Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr ENHERTU®
Trastuzumab deruxtecan for injection

This Patient Medication Information is written for the person who will be taking **ENHERTU**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **ENHERTU**, talk to a healthcare professional.

Serious warnings and precautions box

- 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 ENHERTU is used for:

Breast Cancer
ENHERTU is used to treat 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 a prior treatment that targeted HER2-positive breast cancer.

ENHERTU is used to treat adults who have:

- Hormone receptor (HR)-positive, HER2-low or 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 at least one endocrine treatment for metastatic disease and are not considered suitable for endocrine therapy as the next line of treatment. A test will be performed to make sure ENHERTU is the right treatment.
- 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** the disease has returned during or within 6 months of completing adjuvant chemotherapy (after surgery). If the breast cancer is also hormone receptor positive (HR+), patients should have received hormonal therapy. A test will be performed to make sure ENHERTU is the right treatment.

Stomach (Gastric) Cancer

ENHERTU is used to treat adults who have:

- a HER2-positive stomach cancer called gastric or gastroesophageal junction (GEJ) adenocarcinoma that has spread to areas near the stomach (inoperable locally advanced) or that has spread to other parts of the body (metastatic)
- and who have also received a prior trastuzumab-based treatment.

Unresectable or Metastatic Solid Tumours

ENHERTU is used to treat adults who have:

- HER2-positive (immunohistochemistry 3+) solid cancer that has spread to other parts of the body (metastatic) or cannot be taken out by surgery (unresectable) **and**
- who have received a prior systemic treatment and have no satisfactory alternative treatment options. A test will be performed to make sure ENHERTU is the right treatment.

For the following indication(s) ENHERTU has been approved **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 to treat adults who have a HER2-positive stomach cancer called gastric or gastroesophageal junction (GEJ) adenocarcinoma that has spread to areas near the stomach (inoperable locally advanced) or that has spread to other parts of the body (metastatic), and who have received a prior trastuzumab-based treatment.
- ENHERTU is used to treat adults who have HER2-positive solid cancer that has spread to other parts of the body (metastatic) or cannot be taken out by surgery (unresectable) and who have received a prior systemic treatment and have no satisfactory alternative treatment options.

For the following indication(s) ENHERTU has been approved **without conditions**. This means it has passed Health Canada's review and can be bought and sold in Canada.

- ENHERTU (trastuzumab deruxtecan) is used to treat 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 a prior treatment that targeted HER2-positive breast cancer.
- ENHERTU (trastuzumab deruxtecan) is used to treat 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).
- ENHERTU (trastuzumab deruxtecan) is used to treat adults who have HER2-low or 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 prior therapy. A test will be performed to make sure ENHERTU is the right treatment.

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 ENHERTU works:
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 human epidermal growth factor receptor 2 (HER2) proteins. Once ENHERTU enters the cell, the medicine becomes active and kills the cancer cells.

The ingredients in ENHERTU are:
Medicinal ingredient(s): trastuzumab deruxtecan
Non-medicinal ingredients: L histidine, L histidine hydrochloride monohydrate, polysorbate 80, sucrose.

ENHERTU comes in the following dosage form(s):
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 kidney 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). History of this lung disease or kidney problems may increase the risk of

developing ILD. Your doctor may have to monitor your lungs while you are taking this medicine.
- 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, feeling tired, 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).
- 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.

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.

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 in a healthcare setting.

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

- The recommended dose of ENHERTU for the treatment of HER2-positive breast cancer 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, 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.

Overdose:

If you think you, or a person you are caring for, have taken too much ENHERTU, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or 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.

Possible side effects from using ENHERTU:

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

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, feeling tired, swelling of your hands, ankles or legs, irregular heartbeat, sudden weight gain, dizziness, or loss of consciousness as these may be symptoms of a heart problem.

The frequency and severity of side effects may vary with the dose you received. You may experience the following side effects while you are being treated with ENHERTU:

Very common (may affect more than 1 in 10 people)
- Nausea
- Feeling tired (fatigue)
- Hair loss (alopecia)
- Vomiting
- Constipation
- Feeling less hungry (decreased appetite)
- Diarrhea
- Blood tests showing increased level of liver enzymes such as transaminases
- Pain in muscles and bone
- Decrease in the number of white blood cells (leukopenia)
- Decrease in the number of red blood cells (anemia)
- Decrease in the number of platelets (thrombocytopenia)
- Stomach (abdominal) pain
- Infections of the upper respiratory tract
- Headache
- Coughing
- Sores in or around your mouth (stomatitis)
- Weight loss
- Fever (pyrexia)
- Low potassium in the blood (hypokalemia)
- Indigestion (dyspepsia)
- Numbness and tingling in hands and feet

Common (may affect up to 1 in 10 people)
- Dizziness
- Rash
- Difficulty breathing (dyspnea)
- Bad taste in mouth (dysgeusia)
- Severe nosebleeds (epistaxis)
- Abnormal blood test (increase in blood alkaline phosphatase)
- Abnormal blood test (increase in blood bilirubin or blood creatinine)
- Dry eye
- Itching (pruritus)
- Darkening of the skin (skin hyperpigmentation)
- Blurry vision
- Excessive gas in the stomach or intestine, bloating (abdominal distension)
- Feeling thirsty, dry mouth (dehydration)
- Inflammation of the stomach (gastritis)
- Reactions related to the infusion of the medicine
- Infection of the lungs (pneumonia)
- Swollen hands, ankles, feet (edema)

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Very common			
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): 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)		✓	
Common			
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)		✓	
Uncommon			
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, tell 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 (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare 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.

Keep out of reach and sight of children.

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 the Patient Medication Information by visiting the Health Canada Drug Product Database website (Drug Product Database: Access the database); the manufacturer's website 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 www.astrazeneca.ca.

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