Kadcyla®: HCP Educational Information

EU Healthcare Professional Information

September 2018

WARNING:
Risk of confusion between Kadcyla and Herceptin
During the prescription, preparation and administration processes
Confusion can lead to overdose, undertreating and/or toxicity

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.

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
- Do not administer Kadcyla at doses greater than 3.6 mg/kg q3w

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

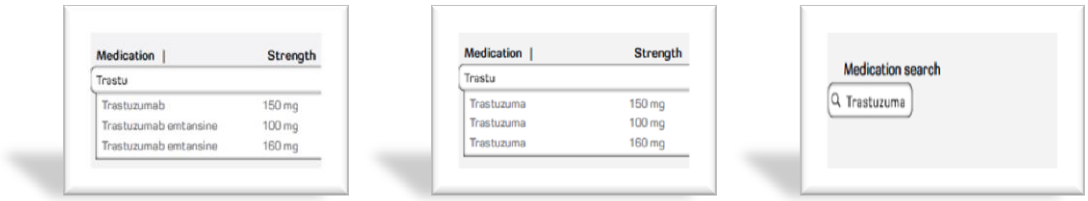
Trademark	Herceptin trastuzumab	Herceptin SC trastuzumab subcutaneous	Kadcyla trastuzumab emtansine
Indication	HER2-positive BC HER2-positive MGC	HER2-positive BC	**HER2-positive MBC**
INN	trastuzumab	trastuzumab	**trastuzumab emtansine**
Dose (q3w)	8 mg/kg LD - 6 mg/kg	Fixed dose of 600 mg	**3.6 mg/kg**
Form	Powder	Solution	**Powder**
Vial content	440 mg	600 mg	**100 mg and 160 mg**
Vial size	20 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



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

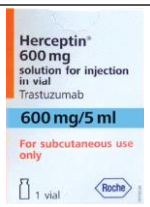
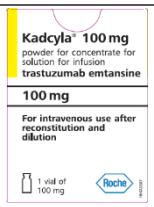
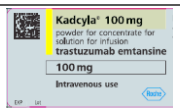
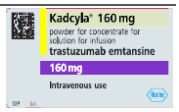
Both Kadcyla and **trastuzumab emtansine** should always be used when prescribing.

Example	Do not truncate either name
Kadcyla (trastuzumab emtansine) Trastuzumab emtansine (Kadcyla)	Kadcyla (trastuzumab e) Kadcyla (trastuzumab) Trastuzumab e

Mitigation measures

- Prescribers must familiarise themselves with the Kadcyla SmPC
- 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
  - 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	Herceptin trastuzumab	Herceptin SC trastuzumab subcutaneous	Kadcyla trastuzumab emtansine	
Content	440 mg	600 mg	100 mg	160 mg
Carton image & colours				
Label colours				
Cap colour				
Distinctive colours	Dark orange/ green	Dark orange/ light blue	Yellow/ white	Yellow/ purple

Potential mitigation measures:

- Pharmacists must familiarise themselves with the Kadcyla SmPC
- 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

Avoiding errors: Nurses/administration phase

Potential mitigation measures:

- Nurses must familiarise themselves with the Kadcyla SmPC. 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
- Do not administer Kadcyla at doses greater than 3.6 mg/kg q3w
- Familiarise yourself with the Kadcyla dose modification for toxicities

Gayane Ghazaryan, Safety Responsible for Hoffmann-La Roche Products in Armenia

12.03.19 / _____
date / signature

Nune Karapetyan, Financial Lead of Hoffmann-La Roche Products in Armenia

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