PATIENT INFORMATION LEAFLET

SHEDULING STATUS: S4

ENHERTU 100 mg powder for concentrate for solution for infusion

trastuzumab deruxtecan

Contains Sugar (Sucrose 450 mg/5 ml)

Serious Warnings and Precautions

- Lung problems that may be severe, life-threatening or that may lead to death. If you develop lung problems your healthcare provider may treat you with corticosteroid medicines. Tell your healthcare provider right away if you get any of the following signs and symptoms:
  - cough
  - trouble breathing or shortness of breath
  - fever
  - other new or worsening breathing symptoms (such as chest tightness, wheezing)
- 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 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 4 months after the last dose.

Read all of this leaflet carefully before you start taking ENHERTU

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ENHERTU has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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What is in this leaflet

1. What ENHERTU is and what it is used for

2. What you need to know before you take ENHERTU

3. How to take ENHERTU

4. Possible side effects

5. How to store ENHERTU

6. Contents of the pack and other information

1. What ENHERTU is and what it is used for

What ENHERTU is

ENHERTU is a cancer medicine that contains the active substance trastuzumab deruxtecan. One part of the medicine is a monoclonal antibody that attaches specifically to cells that have the protein HER2 on their surface (HER2-positive), as some cancer cells do. The other active part of ENHERTU is DXd, a substance that can kill cancer cells. Once the medicine has attached to HER2-positive cancer cells, the DXd enters the cells and kills them.

What ENHERTU is used for

ENHERTU is used to treat adults who have:

- HER2-positive breast cancer that has spread to other parts of the body (metastatic disease) or cannot be removed by surgery and have tried one or more other treatments specifically for HER2- positive breast cancer.
- HER2-low or HER2-ultralow breast cancer that has spread to other parts of the body (metastatic disease) or cannot be removed by surgery and have received prior therapy. A test will be performed to make sure ENHERTU is right for you.
- HER2-mutant non-small cell lung cancer that has spread to other parts of the body or cannot be removed by surgery and have tried a prior treatment. A test will be performed to make sure ENHERTU is right for you.

- HER2-positive stomach cancer that has spread to other parts of the body or to areas near the stomach that cannot be removed by surgery and ~~who~~ have also tried another treatment specifically for HER2-positive stomach cancer.

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2. What you need to know before you take ENHERTU

You must not be given ENHERTU

- if you are allergic to trastuzumab deruxtecan or any of the other ingredients of this medicine (listed in section 6).

If you are not sure if you are allergic, talk to your doctor or nurse before you are given ENHERTU.

Warnings and precautions

Talk to your doctor or nurse before you are given ENHERTU, or during treatment, 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 called interstitial lung disease. A history of lung disease or kidney problems may increase the risk of developing interstitial lung disease. 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 a reduced number of white blood cells called neutrophils.
- new or worsening shortness of breath, cough, tiredness, swelling of ankles or legs, irregular heartbeat, sudden weight gain, dizziness, or loss of consciousness. These may be symptoms of a condition in which your heart cannot pump blood well enough (decreased left ventricular ejection fraction).
- liver problems. Your doctor may have to monitor your liver while you are taking this medicine.

Your doctor will carry out tests before and during treatment with ENHERTU.

Children and adolescents

ENHERTU is not recommended for anyone under the age of 18 years. This is because there is no information on how well it works in this age group.

Other medicines and ENHERTU

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

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Pregnancy, breastfeeding and fertility

Pregnancy

ENHERTU is not recommended during pregnancy because this medicine may harm the unborn baby.

Speak with your doctor immediately if you are pregnant, think you may be pregnant or are planning to become pregnant before or during treatment.

Breastfeeding

You should not breast-feed during treatment with ENHERTU and for at least 7 months after your last dose. This is because it is not known whether ENHERTU passes into breast milk. Talk to your doctor about this.

Contraception

Use effective contraception (birth control) to avoid becoming pregnant while being treated with ENHERTU.

Women taking ENHERTU should continue contraception for at least 7 months after the last dose of ENHERTU.

Men taking ENHERTU whose partner 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. Also talk to your doctor before you stop your contraception.

Fertility

If you are a man being treated with ENHERTU, you should not father a child for 4 months after treatment and take advice on conserving sperm before treatment because the medicine may reduce your fertility. Therefore, discuss this with your doctor before starting treatment.

Driving and using machines

ENHERTU is not likely to reduce your ability to drive or use machines. Be careful if you feel tired, dizzy, or have a headache.

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ENHERTU contains polysorbate 80

This medicine contains 1.5 mg of polysorbate 80 in each 100 mg vial.

Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

3. How you are given ENHERTU

Do not share medicines prescribed for you with any other person.

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

- The recommended dose of ENHERTU for the treatment of:
  - HER2-positive. HER2-low or HER2-ultralow breast cancer is 5.4 mg for every kilogram of your weight, every 3 weeks.
  - HER2-mutant non-small cell lung cancer is 5.4 mg for every kilogram of your weight, every 3 weeks.
  - HER2-positive stomach cancer is 6.4 mg for every kilogram of your weight, every 3 weeks.
- Your doctor or nurse will give you ENHERTU by infusion (drip) into your vein.
- Your first infusion will be given over 90 minutes. If this goes well, 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 get infusion-related symptoms, your doctor or nurse may slow down your infusion or interrupt or stop your treatment.
- Before and during treatment with ENHERTU, your doctor will carry out tests that may include:
  - blood tests to check your blood cells, liver and kidneys.
  - testing to check your heart and lungs.
- Your doctor may lower your dose, or temporarily or permanently stop your treatment depending on your side effects.

If you forget or miss an appointment to get ENHERTU

Contact your doctor right away to reschedule your appointment.

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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 without checking with your doctor.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

ENHERTU can have side effects.

Not all side effects reported for ENHERTU are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ENHERTU, please consult your health care provider for advice.

If the following happens tell your doctor immediately:

- A lung disease called interstitial lung disease with symptoms that can include cough, shortness of breath, fever, or other new or worsening breathing problems
- An infection caused by reduced number of neutrophils (a type of white blood cell) with symptoms that can include chills, fever, sores in your mouth, stomach pain or pain when urinating
- A heart problem called left ventricular dysfunction with symptoms that can include new or worsening shortness of breath, cough, tiredness, swelling of ankles or legs, irregular heartbeat, sudden weight gain, dizziness or unconsciousness

Frequent side effects:

- nausea (feeling sick), vomiting
- tiredness
- decreased appetite
- blood tests showing decreased red or white blood cells, or platelets
- hair loss
- diarrhoea
- constipation

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- blood tests showing increased levels of the liver enzymes such as transaminases
- pain in muscles and bones
- abdominal (belly) pain
- fever
- weight loss
- infection of the lungs
- infections of the nose and throat, including flu-like symptoms
- headache
- blisters in or around your mouth
- cough
- blood tests showing low blood potassium levels
- swelling of ankles and feet
- indigestion
- breathing difficulties
- altered/bad taste in mouth

Less frequent side effects:

- nosebleed
- dizziness
- rash
- blood tests showing increased levels of bilirubin, alkaline phosphatase or creatinine
- blood tests showing decreased red blood cells, white blood cells, and platelets (pancytopenia)
- itching
- dry eye
- skin discolouration
- blurred vision
- feeling thirsty, dry mouth
- bloating
- fever along with a decreased number of white blood cells called neutrophils

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- inflammation of the stomach
- excessive gas in the stomach or intestine
- reactions related to the infusion of the medicine which may include fever, chills, flushing, itching or rash

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website or report to the applicant at https://contactazmedical.astrazeneca.com/. By reporting side effects, you can help provide more information on the safety of ENHERTU.

5. How to store ENHERTU

Store all medicines out of reach of children.

ENHERTU will be stored by healthcare professionals at the hospital or clinic where you receive treatment. The storage details are as follows:

- Do not use this medicine after the expiry date which is stated on the outer carton and vial after EXP. The expiry date refers to the last day of that month.
- Store in a refrigerator (2 °C - 8 °C). Do not freeze.
- The prepared solution for infusion is stable for up to 24 hours at 2 °C - 8 °C protected from light and must be discarded thereafter.

6. Contents of the pack and other information

What ENHERTU contains

The active substance is trastuzumab deruxtecan.

One vial of powder for concentrate for solution for infusion contains 100 mg of trastuzumab deruxtecan. After reconstitution, one vial of 5 mL solution contains 20 mg/mL of trastuzumab deruxtecan.

The other ingredients are:

- L-histidine
- L-histidine hydrochloride monohydrate,

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- sucrose
- polysorbate 80.

What ENHERTU looks like and contents of the pack

ENHERTU 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.

Holder of certificate of registration

AstraZeneca Pharmaceuticals (Pty) Limited

Building 2, Northdowns Office Park

17 Georgian Crescent West, Bryanston

Johannesburg, 2191

☎ (011) 797 6000

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