

Kadcyla[®]▼ (trastuzumab emtansine): HCP Educational Information Brochure

▼ 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. See box on page 10 for details on how to report.

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

For full prescribing information, please refer to the Kadcyla
Summary of Product Characteristics available at www.medicines.ie

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WARNING:

Risk of confusion between Kadcyła (trastuzumab emtansine) and Herceptin (trastuzumab) during the prescription, preparation and administration processes. Confusion can lead to overdose, under treating and/or toxicity.

Kadcyła

Kadcyła 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

Kadcyła, 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

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

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

Trademark			
Indication	HER2-positive BC HER2-positive MGC	HER2-positive BC	HER2-positive MBC
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; MBC, metastatic breast cancer; MGC, metastatic gastric or gastro-oesophageal junction adenocarcinoma

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 Kadcyla)

Written prescriptions: Potential areas of confusion





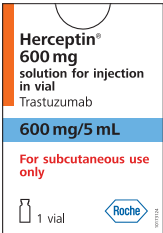
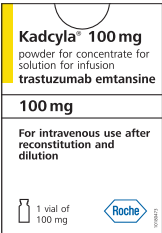
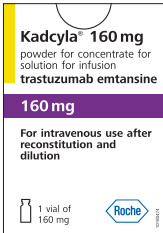

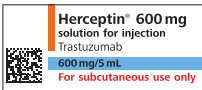
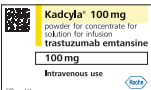





Both Kadcyła and **trastuzumab emtansine** should always be used when prescribing.

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

Mitigation measures

- Prescribers must familiarise themselves with the Kadcyła Summary of Product Characteristics (SmPC) which is available at 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

Trademark				
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

Potential mitigation measures

- Pharmacists must familiarise themselves with the Kadcyla SmPC which is available at 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 – Herceptin IV (trastuzumab), Herceptin SC (trastuzumab) and Kadcyla (**trastuzumab emtansine**)
- 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 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

Avoiding errors: Nurses/administration phase

Potential mitigation measures

- Nurses must familiarise themselves with the Kadcyła SmPC which is available at 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 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 at doses greater than 3.6 mg/kg once every three weeks
- Familiarise yourself with the Kadcyła dose modification for toxicities

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

In the event of a suspected adverse event, please report it to:

The Drug Surveillance Centre
Roche Products (Ireland) Limited

Telephone: (01) 4690700

Fax: (01) 4690793

Email: ireland.drug_surveillance_
centre@roche.com

Alternatively, suspected adverse reactions should be reported to:

The Pharmacovigilance Section
Health Products Regulatory Authority
(HPRA)

Telephone: (01) 6764971

Fax: (01) 6762517

Website: www.hpra.ie

Email: medsafety@hpra.ie

Further information

For additional copies of this risk minimisation material, please refer to the HPRA website (www.hpra.ie) 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 (01 4690700), fax (01 4690791) or email (Ireland.dra@roche.com).

For further information about Kadcyła, please refer to the Kadcyła SmPC available at www.medicines.ie or alternatively contact Medical Information at Roche Products (Ireland) Limited by telephone (01 4690700), fax (01 4690791) or email (Ireland.druginfo@roche.com).

Notes

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