

Kadcyla[®]

trastuzumab emtansine

EU Healthcare Professional Information

Prevention of medication errors

For comprehensive product information please see the accompanying Summary of Product Characteristics (SPC). Over time, the product information is likely to change. These updates to the product information will be available at <http://www.medicinesauthority.gov.mt/rmm>.

This educational material is provided by Roche Products Limited and is mandatory as a condition of the Marketing Authorisation in order to further minimise important selected risks.

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Reporting forms and information can be found at www.medicinesauthority.gov.mt/adrportal. 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.

As Kadcyla is a biological medicine, healthcare professionals should report adverse reactions by brand name and batch number.



WARNING:

Kadcyla[®] (trastuzumab emtansine) and Herceptin[®] (trastuzumab) have similar generic names, but important differences, including dosing and indication.

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 INN 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 & Kadcyła[®]: Differences and similarities¹⁻³

Trademark	 Herceptin [®] trastuzumab	 Herceptin [®] SC trastuzumab subcutaneous	 Kadcyła [®] trastuzumab emtansine
Indication	HER2-positive BC 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

References

1. Kadcyła[®] Summary of Product Characteristics
2. Herceptin[®] Solution for Injection in Vial Summary of Product Characteristics
3. Herceptin[®] Powder for Concentrate for Solution for Infusion Summary of Product Characteristics

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

Medication	Strength
trastu	
trastuzumab	150 mg
trastuzumab emtansine	100 mg
trastuzumab emtansine	160 mg

Alphabetical name sorting trastuzumab and **trastuzumab emtansine** may be positioned one after the other

Medication search

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[®])

Medication	Strength
trastu	
trastuzuma	150 mg
trastuzuma	100 mg
trastuzuma	160 mg

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[®])

Avoiding errors: Physician/prescription phase

Potential mitigation measures

- ✓ Prescribers must familiarise themselves with the Kadcyła® SPC
- ✓ 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

For example: Kadcyła (trastuzumab emtansine)



ALWAYS CONFIRM THE VIAL LABEL

TAKE CARE when dealing with prescriptions containing **trastuzumab**

Avoiding errors: Pharmacists/preparation phase¹⁻³



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 Kadcyła® (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 Kadcyła® 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 Kadcyła®, **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 Kadcyła® 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 Kadcyła® (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 Kadcyła® 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 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
- ✓ The maximum dose of Kadcyła® is 3.6 mg/kg once every 3 weeks.
- ✓ Familiarise yourself with the Kadcyła® dose modification for toxicities

Healthcare professionals should use both the invented name Kadcyła® and the full INN when prescribing, preparing the infusion and administering Kadcyła® to patients.

CHECK POINTS	AVOIDING MEDICATION ERRORS		
	PHYSICIANS/ prescription phase	PHARMACISTS/ ordering & preparation phase	NURSES/ administration phase
Familiarise yourself with the full Kadcyła® SPC	✓	✓	✓
Ensure that both the brand name and INN are written in full	✓	✓	✓
Select correct medication electronically	✓		
Always use brand names + INN	✓	✓	✓
Consider using Kadcyła®-specific stickers	✓	✓	✓
Use Kadcyła®-specific storage bins/labels		✓	✓
Use Kadcyła®-specific IV bag labels		✓	✓
Check vials have the yellow coloured labels specific to Kadcyła®		✓	✓
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

Please forward any feedback or comments relating to the quality and/
or effectiveness of these materials to our medical information team
at: medinfo.uk@roche.com or 0800 3281 629



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