Kadcyla and Herceptin are two very different products with different active substances never to be used interchangeably. Kadcyla is **NOT** a generic version of Herceptin and has different properties, indications and dose.

TAKE CARE *when dealing with prescription names containing* ***trastuzumab***
ALWAYS CONFIRM THE VIAL LABEL

▼ *This medicinal product is subject to additional monitoring.*

trastuzumab emtansine solution for infusion[1]

Kadcyla® ▼
trastuzumab emtansine

Kadcyla 100 mg and 160 mg single-use vials contain powder for concentrate for solution for infusion. After reconstitution:

- The 100 mg vial is designed to deliver 5 ml of 20 mg/ml of trastuzumab emtansine
- The 160 mg vial is designed to deliver 8 ml of 20 mg/ml of trastuzumab emtansine

100 mg vial - WHITE | **160 mg vial - PURPLE**

Dilute in an infusion bag containing 250 ml of 0.45% or 0.9% sodium chloride solution only.

- When using 0.9% sodium chloride solution a 0.22 µm in-line filter is required
- Incompatible with glucose (5%) solution

For metastatic breast cancer ONLY as a single agent - not approved in early breast cancer.

Recommended dose is 3.6 mg/kg administered as an intravenous infusion every 3 weeks (21-day cycle).

- No loading dose required
- Initial dose should be administered as a 90-minute intravenous infusion
- If prior infusion was well tolerated, subsequent doses may be administered as 30-minute infusions
- Dose may be reduced for toxicity: refer to SPC for full information

NOTE

⊗ **DO NOT** substitute Kadcyla for Herceptin
⊗ **DO NOT** substitute Herceptin for Kadcyla

trastuzumab solution for injection[2]

Herceptin® SC
trastuzumab
subcutaneous

- Each 5 ml vial of contains 600 mg of trastuzumab
- No reconstitution required

600 mg/5 ml vial - LIGHT BLUE

- The hypodermic injection needle must be attached to the syringe immediately prior to administration, followed by volume adjustment to 5 ml
- Herceptin subcutaneous formulation is a ready to use solution which should not be mixed or diluted with any other products

For metastatic and early breast cancer.

- Recommended dose is 600 mg/5 ml irrespective of patient's body weight
- No loading dose
- Administer subcutaneously over 2-5 minutes every 3 weeks

There is no dose reduction schedule for Herceptin subcutaneous formulation

▼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.

trastuzumab solution for infusion[3]

Herceptin®
trastuzumab

- Each 150 mg Herceptin vial contains 150 mg powder for concentrate for solution for infusion
- After reconstitution, the Herceptin solution contains 21 mg/ml of trastuzumab

150 mg vial - RED

Dilute in an infusion bag containing 250 ml of 0.9% sodium chloride solution.

- No filter is required
- Incompatible with glucose-containing solutions

For metastatic and early breast cancer.

Weekly schedule

- Recommended loading dose of 4 mg/kg as a 90-minute intravenous infusion
- If the loading dose is well tolerated, administer subsequent doses as a 30-minute infusion at a dose of 2 mg/kg

Three-weekly schedule

- Administer Herceptin at an initial loading dose of 8 mg/kg body weight as a 90-minute infusion
- If the loading dose is well tolerated, administer subsequent doses as a 30-minute infusion at a dose of 6 mg/kg

There is no dose reduction schedule for Herceptin solution for infusion

References 1. Kadcyla SPC, November 2013 2. Herceptin Solution for Injection SPC, December 2013
3. Herceptin Powder for Concentrate for Solution for Infusion SPC, December 2013

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

Roche

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*).

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

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