

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 Herceptin (trastuzumab) during the prescription, preparation and administration processes. Confusion can lead to overdose, undertreating and/or toxicity.

Table of Contents

Kadcyla.....	Page 3
Indication.....	Page 3
Important information.....	Page 3
Overview of Herceptin, Herceptin SC & Kadcyla: Differences and similarities.....	Page 4
Avoiding errors: Physicians/prescription phase	Page 5
Avoiding errors: Pharmacists/preparation phase.....	Page 7
Avoiding errors: Nurses/administration phase.....	Page 9
Call for reporting	Page 10
Further Information.....	Page 10

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

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) and Herceptin (trastuzumab) are two **different** products with **different** active substances
- Trastuzumab emtansine and trastuzumab are not interchangeable
- Kadcyla (**trastuzumab emtansine**) is **not** a generic version or biosimilar of Herceptin (trastuzumab) and has different properties, indications and dose
- Do not administer trastuzumab emtansine in combination with trastuzumab or with a chemotherapy
- Do not administer trastuzumab emtansine at doses greater than 3.6 mg/kg once every three weeks

Overview of Herceptin, Herceptin SC & Kadcylla: Differences and similarities

Trademark			
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 (trastuzumab vs **trastuzumab emtansine**) errors can occur when prescribing.

Electronic systems: Potential areas of confusion

Medication	Strength
Trastu	
Trastuzumab	150mg
Trastuzumab emtansine	100mg
Trastuzumab emtansine	160mg

Medication	Strength
Trastu	
Trastuzuma	150mg
Trastuzuma	100mg
Trastuzuma	160mg

Medication search

Trastuzuma

Alphabetical name sorting	Name truncation & Limited text field
Trastuzumab and trastuzumab emtansine 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" for Herceptin and Kadcyła)

Written prescriptions: Potential areas of confusion






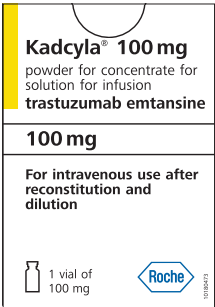

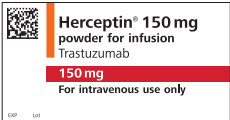
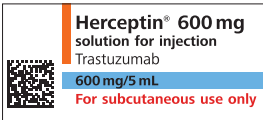
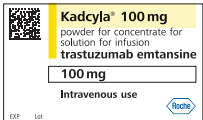
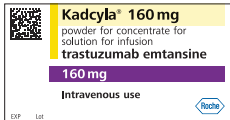




Both Kadcylla and **trastuzumab emtansine** should always be used and confirmed when prescribing. It must be verified that the non-proprietary name is trastuzumab emtansine.

Example	Do NOT truncate either name
<i>Kadcyla (trastuzumab emtansine)</i> <i>Trastuzumab emtansine (Kadcyla)</i>	<i>Kadcyla (trastuzumab e)</i> <i>Kadcyla (trastuzumab)</i> <i>Trastuzumab e</i>

Mitigation measures

- Prescribers must familiarise themselves with the Kadcylla Summary of Product Characteristics (SmPC) which is available at www.medicines.ie and www.ema.europa.eu
- Refer to Kadcylla 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 Kadcylla (**trastuzumab emtansine**) and not trastuzumab
 - Request use of brand names, where possible
- Written prescriptions
 - Ensure that both Kadcylla 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

Trademark				
Content	<p>150 mg</p>	<p>600 mg</p>	<p>100 mg</p>	<p>160 mg</p>
Carton image & colours				
Label colours				
Cap colour				
Distinctive colours	<p>Dark orange / red</p>	<p>Dark orange / light blue</p>	<p>Yellow / white</p>	<p>Yellow / purple</p>

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 Kadcyła 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 three types of medication with a similar INN – trastuzumab, trastuzumab SC and **trastuzumab emtansine**
- Double check the intended medication is Kadcyła (**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 carton
- Ensure the correct medication is ordered from the wholesaler and that the correct medication is received in the pharmacy
- Store Kadcyła (trastuzumab emtansine) in a different place in the fridge to trastuzumab IV and trastuzumab SC

Avoiding errors: Nurses/administration phase

Potential mitigation measures

- Nurses must familiarise themselves with the Kadcyła 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 Kadcyła 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 Kadcyła and **trastuzumab emtansine** when discussing the drug with the patient
- Do not administer Kadcyła (trastuzumab emtansine) at doses greater than 3.6 mg/kg q3w
- Familiarise yourself with the Kadcyła (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].

