▼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 X | XX.2021

Daiichi-Sankyo | AstraZeneca

Reporting suspected adverse drug reactions

Please report suspected adverse drug reactions to [MAH ADDRESS]

Job code: XXXXX | Date of preparation: XX.2021

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.

Indication

ENHERTU® as monotherapy is indicated 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.

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 5.4 mg/kg 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.

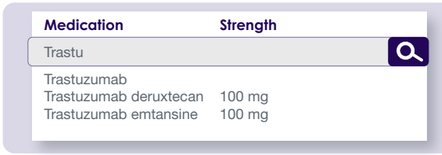
Avoiding errors: Physicians/prescription phase

Written prescriptions: Potential areas of confusion

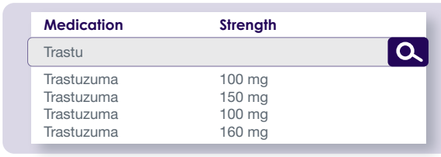
Both **ENHERTU** and **trastuzumab deruxtecan** should always be used when prescribing.

For example: ENHERTU (trastuzumab deruxtecan)

Electronic systems: Potential areas of confusion



Alphabetical name sorting
trastuzumab, trastuzumab emtansine and **trastuzumab deruxtecan** 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.XXXXXX.XX**	✓
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	✓

Version 4 // 07.12.2020

Avoiding errors: Pharmacists/ordering & preparation phase

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® or Kadcyla® (trastuzumab emtansine).

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.**

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	**ROSE**	

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.**

Check list – Avoiding errors

Check Point	PHYSICIANS prescription phase	PHARMACISTS ordering & preparation phase	NURSES administration phase
Familiarise themselves with the ENHERTU® Summary of Product Characteristics (SmPC) which is available at www.XXXXXX.XX	✓	✓	✓
Always refer to both ENHERTU® and trastuzumab deruxtecan	✓	✓	✓
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	✓		
Do not abbreviate, truncate or omit any name on the prescription	✓		
Ensure the correct medication is clearly recorded in the prescription and patient notes	✓		✓
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		✓	✓
Check vials have the LABLES SPECIFIC TO ENHERTU®		✓	✓
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®)		✓	
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			✓
Remember the maximum dose of ENHERTU® is 5.4 mg/kg once every 3 weeks	✓	✓	✓
Remember ENHERTU® is diluted with 5% glucose solution		✓	✓
Familiarise yourself with the ENHERTU® dose modification for toxicities	✓		✓