

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**  
**PATIENT MEDICATION INFORMATION**



**Trastuzumab deruxtecan for injection**

Read this carefully before you start treatment with **ENHERTU** and each time you get an infusion. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **ENHERTU**.

**Serious Warnings and Precautions**

- Lung problems that may be severe, life-threatening or that may lead to death. Tell your healthcare provider right away if you get any of the following signs and symptoms at any time during treatment:
  - 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.

- 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.

- There is a risk of ENHERTU medication errors. Verify with your healthcare provider that you are receiving the authorized ENHERTU (trastuzumab deruxtecan) dose and NOT trastuzumab or trastuzumab emtansine.

**What is ENHERTU used for?**

ENHERTU is used in adults who have:

- HER2-positive breast cancer that has spread to other parts of the body (metastatic) or cannot be taken out by surgery **and**
- also received prior trastuzumab emtansine (T-DM1).

For the following indication(s) ENHERTU has been approved *with conditions* (Notice of Compliance with Conditions - NOC/c). This means it has passed Health Canada's review and can be bought and sold in Canada, but the manufacturer has agreed to complete more studies to make sure the drug works the way it should. For more information, talk to your healthcare professional.

- ENHERTU (trastuzumab deruxtecan) is used in adults who have HER2-positive breast cancer that has spread to other parts of the body (metastatic) or cannot be taken out by surgery and also received prior trastuzumab emtansine (T-DM1).

### **What is a Notice of Compliance with Conditions (NOC/c)?**

A Notice of Compliance with Conditions (NOC/c) is a type of approval to sell a drug in Canada.

Health Canada only gives an NOC/c to a drug that treats, prevents, or helps identify a serious or life-threatening illness. The drug must show promising proof that it works well, is of high quality, and is reasonably safe. Also, the drug must either respond to a serious medical need in Canada, or be much safer than existing treatments.

Drug makers must agree in writing to clearly state on the label that the drug was given an NOC/c, to complete more testing to make sure the drug works the way it should, to actively monitor the drug's performance after it has been sold, and to report their findings to Health Canada.

### **How does ENHERTU work?**

ENHERTU contains the active substance trastuzumab deruxtecan, which 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 (known as HER2 positive). Once ENHERTU enters the cell, the medicine becomes active and kills the cancer cells.

### **What are the ingredients in ENHERTU?**

Medicinal ingredients: trastuzumab deruxtecan

Non-medicinal ingredients: L histidine, L histidine hydrochloride monohydrate, polysorbate 80, sucrose.

### **ENHERTU comes in the following dosage forms:**

Vial containing 100 mg of trastuzumab deruxtecan

### **Do not use ENHERTU if:**

- You are allergic to trastuzumab deruxtecan or to any ingredients in ENHERTU. If you are not sure, talk to your healthcare professional before you are given ENHERTU.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ENHERTU. Talk about any health conditions or problems you may have, including if you:**

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

**Other warnings you should know about:**

When you first receive this medicine and anytime during treatment, immediately tell your doctor or nurse 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]/ pneumonitis).
- 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).
- new or worsening shortness of breath, cough, fatigue, 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 (decreased left ventricular ejection fraction [LVEF]).
- chills or shaking, shortness of breath or wheezing, itching, rash or hives, flushing, dizziness, fever, feeling like passing out (infusion related reaction).

**Children and adolescents**

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

**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.

**Driving and using machines:** ENHERTU may reduce your ability to drive or use machines. Be careful if you feel tired, dizzy or have a headache.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**How to take ENHERTU:**

Enhertu will be given to you by a healthcare professional.

**Usual dose:**

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.
- If you experience infusion related symptoms, your doctor or nurse may slow, interrupt or stop your treatment.

**Overdose:**

If you think you have been given too much ENHERTU, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

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.

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.

**What are possible side effects from using ENHERTU?**

Like all medicines, this medicine can cause side effects, although not everybody gets them. 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.

**Tell your doctor right away if you notice any of the following 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.

- cough, shortness of breath, fever, or other new or worsening breathing problems as these may be symptoms of a lung problem.

- chills, fever, sores in your mouth, stomach pain or pain when urinating as these may be symptoms of an infection.
- new onset or worsening shortness of breath, cough, fatigue, swelling of your ankles or legs, irregular heartbeat, sudden weight gain, dizziness, or loss of consciousness as these may be symptoms of a heart problem.

You may experience the following side effects:

**Very common (may affect more than 1 in 10 people)**

- Nausea
- Feeling tired (fatigue)
- Vomiting
- Hair loss (alopecia)
- Constipation
- Feeling less hungry
- Diarrhea
- Coughing
- Stomach (abdominal) pain
- Headache
- Sores in or around your mouth (stomatitis)
- Indigestion (dyspepsia)
- Severe nosebleeds (epistaxis)
- Rash
- Dry eye, which may cause reduced vision
- Dizziness
- Abnormal liver enzyme results (increase in alanine aminotransferase)
- Decrease in the number of platelets (thrombocytopenia)
- Low potassium in the blood (hypokalemia)
- Abnormal liver enzyme results (increase in aspartate aminotransferase)

These are not all the possible side effects you may feel when taking ENHERTU. If you experience any side effects not listed here, contact your healthcare professional.

<b>Serious side effects and what to do about them</b>			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>VERY COMMON</b> Lung problems (interstitial lung disease/ pneumonitis): Cough, shortness of breath, fever, or other new or worsening breathing problems as these may be symptoms of a lung problem.		√	
Decrease in the number of white blood cells (leukocytes, lymphocytes, or neutrophils):		√	

<b>Serious side effects and what to do about them</b>			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Fever or infection. Fatigue. Aches and pains. Flu-like symptoms.			
Decrease in the number of red blood cells (anemia): Fatigue, pale skin, shortness of breath, weakness		√	
Infections of the upper respiratory tract		√	
Difficulty breathing (dyspnea)		√	
<b>COMMON</b> Fever along with a decrease in the number of neutrophils (febrile neutropenia)		√	
Reactions related to the infusion of the medicine. Symptoms within 24 hours of infusion: chills or shaking, shortness of breath or wheezing, itching, rash or hives, flushing, dizziness, fever, feeling like passing out		√	
New onset or worsening shortness of breath, cough, fatigue, swelling of your ankles or legs, irregular heartbeat, sudden weight gain, dizziness, or loss of consciousness as these may be symptoms of a heart problem (decreased ejection fraction)		√	
<b>UNCOMMON</b> Serious complication of infection (sepsis)		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

### **Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mpps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### **Storage:**

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

### **If you want more information about ENHERTU:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<http://hc-sc.gc.ca/index-eng.php>); the manufacturer's website [www.astrazeneca.ca](http://www.astrazeneca.ca), or by calling 1-800-668-6000.
- This Patient Medication Information is current at the time of printing. The most up-to date version can be found at [astrazeneca.ca](http://astrazeneca.ca).

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