FOR USE IN MALTA

Kadcyla® (trastuzumab emtansine) HCP Educational Information

This is additional risk minimisation material provided by Roche Products (Ireland) Limited as a licence requirement for this medicine and forms part of the Kadcyla Risk Management Plan.

WARNING:

Risk of confusion between Kadcyla® (trastuzumab emtansine) and other trastuzumab-containing products such as Herceptin® (trastuzumab) or Enhertu® (trastuzumab deruxtecan)

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 trademark name Kadcyla, and the full INN trastuzumab emtansine when prescribing, preparing and administering Kadcyla to patients

This material should be read in conjunction with the Summary of Product Characteristics (SmPC) which is available on www.ema.europa.eu or www.medicines.ie before prescribing this medicine.

MT version 14.0.1
Date of Malta Medicines Authority Approval: December 2021

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Kadcyla

Kadcyla® (trastuzumab emtansine) 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

Early Breast Cancer (EBC)

Kadcyla, as a single agent, is indicated for the adjuvant treatment of adult patients with **HER2-positive early breast cancer** who have residual invasive disease, in the breast and/or lymph nodes, after neoadjuvant taxane-based HER2-targeted therapy.

Metastatic Breast Cancer (MBC)

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.

Important information

- Kadcyla (trastuzumab emtansine) is **a different product** than other trastuzumab-containing products such as Herceptin (trastuzumab) or Enhertu (trastuzumab deruxtecan)
- Kadcyla (trastuzumab emtansine) is **NOT a generic version or biosimilar** of Herceptin (trastuzumab)
- Kadcyla (trastuzumab emtansine) is **NOT interchangeable** with other trastuzumab containing products such as Herceptin (trastuzumab) or Enhertu (trastuzumab deruxtecan)
- **Do NOT** administer Kadcyla (trastuzumab emtansine) **in combination** with other trastuzumab-containing products such as Herceptin (trastuzumab) or Enhertu (trastuzumab deruxtecan) **or with a chemotherapy**
- **Do NOT** administer Kadcyla (trastuzumab emtansine) at **doses greater than 3.6 mg/kg** once every three weeks
- Both the trademark name Kadcyla, and the full INN trastuzumab emtansine should be used and confirmed when prescribing, preparing and administering Kadcyla to patients

Differences and similarities between Roche products Herceptin, Herceptin SC & Kadcyla

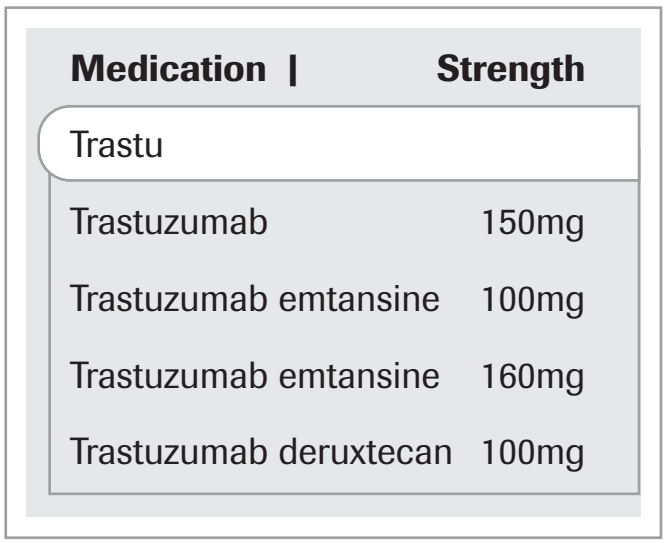
Trademark	Herceptin® trastuzumab	Herceptin® SC trastuzumab subcutaneous	Kadcyla® trastuzumab emtansine
Indication	HER2-positive BC HER2-positive MGC	HER2-positive BC	**HER2-positive BC**
International Nonproprietary Name (INN)	trastuzumab	trastuzumab	**trastuzumab emtansine**
Route of administration	Intravenous (IV)	Subcutaneous (SC)	**Intravenous (IV)**
Dose (once every three weeks)	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**

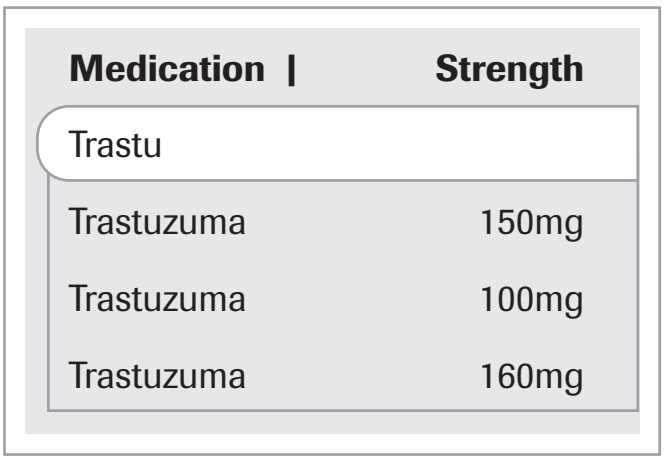
BC, breast cancer; LD, loading dose; MGC, metastatic gastric or gastro-oesophageal junction adenocarcinoma.
Please be aware that biosimilars of Herceptin (trastuzumab) and other drugs containing trastuzumab may also be available for administration by IV infusion.

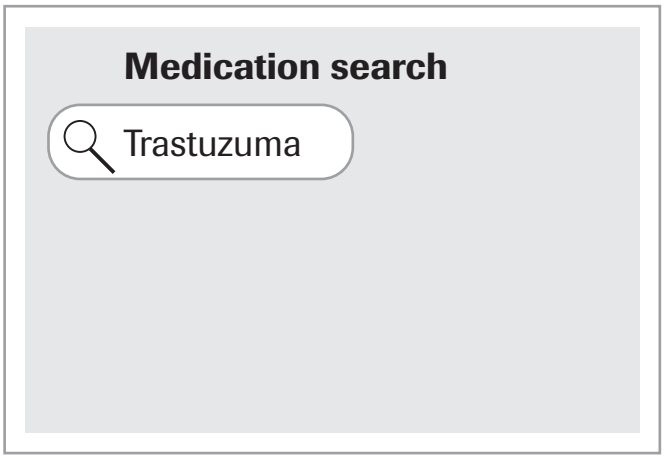
Avoiding errors: Physicians/prescription phase

Due to the similar INN between **Kadcyla (trastuzumab emtansine)** and other trastuzumab-containing products such as Herceptin (trastuzumab) or Enhertu (trastuzumab deruxtecan) errors can occur when prescribing.

Electronic systems: Potential areas of confusion (graphics updates)







Alphabetical name sorting	Name truncation & Limited text field
Trastuzumab and trastuzumab SC, **trastuzumab emtansine** and trastuzumab deruxtecan may be positioned one after the other	If the system only displays part of the medication name in its drop-down menu or text window (e.g. trastuzumab, trastuzumab SC, **trastuzumab emtansine** and trastuzumab deruxtecan)

Written prescriptions: Potential areas of confusion

Both **Kadcyla** and **trastuzumab emtansine** should always be used and confirmed when prescribing. It must be verified that the non-proprietary name is trastuzumab emtansine.

Example	Do NOT truncate either name
Kadcyla (trastuzumab emtansine) Trastuzumab emtansine (Kadcyla)	Kadcyla (trastuzumab e) Kadcyla (trastuzumab) Trastuzumab e

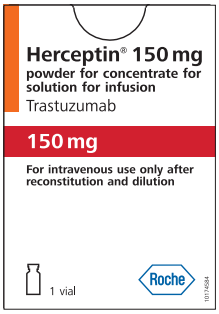
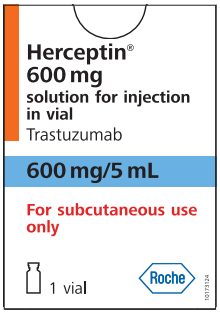
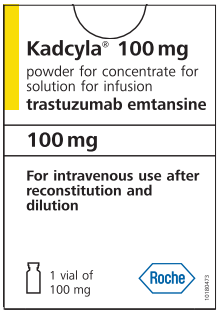
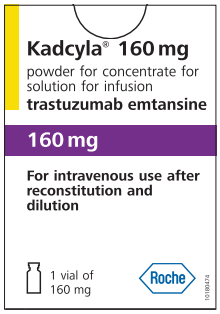
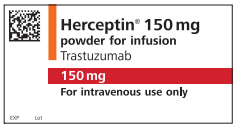
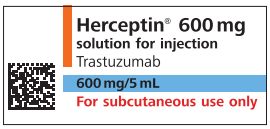
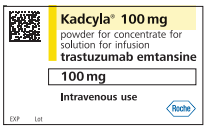
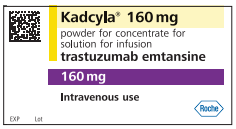
Mitigation measures

- Prescribers must familiarise themselves with the Kadcyla Summary of Product Characteristics (SmPC) which is available at www.medicines.ie and www.ema.europa.eu
- 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 another trastuzumab-containing product such as Herceptin (trastuzumab) or Enhertu (trastuzumab deruxtecan)
  - 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
  - Do not abbreviate, truncate or omit any name
- Ensure the correct medication is clearly recorded in the patient history

Avoiding errors: Pharmacists/preparation phase

Healthcare professionals should check the product carton, vial label and vial cap colour to ensure that the medicinal product being prepared and administered is **Kadcyla (trastuzumab emtansine)** and not another trastuzumab-containing product such as Herceptin (trastuzumab) or Enhertu (trastuzumab deruxtecan).

Differences and similarities between Roche products Herceptin, Herceptin SC & Kadcyla:

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

Please be aware that biosimilars of Herceptin (trastuzumab) and other drugs containing trastuzumab may also be available for administration by IV infusion.

Potential mitigation measures

- Pharmacists must familiarise themselves with the Kadcyla SmPC which is available at www.medicines.ie and www.ema.europa.eu
- 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 four types of medication with a similar INN (e.g. trastuzumab, trastuzumab SC and trastuzumab emtansine and trastuzumab duruxtecan)
- Double check the intended medication is **Kadcyla (trastuzumab emtansine)** and that both the brand name and the INN are entered in the prescription and/or medical history and in pharmacy computer systems
- In case of any doubt, consult with the treating physician
- Familiarise yourself with the different cartons, labels and cap colours to select the correct product
- Ensure the correct medication is ordered from the wholesaler and that the correct medication is received in the pharmacy
- Store **Kadcyla (trastuzumab emtansine)** in a different place in the fridge to other trastuzumab-containing products (e.g. Herceptin, Herceptin SC or Enhertu)

Avoiding errors: Nurses/administration phase

Potential mitigation measures

- Nurses must familiarise themselves with the Kadcyla SmPC which is available at www.medicines.ie and www.ema.europa.eu.
- 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
- **Do NOT** administer Kadcyla (trastuzumab emtansine) at **doses greater than 3.6 mg/kg** once every 3 weeks
- Familiarise yourself with the **Kadcyla (trastuzumab emtansine)** dose modification for toxicities

Call for reporting

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).

Where possible, 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:
Post: The Drug Surveillance Centre, Roche Products (Ireland) Limited,
3004 Lake Drive, Citywest, Naas Road, Dublin 24, Ireland.
Telephone: 00 353 (0)1 4690700
Email: ireland.drug_surveillance_centre@roche.com

Alternatively, suspected adverse reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at:
http://www.medicinesauthority.gov.mt/adrportal, and sent by post or email to:
Post: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority,
Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000, Malta.
Email: postlicensing.medicinesauthority@gov.mt

Further Information

For electronic copies of this risk minimisation material, refer to the Malta Medicines Authority website [http://www.medicinesauthority.gov.mt/rmm] and download the required material.
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] or email [ireland.drug_surveillance_centre@roche.com].

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

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