Kadcyla®: HCP Educational Information

Healthcare Professional Information

This material should be read in conjunction with Kadcyla Local Package Insert, which comes along with the medication packaging.

WARNING

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

Early Breast Cancer (EBC)

Kadcyla, as a single agent, is indicated for the adjuvant treatment of patients with **HER2-positive early breast cancer** who have residual invasive disease, after neoadjuvant taxane and trastuzumab-based treatment.

Metastatic Breast Cancer (MBC)

Kadcyla, as a single agent, is indicated for the treatment of patients with **HER2-positive, metastatic breast cancer** who previously received trastuzumab and a taxane, separately or in combination. Patients should have either:

- Received prior therapy for metastatic disease, or
- Developed disease recurrence during or within six months of completing adjuvant therapy.

Important Information:

- Kadcyla (trastuzumab emtansine) is **a different product** than other trastuzumab-containing products such as Herceptin (trastuzumab) or 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 trastuzumab deruxtecan
- **Do NOT** administer Kadcyla (trastuzumab emtansine) in combination with other trastuzumab-containing products such as Herceptin (trastuzumab) or 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:

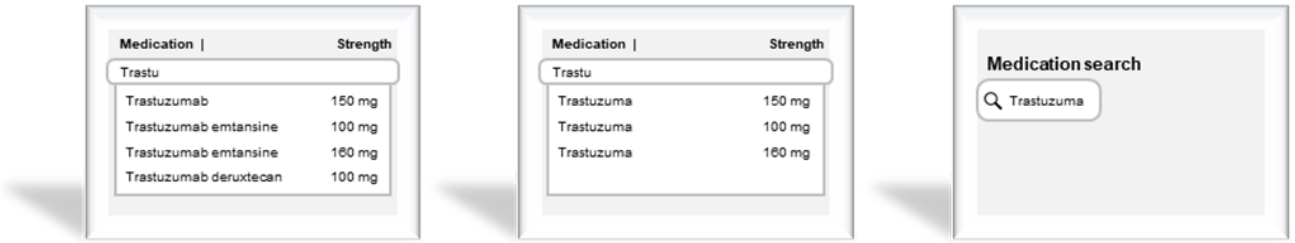
Trademark	Herceptin trastuzumab	Herceptin SC trastuzumab subcutaneous	Kadcyla trastuzumab emtansine
Indication	HER2-positive BC HER2-positive MGC	HER2-positive BC	**HER2-positive BC**
INN	trastuzumab	trastuzumab	**trastuzumab emtansine**
Dose (q3w)	8 mg/kg LD - 6 mg/kg	Fixed dose of 600 mg	**3.6 mg/kg**
Form	Powder	Solution	**Powder**
Vial content	150 mg and 440mg	600 mg	**100 mg and 160 mg**
Vial size	15 ml and 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 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

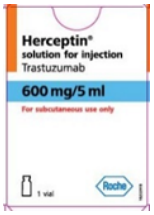
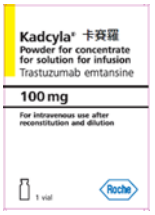
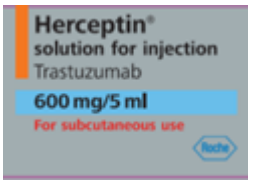
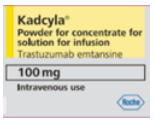
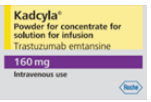
Mitigation measures

- Prescribers must familiarise themselves with the Kadcyla Package Insert (PI)
- 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 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 trastuzumab deruxtecan.

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

Trademark	Herceptin trastuzumab		Herceptin SC trastuzumab subcutaneous	Kadcyla trastuzumab emtansine	
Content	150 mg	440 mg	600 mg	100 mg	160 mg
Carton image & colours					
Label colours					
Cap colours					
Distinctive colours	Dark orange/ red	Dark orange/ green	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 Package Insert (PI)
- 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 trastuzumab deruxtecan).

Avoiding errors: Nurses/administration phase

Potential mitigation measures

- Nurses must familiarise themselves with the Kadcyla Package Insert (PI)
- 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

Reporting Suspected Adverse Event and Special Situations

- Reporting suspected adverse events and special situations of medicinal product is important.
- It allows continued monitoring of the benefit-risk balance of the medicinal product.
- Healthcare Professionals are requested to report any suspected adverse events and special situations such as medication error or pregnancy involving Roche products to Roche Hong Kong Patient Safety at hong_kong.drug_safety@roche.com.
- **Pregnancy Disclaimer:**
  If a patient becomes pregnant while receiving Kadcyla, or within 7 months following the last dose of Kadcyla, please immediately report pregnancy to hong_kong.drug_safety@roche.com. Additional information will be requested during a Kadcyla-exposed pregnancy and the first year of the infant's life. This will enable Roche to better understand the safety of Kadcyla and to provide appropriate information to health authorities, healthcare providers and patients.
- For additional information, please refer to Kadcyla Package Insert (PI).