

# **Kadcyla<sup>®</sup> (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<sup>®</sup> Risk Management Plan.**

**WARNING:**

**Risk of confusion between Kadcyla<sup>®</sup> (trastuzumab emtansine) and Herceptin<sup>®</sup> and its biosimilars (trastuzumab) during the prescription, preparation and administration processes. Confusion can lead to overdose, undertreating and/or toxicity.**

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# 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® and its biosimilars (trastuzumab) are **different** products with **different** active substances
- Kadcyla® (trastuzumab emtansine) and Herceptin® and its biosimilars (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 chemotherapy
- Do not substitute or combine trastuzumab emtansine with or for trastuzumab
- Do not administer trastuzumab emtansine at doses greater than 3.6 mg/kg once every three weeks

# Overview of Herceptin<sup>®</sup>, Herceptin<sup>®</sup> SC & Kadcyła<sup>®</sup>: Differences and similarities

<b>Trademark<sup>®</sup></b>			
<b>Indication</b>	HER2-positive BC HER2-positive MGC	HER2-positive BC	<b>HER2-positive BC</b>
<b>International Nonproprietary Name (INN)</b>	trastuzumab	trastuzumab	<b>trastuzumab emtansine</b>
<b>Route of administration</b>	Intravenous (IV)	Subcutaneous (SC)	<b>Intravenous (IV)</b>
<b>Dose (once every three weeks)</b>	8 mg/kg LD - 6 mg/kg	Fixed dose of 600 mg	<b>3.6 mg/kg</b>
<b>Form</b>	Powder	Solution	<b>Powder</b>
<b>Vial content</b>	150 mg	600 mg	<b>100 mg and 160 mg</b>
<b>Vial size</b>	15 ml	5 ml	<b>15 ml and 20 ml</b>

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

Please be aware that biosimilars of Herceptin<sup>®</sup> (trastuzumab) and other drugs containing trastuzumab (**with the same or a different strength**) may also be available for administration by IV infusion. **Please note that the availability of a particular product is dependent on the specific healthcare setting. The healthcare professional is invited to consult the correspondent SmPC in the website [www.medicines.ie](http://www.medicines.ie) for approved indications and updated product information for each of those products.**

# 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 <b>trastuzumab emtansine</b> 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 Kadcyla®)

## Written prescriptions: Potential areas of confusion






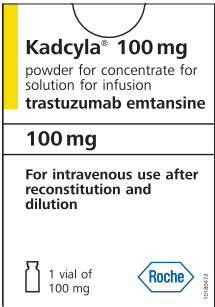
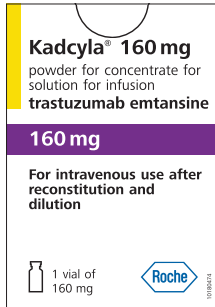
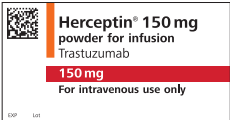
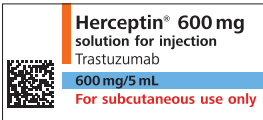
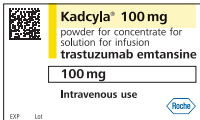
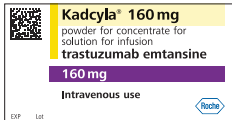




Both Kadcyła® and **trastuzumab emtansine** should always be used and confirmed when prescribing. It must be verified that the non-proprietary name is trastuzumab emtansine.

Example	Do <b>NOT</b> 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 Kadcyła® Summary of Product Characteristics (SmPC) which is available at [www.medicines.ie](http://www.medicines.ie)
- Refer to Kadcyła® 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 Kadcyła® (**trastuzumab emtansine**) and not trastuzumab
  - Request use of brand names, where possible
- Written prescriptions
  - Ensure that both Kadcyła® 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

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

Please be aware that biosimilars of Herceptin® (trastuzumab) and other drugs containing trastuzumab (**with the same or a different strength**) may also be available for administration by IV infusion. **Please note that the availability of a particular product is dependent on the specific healthcare setting. The healthcare professional is invited to consult the correspondent SmPC in the website [www.medicines.ie](http://www.medicines.ie) for approved indication and updated product information for each of those products.**

## Potential mitigation measures

- Pharmacists must familiarise themselves with the Kadcyła<sup>®</sup> SmPC which is available at [www.medicines.ie](http://www.medicines.ie)
- 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<sup>®</sup> (**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<sup>®</sup> (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<sup>®</sup> SmPC which is available at [www.medicines.ie](http://www.medicines.ie). 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<sup>®</sup> 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<sup>®</sup> and **trastuzumab emtansine** when discussing the drug with the patient
- Do not administer Kadcyła<sup>®</sup> (trastuzumab emtansine) at doses greater than 3.6 mg/kg q3w
- Familiarise yourself with the Kadcyła<sup>®</sup> (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.

**Telephone:** (01) 4690700

**Email:** ireland.drug\_surveillance\_centre@roche.com

### **Alternatively, suspected adverse reactions should be reported to:**

**Post:** HPRA Pharmacovigilance, The Health Products Regulatory Authority,  
Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2.

**Telephone:** (01) 6764971

**Email:** info@hpra.ie

**Website:** www.hpra.ie

## Further Information

**For electronic copies of this risk minimisation material,** refer to [www.hpra.ie](http://www.hpra.ie) and download the required material (enter 'Kadcyla' or 'trastuzumab emtansine' in the search box and click on 'EdM' next to any of the medicines that appear). **Alternatively if you would like hard copies,** please contact Roche Products (Ireland) Limited, 3004 Lake Drive, Citywest, Naas Road, Dublin 24 by mail, telephone (01 4690700) or email ([Ireland.drug\\_surveillance\\_centre@roche.com](mailto:Ireland.drug_surveillance_centre@roche.com)).

**For further information about Kadcyla<sup>®</sup>,** please contact Medical Information at Roche Products (Ireland) Limited by telephone (01 4690700) or email ([Ireland.druginfo@roche.com](mailto:Ireland.druginfo@roche.com)).



