# Kadcyla®▼

trastuzumab emtansine

## EU Healthcare Professional Information

## prevention of medication errors

▼ This medicinal product is subject to additional monitoring

This material is provided by Roche Products Ltd as a licence requirement for this medicine and forms part of the Risk Management Plan



**WARNING:**

**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 non-proprietary 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]

| | Herceptin® trastuzumab | Herceptin® SC trastuzumab subcutaneous | Kadcyla® trastuzumab emtansine |
|---|---|---|---|
| **Trademark** | | | |
| **Indication** | HER2-positive BC<br>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





# Kadcyla and Herceptin IV/Herceptin SC:

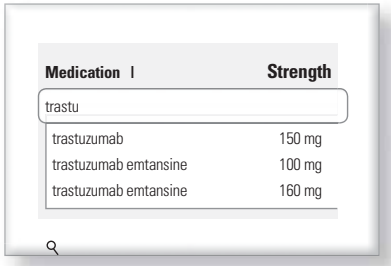
## Potential for prescription errors

### Written prescriptions: Potential areas of confusion

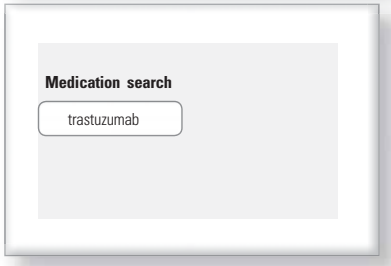
Both Kadcyla and **trastuzumab emtansine** should always be used when prescribing.

*For example:* Kadcyla (trastuzumab emtansine)

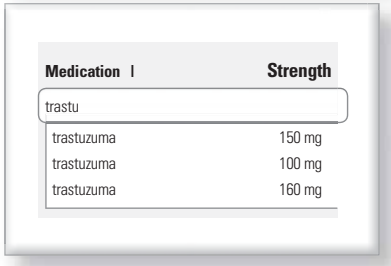
### Electronic systems: Potential areas of confusion when prescribing




**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 SPC
- ✔ 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)







**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** |

# 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 SPC
- ✔ 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 SPC. 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 SPC | ✔ | ✔ | ✔ |
| 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 | | ✔ | ✔ |
| 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 SPC, packaging, labelling and identification strategy**



**Similar Infusion bags**

**References**

1. Kadcyla Summary of Product Characteristics, November 2013
2. Herceptin Solution for Injection Summary of Product Characteristics, December 2013
3. Herceptin Powder for Concentrate for Solution for Infusion Summary of Product Characteristics, December 2013

***▼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. Reporting forms and information can be found at www.medicinesauthority.gov.mt/adrportal and sent by email to postlicensing.medicinesauthority@gov.mt or posted to ADR Reporting, The Medicines Authority Post-licensing Directorate, 203, Level 3, Rue D'Argens, Gżira GŻR 1368, MALTA. As Kadcyla is a biological medicine, healthcare professionals are encouraged to report adverse reactions by brand name and batch number. Adverse events should also be reported to Roche Products Ltd. Please contact Roche Drug Safety Centre by emailing welwyn.uk_dsc@roche.com or calling +44 (0)1707 367554.***

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Please provide us with feedback on the quality and utility of the materials within this Kadcyla Risk Management Plan. A short survey can be found at:

www.RocheRMPsurvey.co.uk

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