Kadcyla®
(trastuzumab emtansine)

EU Healthcare Professional Information

Prevention of medication error

For comprehensive product information please see the current Kadcyla Summary of Product Characteristics (SmPC) available on www.ema.europa.eu or www.medicines.ie.

This educational material is provided by Roche Products (Ireland) Limited and is mandatory as a condition of the Marketing Authorisation in order to further minimise important selected risks.

MT v6.0.1
Date of Malta Medicines Authority Approval: May 2019

Reporting of suspected adverse events or reactions

Reporting suspected adverse events or 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 events or reactions (see details below).

As this product is a biological medicine, healthcare professionals should report adverse events or reactions by brand name and batch number.

In the event of a suspected adverse event, please report it to:
The Drug Surveillance Centre, Roche Products (Ireland) Limited,
3004 Lake Drive, Citywest, Naas Road, Dublin 24, Ireland.
Telephone: 00 353 (0)1 4690700
Fax: 00 353 (0)1 4690793
Email: ireland.drug_surveillance_centre@roche.com

Alternatively, suspected adverse reactions should be reported to:
Pharmacovigilance Section at Post-Licensing Directorate,
Medicines Authority, Sir Temi Żammit Buildings,
Malta Life Sciences Park, San Ġwann SĠN 3000, Malta.
Reporting forms and information can be found at
www.medicinesauthority.gov.mt/adrportal

WARNING:

Kadcyla® (trastuzumab emtansine) and Herceptin® (trastuzumab) have similar generic names, but important differences, including dosing and indication.

Risk of confusion between Kadcyla® and Herceptin® during the prescription, preparation and administration processes.

Confusion can lead to overdose, undertreating and/or toxicity.

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

Kadcyla

Kadcyla® is an antibody–drug conjugate containing humanised anti-HER2 IgG1 antibody trastuzumab linked to DM1, a microtubule-inhibitory maytansinoid. **Emtansine refers to the combination of the linker and DM1.**

Indication

Kadcyla®, as a single agent, is indicated for the treatment of adult patients with HER2-positive, unresectable, locally advanced or metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination.

Patients should have either:

- Received prior therapy for locally advanced or metastatic disease, or
- Developed disease recurrence during or within 6 months of completing adjuvant therapy.

Kadcyla® and Herceptin® IV / Herceptin® SC: Take care

1. Kadcyla® is an antibody-drug conjugate (ADC) containing humanised anti-HER2 IgG1 antibody trastuzumab and DM1, a microtubule-inhibitory maytansinoid; it is NOT trastuzumab.
2. Kadcyla® is NOT a generic version of Herceptin® and has different properties, indications and dose.
3. Do not substitute or combine Kadcyla® with or for Herceptin®.
4. Never administer Kadcyla® in combination with chemotherapy.
5. The maximum dose of Kadcyla® is 3.6 mg/kg once every 3 weeks.
6. If a prescription for Kadcyla® is written electronically, it is important to ensure that the medication prescribed is trastuzumab emtansine and not trastuzumab.
7. Both the invented name Kadcyla®, and its full INN name (trastuzumab emtansine) should be used and confirmed when prescribing, preparing the infusion solution and administering Kadcyla® to patients.
8. In order to prevent medication errors it is important to review the Summary of Product Characteristics and to check the outer carton and vial labels to ensure that the medicinal product being prepared and administered is Kadcyla® and not Herceptin®.

Kadcyla® and Herceptin® IV / Herceptin® SC:

IMPORTANT INFORMATION:

- Kadcyla® and Herceptin® are two **different** products with **different** active substances.
- Kadcyla® and Herceptin® are not interchangeable.
- Kadcyla® (**trastuzumab emtansine**) is **not** a generic version or biosimilar of Herceptin® (trastuzumab).
- Do not administer Kadcyla® in combination with trastuzumab or with a chemotherapy.
- The maximum dose of Kadcyla® is 3.6 mg/kg once every 3 weeks.

Kadcyla® (trastuzumab emtansine) and **Herceptin®** (trastuzumab) have similar generic names, but important differences, including dosing and indication.

DO NOT ADMINISTER Kadcyla® (**trastuzumab emtansine**) in combination with or in place of Herceptin® (**trastuzumab**).

ALWAYS CONFIRM THE VIAL LABEL
TAKE CARE when dealing with prescriptions containing **trastuzumab**

Overview of Herceptin®, Herceptin® SC & Kadcyla®: Differences and similarities[1-3]

Trademark	Herceptin® trastuzumab	Herceptin® SC trastuzumab subcutaneous	Kadcyla® trastuzumab emtansine
Indication	HER2-positive BC HER2-positive MGC	HER2-positive BC	**HER2-positive MBC**
INN	trastuzumab	trastuzumab	**trastuzumab emtansine**
Dose (q3w)	8 mg/kg LD - 6 mg/kg	Fixed dose of 600 mg	**3.6 mg/kg**
Form	Powder	Solution	**Powder**
Vial content	150 mg	600 mg	**100 mg and 160 mg**
Vial size	15 ml	5 ml	**15 ml and 20 ml**

BC, breast cancer; LD, loading dose; MBC, metastatic breast cancer; MGC, metastatic gastric or gastro-oesophageal junction adenocarcinoma.

References

1. Kadcyla® Summary of Product Characteristics
2. Herceptin® Solution for Injection in Vial Summary of Product Characteristics
3. Herceptin® Powder for Concentrate for Solution for Infusion Summary of Product Characteristics

Kadcyla® and Herceptin® IV / Herceptin® SC: Potential for prescription errors

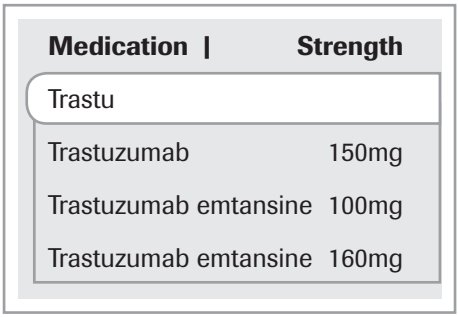
Written prescriptions: Potential areas of confusion

Both Kadcyla® and **trastuzumab emtansine** should always be used when prescribing.

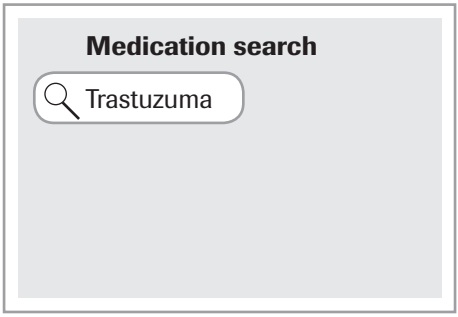
For example:

Kadcyla (trastuzumab emtansine)

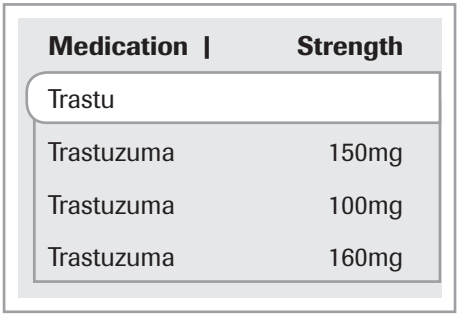
Electronic systems: Potential areas of confusion when prescribing



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



Limited text field
If the system only displays part of the medication name in its drop-down menu or text window (e.g. “trastuzumab” for Herceptin® and Kadcyla®).



Name truncation
If the system only displays part of the medication name in its drop-down menu or text window (e.g. “trastuzumab” for Herceptin® and Kadcyla®).

Risk: Similar INN

Avoiding errors: Physician/prescription phase

Potential mitigation measures

- Prescribers must familiarise themselves with the Kadcyla® SmPC.
- Refer to Kadcyla® and **trastuzumab emtansine** 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 Kadcyla®, **trastuzumab emtansine**, and not trastuzumab.
  - Request use of brand names, where possible.
- Written prescriptions
  - Ensure that both Kadcyla® and **trastuzumab emtansine** are written on the prescription and in the patient notes.

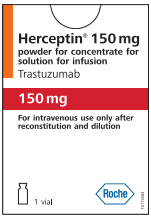
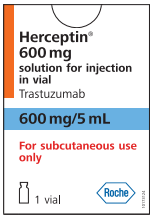
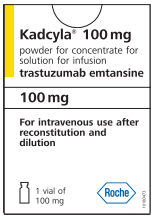
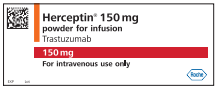
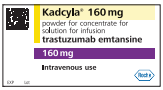
    For example:

Kadcyla (trastuzumab emtansine)

  - Do not abbreviate, truncate or omit any name.
- Ensure the correct medication is clearly recorded in the patient history.

ALWAYS CONFIRM THE VIAL LABEL
TAKE CARE when dealing with prescriptions containing **trastuzumab**

Avoiding errors: Pharmacists/preparation phase[1-3]

Trademark	Herceptin® trastuzumab	Herceptin® SC trastuzumab subcutaneous	Kadcyla® trastuzumab emtansine	
Content	150 mg	600 mg	**100 mg**	**160 mg**
Carton image & colours				
Label colours				
Cap colour				
Distinctive colours	**Dark orange / red**	**Dark orange / light blue**	**Yellow / white**	**Yellow / purple**

References

1. Kadcyla® Summary of Product Characteristics
2. Herceptin® Solution for Injection in Vial Summary of Product Characteristics
3. Herceptin® Powder for Concentrate for Solution for Infusion Summary of Product Characteristics

Risk: Commercial Appearance

Healthcare professionals should check vial labels, including colour of labels, to ensure that the medicinal product being prepared and administered is Kadcyla® (trastuzumab emtansine) and not Herceptin® (trastuzumab). Always make sure that when trastuzumab emtansine is written it is on the same line/together.

Avoiding errors: Pharmacists/preparation phase

Potential mitigation measures

- Pharmacists must familiarise themselves with the Kadcyla® 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 three types of medication with a similar INN (**trastuzumab**, **trastuzumab** SC and **trastuzumab emtansine**).
- Double check the intended medication is Kadcyla®, **trastuzumab emtansine**, 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 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 Kadcyla® in a different place in the fridge to Herceptin® IV and Herceptin® SC.

Risk: Similar Infusion bags

Healthcare professionals should check vial labels, including colour of labels, to ensure that the medicinal product being prepared and administered is Kadcyla® (trastuzumab emtansine) and not Herceptin® (trastuzumab). Always make sure that when trastuzumab emtansine is written it is on the same line/together.

Avoiding errors: Nurses/administration phase

Potential mitigation measures

- Nurses must familiarise themselves with the Kadcyla® 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 Kadcyla® and **trastuzumab emtansine** 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 Kadcyla® and **trastuzumab emtansine** when discussing the drug with the patient.
- The maximum dose of Kadcyla® is 3.6 mg/kg once every 3 weeks.
- Familiarise yourself with the Kadcyla® dose modification for toxicities.

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

	AVOIDING MEDICATION ERRORS		
CHECK POINTS	**PHYSICIANS**/ prescription phase	**PHARMACISTS**/ ordering & preparation phase	**NURSES**/ administration phase
Familiarise yourself with the full Kadcyla® SmPC	✓	✓	✓
Ensure that both the brand name and INN are written in full	✓	✓	✓
Select correct medication electronically	✓		
Always use brand names + INN	✓	✓	✓
Consider using Kadcyla®-specific stickers	✓	✓	✓
Use Kadcyla®-specific storage bins/labels		✓	✓
Use Kadcyla®-specific IV bag labels		✓	✓

	AVOIDING MEDICATION ERRORS		
CHECK POINTS	**PHYSICIANS**/ prescription phase	**PHARMACISTS**/ ordering & preparation phase	**NURSES**/ administration phase
Check vials have the yellow coloured labels specific to Kadcyla®		✓	✓
Check labels read "trastuzumab emtansine" and are yellow in colour		✓	✓
Record administered drug in patient file		✓	✓
Record prescription in patient file	✓		

Ensure familiarisation with SmPC, packaging, labelling and identification strategy.

Further Information

For additional copies of this risk minimisation material, refer to the Malta Medicines Authority website [http://www.medicinesauthority.gov.mt/rmm] and download the required material or alternatively if you would like hard copies, please contact Roche Products (Ireland) Limited, 3004 Lake Drive, Citywest, Naas Road, Dublin 24 by mail, telephone [00 353 (0)1 4690700], fax [00 353 (0)1 4690791] or email [ireland.drug_surveillance_centre@roche.com].

For further information about Kadcyla, please contact Medical Information at Roche Products (Ireland) Limited by telephone [00 353 (0)1 4690700], fax [00 353 (0)1 4690791] or email [Ireland.druginfo@roche.com].

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