Kadcyla®: HCP Educational Information

EU Healthcare Professional Information

March 2022

WARNING

Risk of confusion between Kadcyla® (trastuzumab emtansine) and other trastuzumab-containing products such as Herceptin® (trastuzumab) or Enhertu® (trastuzumab deruxtecan)

There are important differences between these products and confusion during the prescription, preparation and administration processes can lead to overdose, undertreating and/or toxicity

Healthcare professionals should use both the trademark name Kadcyla, and the full INN trastuzumab emtansine when prescribing, preparing and administering Kadcyla to patients

Kadcyla (trastuzumab emtansine):

Kadcyla (trastuzumab emtansine) 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

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.

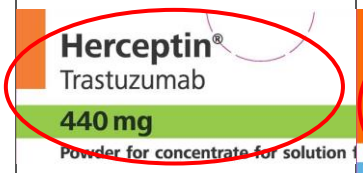
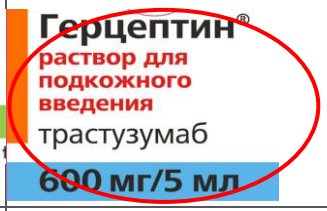
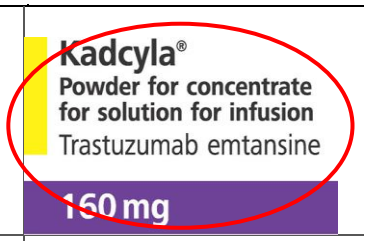
Patients should have either:

- 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) is **a different product** than other trastuzumab-containing products such as Herceptin (trastuzumab) or Enhertu (trastuzumab deruxtecan)
- Kadcyla (trastuzumab emtansine) is **NOT a generic version or biosimilar** of Herceptin (trastuzumab)
- Kadcyla (trastuzumab emtansine) is **NOT interchangeable** with other trastuzumab-containing products such as Herceptin (trastuzumab) or Enhertu (trastuzumab deruxtecan)
- **Do NOT** administer Kadcyla (trastuzumab emtansine) **in combination** with other trastuzumab-containing products such as Herceptin (trastuzumab) or Enhertu (trastuzumab deruxtecan) **or with a chemotherapy**
- **Do NOT** administer Kadcyla (trastuzumab emtansine) at **doses greater than 3.6 mg/kg** once every 3 weeks
- Both the trademark name Kadcyla, and the full INN trastuzumab emtansine should be used and confirmed when prescribing, preparing and administering Kadcyla to patients

Differences and similarities between Roche products Herceptin, Herceptin SC & Kadcyla:

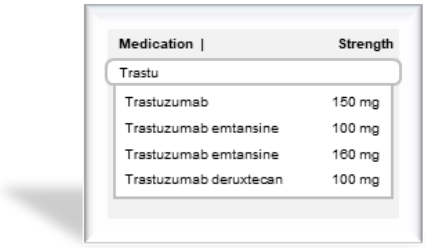
Trademark			
Indication	HER2-positive BC HER2-positive MGC	HER2-positive BC	**HER2-positive BC**
INN	trastuzumab	trastuzumab	**trastuzumab emtansine**
Dose (q3w)	8 mg/kg LD - 6 mg/kg	Fixed dose of 600 mg	**3.6 mg/kg**
Form	Powder	Solution	**Powder**
Vial content	440 mg	600 mg	**100 mg and 160 mg**
Vial size	20 ml	5 ml	**15 ml and 20 ml**

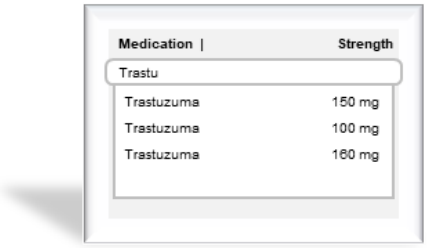
BC, breast cancer; LD, loading dose; MGC, metastatic gastric or gastro-oesophageal junction adenocarcinoma.
Please be aware that biosimilars of Herceptin (trastuzumab) and other drugs containing trastuzumab may also be available for administration by IV infusion.

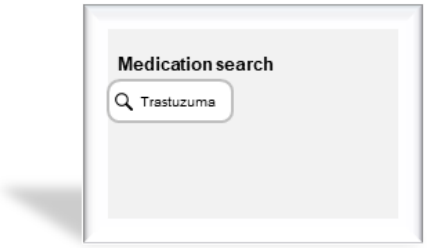
Avoiding errors: Physicians/prescription phase

Due to the similar INN between **Kadcyla (trastuzumab emtansine)** and other trastuzumab-containing products such as Herceptin (trastuzumab) or Enhertu (trastuzumab deruxtecan) errors can occur when prescribing.

Electronic systems: Potential areas of confusion







Alphabetical name sorting	Name truncation & Limited text field
Trastuzumab, trastuzumab SC, **trastuzumab emtansine** and trastuzumab deruxtecan may be positioned one after the other	If the system only displays part of the medication name in the drop-down menu or text window (trastuzumab, trastuzumab SC, **trastuzumab emtansine** and trastuzumab deruxtecan)

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

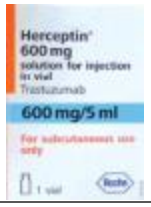
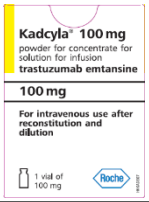
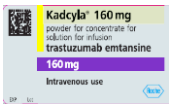
Mitigation measures

- Prescribers must familiarise themselves with the Kadcyla Summary of Product Characteristics (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 another trastuzumab-containing product such as Herceptin (trastuzumab) or Enhertu (trastuzumab deruxtecan)
  - 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

Healthcare professionals should check the product carton, vial label and vial cap colour to ensure that the medicinal product being prepared and administered is **Kadcyla (trastuzumab emtansine)** and not another trastuzumab-containing product such as Herceptin (trastuzumab) or Enhertu (trastuzumab deruxtecan).

Differences and similarities between Roche products Herceptin, Herceptin SC & Kadcyla:

Trademark	Herceptin® Trastuzumab 440 mg Powder for concentrate for solution for infusion	Герцептин® раствор для подкожного введения трастузумаб 600 мг/5 мл	Kadcyla® Powder for concentrate for solution for infusion Trastuzumab emtansine	
Content	440 mg	600 mg	100 mg	160 mg
Carton image & colours				
Label colours				
Cap colour				
Distinctive colours	Dark orange/ Green red	Dark orange/ light blue	Yellow/ white	Yellow/ purple

Please be aware that biosimilars of Herceptin (trastuzumab) and other drugs containing trastuzumab may also be available for administration by IV infusion

Potential mitigation measures:

- Pharmacists must familiarise themselves with the Kadcyla Summary of Product Characteristics (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 multiple types of medication with a similar INN (e.g. trastuzumab, trastuzumab SC, trastuzumab emtansine and trastuzumab deruxtecan)
- 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 product
- Ensure the correct medication is ordered from the wholesaler and that the correct medication is received in the pharmacy
- Store **Kadcyla (trastuzumab emtansine)** in a different place in the fridge to other trastuzumab-containing products (e.g. Herceptin, Herceptin SC or Enhertu).

Avoiding errors: Nurses/administration phase

Potential mitigation measures:

- Nurses must familiarise themselves with the Kadcyla Summary of Product Characteristics (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 (trastuzumab emtansine) at **doses greater than 3.6 mg/kg** once every 3 weeks
- Familiarise yourself with the **Kadcyla (trastuzumab emtansine)** dose modification for toxicities

If you need additional copies of the Patient or HCP Guides or have information on adverse event you may contact with the Scientific Centre of Drug and Medical Technology Expertise after academician Emil Gabrielyan via contacts presented below: address: RA, Yerevan 0051, 49/5 Komitas avenue, tel.: (374 60) 830073, (+374 10) 230896, hot line: (+374 10) 200505; (+374 96) 220505; or email: vigilance@pharm.am; or via website: www.pharm.am:

Healthcare professionals should report any case of exposure to any Roche`s products (regardless of the outcome) via following contact details: Gayane Ghazaryan, Medical Manager/Drug Regulatory and Local person for Pharmacovigilance of Roche Products in Armenia, mob.: +374 91 796688 or email address: gayaneh.ghazaryan@gmail.com; or Nune Karapetyan, Local backup for Pharmacovigilance of Roche Products in Armenia via mob.: +374 91 721153 or email address: nune.karapetyan.roche@gmail.com.

Also you may contact to Local Safety Responsible, Roche Georgia LLC via tel: +995 322 506284, +995 322 507284 or emailing to georgia.safety@roche.com.

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Local person for Pharmacovigilance for Hoffmann- La Roche products in Armenia, Acti Group LLC.

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Country Medical Director for Georgia/Armenia, Roche Georgia LLC.