

Consumer Medicine Information

This medicine has **provisional registration** in Australia for the treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens. The decision to provisionally register this medicine has been made on the basis of promising results from preliminary studies. More evidence is required to be submitted when available to substantiate the benefit of the medicine for this use.

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 HER2 proteins (known as HER2-positive). Once ENHERTU enters the cell, the medicine becomes active and kills the cancer cells.

ENHERTU is used in adults who have:

- HER2-positive breast cancer that has spread to other parts of the body or cannot be taken out by surgery **and**
- have also received two or more prior treatments that targeted HER2-positive breast cancer.

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 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.
- 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.

Children and adolescents

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