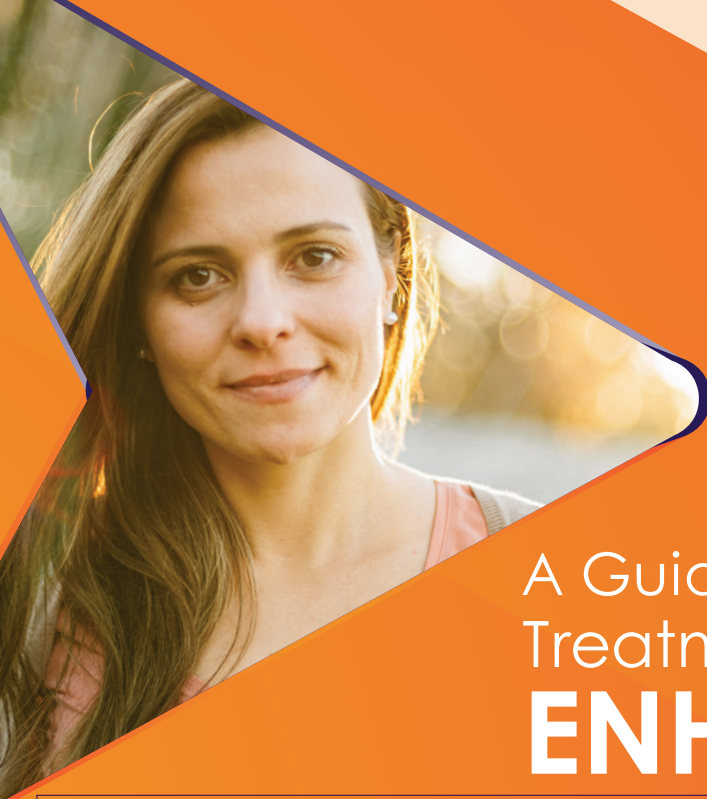




A Guide to Your Treatment with **ENHERTU**

For the following indication(s) ENHERTU has been approved without conditions. This means that 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 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.

This brochure may help you get to know your treatment.

Now that you have been prescribed ENHERTU, you might have some questions.

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.



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Get to know ENHERTU

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 a prior treatment that targeted HER2-positive breast cancer

ENHERTU is also used to treat adults who have:

- 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.

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

Important information about ENHERTU



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.
- 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 have taken 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.

Precautions when it comes to ENHERTU

Serious warnings and precautions with ENHERTU treatment



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.

Do not use ENHERTU if:

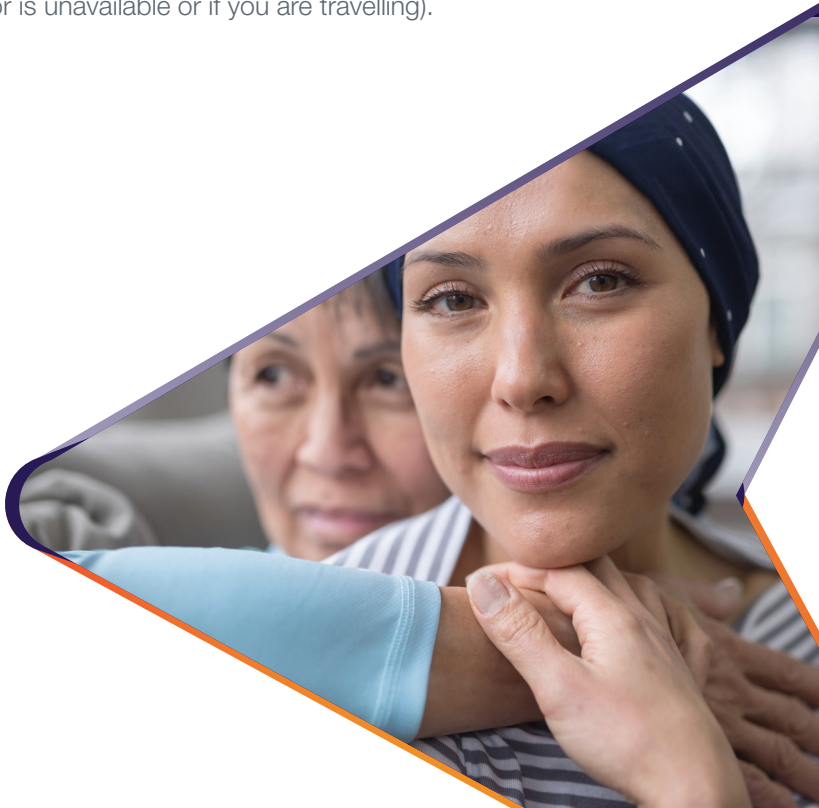
- You are allergic to trastuzumab deruxtecan or to any ingredients in ENHERTU. If you are not sure, talk to your healthcare professional before you are given ENHERTU.

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).

Please read the “ENHERTU® Patient Guide for Potential Lung Problems (Interstitial Lung Disease/Pneumonitis)” before you start receiving ENHERTU and before each infusion.

- This Patient Guide has been designed to help you identify symptoms of lung problems that you may experience while you are on treatment with ENHERTU. This Guide also contains a Patient Wallet Card that you should keep with you and show to any doctor you consult (for example, if your regular doctor is unavailable or if you are travelling).



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 booklet.

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.

When you first receive this medicine and anytime during treatment, tell your doctor or nurse 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.
- 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 hands, 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]).



- Reactions related to the infusion:
Chills or shaking, shortness of breath or wheezing, itching, rash or hives, flushing, dizziness, fever, feeling like passing out.

You may experience the following side effects:

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

- Nausea
- Feeling tired (fatigue)
- Vomiting
- Hair loss (alopecia)
- Constipation
- Feeling less hungry
- Diarrhea
- Blood tests showing increased level of liver enzymes such as transaminases
- Pain in muscles and bone
- Decrease in the number of platelets (thrombocytopenia)
- Infections of the upper respiratory tract
- Stomach (abdominal) pain
- Headache
- Sores in or around your mouth (stomatitis)
- Weight loss
- Coughing
- Low potassium in the blood (hypokalemia)
- Fever (pyrexia)
- Severe nosebleeds (epistaxis)
- Indigestion (dyspepsia)
- Difficulty breathing (dyspnea)
- Rash
- Dizziness
- Numbness and tingling in hands and feet

Common side effects (may affect up to 1 in 10 people)

- Abnormal blood test (increase in blood alkaline phosphatase)
- Abnormal blood test (increase in blood bilirubin or blood creatinine)
- Bad taste in mouth (dysgeusia)
- Dry eye
- Itching (pruritus)
- Darkening of the skin (skin hyperpigmentation)
- Excessive gas in the stomach or intestine, bloating
- Blurry vision
- 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)

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.

Potential serious side effects from using ENHERTU and what to do about them

Talk to your healthcare professional if you experience any of these symptoms or side effects.

Very common



Lung problems (interstitial lung disease/pneumonitis):

- Cough
- Shortness of breath
- Fever
- 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



**Potential symptoms of a heart problem
(decreased ejection fraction):**

- New onset or worsening shortness of breath
- Cough
- Fatigue
- Swelling of your ankles or legs
- Irregular heartbeat
- Sudden weight gain
- Dizziness
- Loss of consciousness

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, talk to your healthcare professional.

Other warnings you should know about



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.

Additional safety information

Product inquiries & reporting side effects

For further product/medical information or to report an adverse event, you may contact the AstraZeneca Medical Information Department at:

- Phone: 1-800-668-6000 (English); 1-800-461-3787 (French)
- E-mail: medinfo.canada@astrazeneca.com
- Online: report adverse events at <https://contactazmedical.astrazeneca.com>

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 (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>), 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 astrazeneca.ca.

Visit enhertu.ca for additional information and resources. Use the Drug Identification Number (DIN) for ENHERTU to sign in: 02514400.



Track your side effects

Use the tracker sheets in your ENHERTU Tracker to record any side effects that occur following your ENHERTU infusion.

To help avoid side effects and ensure proper use, talk to your doctor or nurse 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



any blood problems
(low blood count)

Contact your doctor if you notice any change to your overall health during your treatment with ENHERTU.

YOUR DAILY SIDE EFFECT TRACKER

This tracker is designed for you to record your side effects over a three-week period. It can be used alongside My ENHERTU Tracker to facilitate treatment conversations with healthcare professionals (i.e., oncologist, nurse, pharmacist).

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For the following indication(s), ENHERTU has been approved with conditions (NOC(s)). 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 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 (TDM1).

Keep track of your side effects here. Add details to help you remember how you were feeling throughout your treatment.
This is not a complete list of potential side effects. Please refer to "A Guide to your Treatment with ENHERTU" for information that includes serious side effects and what to do about them.
These include lung, heart, and immune problems, as well as problems in other organs and infusion-related reactions.

Name:		Treatment:				Infusion date:				Your weight:			
Examples											Notes (including other potential side effects)		
DAY 0 (BEFORE starting treatment)	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot		
WEEK 1	DAY 1 (treatment)	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot		
	DAY 2	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot		
	DAY 3	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot		
	DAY 4	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot		
	DAY 5	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot		
	DAY 6	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot		
	DAY 7	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot		
		None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot	None A lot		

Helpful links

To access these resources, please visit the links or scan the QR codes below.



Canadian Breast Cancer Network

<https://www.cbcn.ca/en/>



Rethink Breast Cancer

<https://rethinkbreastcancer.com/>



Canadian Cancer Society

<https://www.cancer.ca/en/cancer-information/cancer-type/breast/breast-cancer/>



Quebec Breast Cancer Foundation

<https://rubanrose.org/en/>



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trastuzumab deruxtecan

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