic disease and are not considered suitable for further endocrine therapy as the next line of treatment. A test may be performed to make sure ENHERTU is right for you.
- HER2-positive stomach cancer called gastric or gastroesophageal junction (GEJ) adenocarcinoma that has spread to areas near the stomach (locally advanced) or that has spread to other parts of the body (metastatic) **and** who have also received a prior treatment, including one that targeted HER2-positive stomach cancer.
- Other HER2-positive solid tumours that have spread to other parts of your body (metastatic) or cannot be taken out by surgery in patients who have received prior treatment and who have no other treatment options. A test may be performed to make sure ENHERTU is right for you.
- Non-small cell lung cancer that has a certain mutation in the HER2 gene and where the cancer has spread to other parts of the body (metastatic) or cannot be taken out by surgery and who have received a prior treatment. A test will be performed to make sure ENHERTU is right for you.

2. What should I know before I use ENHERTU?

Warnings and precautions

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 additional information under Section 5 ([What should I know while receiving ENHERTU?](#)) and Section 6 ([Are there any 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.
- Patients who could become pregnant should continue to take contraception for at least 7 months after your last dose of ENHERTU. Talk to your doctor before stopping your contraception.
- Patients whose sperm could cause their partner to 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.

3. What if I am 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.

4. How is ENHERTU given to me?

How you are given ENHERTU

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

- The recommended dose of ENHERTU for the treatment of HER2-positive or HER2-low or HER2-ultralow breast cancer, other HER2-positive solid tumours or non-small cell lung cancer that has a certain mutation in the HER2 gene is 5.4 mg for every kilogram of your body weight, every 3 weeks.
- The recommended dose of ENHERTU for the treatment of HER2-positive stomach cancer is 6.4 mg for every kilogram of your body weight given 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.

5. What should I know while 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](#) 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 dysfunction).
- become pregnant while using ENHERTU.
- experience any of the serious side effects listed in Section 6 ([Are there any side effects?](#)).

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.

Patients who could become pregnant should continue to take contraception for at least 7 months after your last dose of ENHERTU.

Patients whose sperm could cause their partner to 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.

Looking after your medicine

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

6. Are there any 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
• 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).	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. See Section 5 (What should I know while receiving ENHERTU?). Getting medical treatment right away may help keep these problems from becoming more serious.

You may experience the following side effects:

Very common (may affect more than 1 in 10 people)	What to do
- Nausea - Feeling tired (fatigue) - Vomiting - Hair loss (alopecia) - Constipation - Feeling less hungry (decreased appetite) - 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 - 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)	Speak to your doctor if you have any of these very common side effects and they worry you.

Common (may affect up to 1 in 10 people)	What to do
- Swelling of the ankles or feet (peripheral oedema) - Coughing with phlegm, fever, chills (pneumonia) - Reactions related to the infusion of the medicine	Speak to your doctor if you have any of these common side effects and

Common (may affect up to 1 in 10 people)	What to do
- Dizziness - Fever along with a decrease in the number of neutrophils (febrile neutropenia) - 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)	they worry you.

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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor before you decide to stop taking any of your medicines.

7. Product details

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

What ENHERTU contains

Active ingredient (main ingredient)	Trastuzumab deruxtecan
Other ingredients (inactive ingredients)	Histidine, histidine hydrochloride monohydrate, sucrose, and polysorbate 80

What ENHERTU looks like

ENHERTU (Aust R 343262) is a white to yellowish-white lyophilised powder supplied in a clear amber vial with a rubber stopper, aluminium seal and plastic flip-off cap.

Each carton contains 1 vial.

Who distributes ENHERTU

AstraZeneca Pty Ltd
ABN 54 009 682 311
66 Talavera Road
MACQUARIE PARK NSW 2113
Telephone: 1800 805 342

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