▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

ENHERTU® ▼
trastuzumab deruxtecan

Health Care Professional Guide for Prevention of Product Confusion Medication Errors

This HCP guide is a condition of the Marketing Authorisation for ENHERTU®. It serves to minimise the important potential risk of medication error in addition to the SmPC. HCPs should read it before prescribing and administering ENHERTU® (trastuzumab deruxtecan).

Version 1 | November 2022

Daiichi-Sankyo | AstraZeneca

WARNING

Risk of confusion between ENHERTU® (trastuzumab deruxtecan) and other trastuzumab-containing products including Kadcyla® (trastuzumab emtansine).

There are important differences between these products and confusion during the prescription, preparation and administration processes can lead to overdose, undertreating and/or toxicity.

Healthcare professionals should use both the invented name ENHERTU® and the full INN, trastuzumab deruxtecan, when prescribing, preparing the infusion and administering ENHERTU® to patients.

ENHERTU®

ENHERTU® (trastuzumab deruxtecan) is an antibody-drug conjugate (ADC) that contains a humanised anti-HER2 IgG1 monoclonal antibody (mAb) with the same amino acid sequence as trastuzumab, covalently linked to DXd, an exatecan derivative and a topoisomerase I inhibitor (for information on approved indications, see approved SmPC at **www.ema.europa.eu**).

Important Information

1	ENHERTU® (trastuzumab deruxtecan) is **NOT** a generic version or biosimilar of trastuzumab (e.g. Herceptin®)
2	ENHERTU® (trastuzumab deruxtecan) and Kadcyla® (trastuzumab emtansine) are **2 different products**, both antibody-drug conjugates (ADC) but with different properties, dosing regimens and not identical indications.
3	ENHERTU® (trastuzumab deruxtecan) is **NOT interchangeable** with trastuzumab-containing products such as Herceptin® (trastuzumab) or Kadcyla® (trastuzumab emtansine)
4	**Do NOT** administer ENHERTU® (trastuzumab deruxtecan) **in combination** with other trastuzumab-containing products such as Herceptin® (trastuzumab) or Kadcyla® (trastuzumab emtansine) **or with a chemotherapy**
5	**Do NOT** administer ENHERTU® (trastuzumab deruxtecan) at doses greater than indicated in approved SmPC once every 3 weeks
6	Both the invented name ENHERTU®, and its full INN trastuzumab deruxtecan should be used and confirmed when prescribing, preparing the infusion solution and administering ENHERTU® to patients.

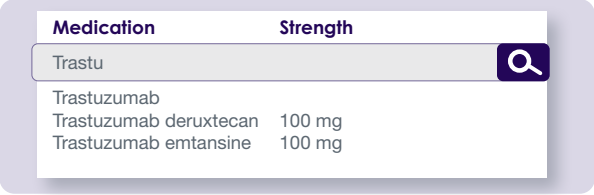
Avoiding errors: Physicians/prescription phase

Written prescriptions: Potential areas of confusion

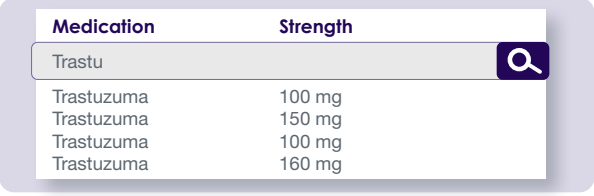
Both **ENHERTU** and **trastuzumab deruxtecan** should always be used when prescribing.

For example: ENHERTU (trastuzumab deruxtecan)

Electronic systems: Potential areas of confusion



Alphabetical name sorting
trastuzumab, **trastuzumab deruxtecan** and trastuzumab emtansine and may be positioned one after the other



Name truncation
If the system only displays part of the medication name in its drop-down menu or text window (e.g. trastuzumab, trastuzumab deruxtecan or trastuzumab emtansine)

Limited text field
If the system only displays part of the medication name in its drop-down menu or text window (e.g. trastuzumab, trastuzumab deruxtecan and trastuzumab emtansine)

Mitigation measures

Prescribers must familiarise themselves with the ENHERTU® Summary of Product Characteristics (SmPC) which is available at **www.ema.europa.eu**	✓
Refer to **ENHERTU®** and **trastuzumab deruxtecan** when discussing the drug with the patient	✓
Electronic systems • Check correct medication before clicking • Always select the correct medication in the electronic medical record • Ensure the medication prescribed is **ENHERTU® (trastuzumab deruxtecan)** and not trastuzumab or trastuzumab emtansine • Request use of brand names, where possible	✓
Written prescriptions • Ensure that both **ENHERTU®** and **trastuzumab deruxtecan** are written on the prescription and in the patient notes • Do not abbreviate, truncate or omit any name • Ensure the correct medication is clearly recorded in the patient history	✓

Avoiding errors: Pharmacists/ordering & preparation phase

Potential mitigation measures	
✓	Pharmacists must familiarise themselves with the ENHERTU® Summary of Product Characteristics (SmPC)
✓	Check that protocols to avoid medication errors are in place at the hospital/site and that they are followed
✓	Be aware when reading prescriptions that there are multiple types of medication with a similar INN (e.g. **trastuzumab, trastuzumab SC, trastuzumab emtansine and trastuzumab deruxtecan**)
✓	Double check the intended medication is ENHERTU® (trastuzumab deruxtecan) and that both are entered in the prescription and/or medical history
✓	In case of any doubt, consult with the treating physician
✓	Familiarise yourself with the different cartons, labels and cap colours available for all trastuzumab containing products to select the correct carton
✓	Ensure the correct medication is ordered from the wholesaler and that the correct medication is received in the pharmacy
✓	Store ENHERTU® in a different place in the fridge to other trastuzumab containing products (e.g. Herceptin® or Kadcyla®)
✓	Ensure ENHERTU® is diluted in an infusion bag using 5% glucose solution. **Do not use sodium chloride solution.**

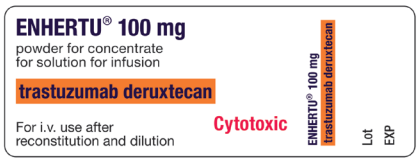
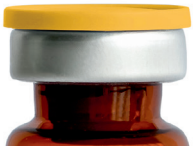
Avoiding errors: Nurses/administration phase

Potential mitigation measures	
✓	Nurses must familiarise themselves with the ENHERTU® Summary of Product Characteristics (SmPC)
✓	Ensure that protocols to avoid medication errors are in place at the hospital/site and that they are followed
✓	Check both the prescription and patient notes to ensure that ENHERTU® and **trastuzumab deruxtecan** have been recorded as the prescribed medication
✓	On receipt of the infusion bag, check the label on the infusion bag against the prescription and patient notes
✓	Consider using a two nurse double-checking system prior to infusion to ensure that the appropriate product and dosage is administered
✓	Refer to both **ENHERTU®** and **trastuzumab deruxtecan** when discussing the drug with the patient
✓	The maximum dose of ENHERTU® is 5.4 mg/kg once every 3 weeks
✓	Familiarise yourself with the ENHERTU® dose modification for toxicities
✓	Ensure ENHERTU® is diluted in an infusion bag using 5% glucose solution. **Do not use sodium chloride solution.**

Healthcare professionals should check vial labels, including colour of labels, to ensure that the medicinal product being prepared and administered is ENHERTU® (trastuzumab deruxtecan) and not a trastuzumab-containing products such as Herceptin® (trastuzumab) or Kadcyla® (trastuzumab emtansine).

An overview of the unique features can be found on page 6.

Overview of ENHERTU®

Trademark	ENHERTU® trastuzumab deruxtecan	
Indication	**unresectable or metastatic HER2-positive BC**	
International Nonproprietary Name (INN)	**trastuzumab deruxtecan**	
Content of vial	**100 mg**	
	Distinctive colour	
Carton image & colours	**ORANGE** **DARK PURPLE**	
Label colour	**ORANGE** **DARK PURPLE**	
Vial colour	**AMBER**	
Cap colour	**YELLOW**	

Check list – Avoiding medication errors

Avoiding medication errors due to possible confusion of ENHERTU® (trastuzumab deruxtecan) with other trastuzumab containing products

Prescription Phase

Mitigation measures	✓
Familiarise yourself with the ENHERTU® Summary of Product Characteristics (SmPC).	
Ensure the medication prescribed is ENHERTU® (trastuzumab deruxtecan) and not trastuzumab or trastuzumab emtansine.	
Refer to ENHERTU® and trastuzumab deruxtecan when discussing the drug with the patient.	
Ensure that both ENHERTU® and trastuzumab deruxtecan are written on the prescription and in the patient notes. Do not abbreviate, truncate or omit any name.	
Ensure the correct medication is clearly recorded in the patient history.	
Check the correct medication is identified in electronic systems before selecting.	

Ordering and Preparation

Mitigation measures	✓
Check that protocols to avoid medication errors are in place at the hospital/site and that they are followed.	
Ensure the correct medication is ordered from the wholesaler and that the correct medication is received in the pharmacy.	
Store ENHERTU® in a different place in the fridge to other trastuzumab containing products (e.g. Herceptin® or Kadcyla®).	
Familiarise yourself with the ENHERTU® Summary of Product Characteristics (SmPC).	
Be aware that there are multiple types of medication with a similar INN (e.g. trastuzumab, trastuzumab SC, trastuzumab emtansine and trastuzumab deruxtecan).	
Check the intended medication is ENHERTU® (trastuzumab deruxtecan).	
Familiarise yourself with the different cartons, labels and cap colours available for all trastuzumab containing products.	
Check vial labels, including colour of labels, to ensure that the medicinal product being prepared is ENHERTU® (trastuzumab deruxtecan) and not a trastuzumab-containing products such as Herceptin® (trastuzumab) or Kadcyla® (trastuzumab emtansine).	
Ensure ENHERTU is diluted in an infusion bag using 5% glucose solution. Do not use sodium chloride solution.	
In case of any doubt, consult with the treating physician.	

Administration

Mitigation measures	✓
Ensure that protocols to avoid medication errors are in place at the hospital/site and that they are followed.	
Familiarise yourself with the ENHERTU® Summary of Product Characteristics (SmPC).	
Refer to both ENHERTU® and trastuzumab deruxtecan when discussing the drug with the patient.	
Check both the prescription and patient notes to ensure that ENHERTU® and trastuzumab deruxtecan have been recorded.	
Consider using a two nurse double-checking system prior to infusion.	
On receipt of the infusion bag, check the label on the infusion bag against the prescription and patient notes.	
Ensure ENHERTU® is diluted in an infusion bag using 5% glucose solution. Do not use sodium chloride solution.	

Reporting suspected adverse drug reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions using the Medicines Authority ADR reporting form: https://medicinesauthority.gov.mt/adrportal or report directly to Daiichi Sankyo by email to DLEU-CSPV@daiichi-sankyo.eu.

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Daiichi-Sankyo | AstraZeneca