

To Whom It May Concern

Basel, 27 January 2025

KADCYLA® 100 mg powder for concentrate for solution for infusion KADCYLA® 160 mg powder for concentrate for solution for infusion

Dear Sir/Madam,

Please find the information about the stability of Kadcyla below.

Unopened vial

Shelf life is 4 years. Store in a refrigerator (2°C-8°C).

After opening a vial / after first puncture – not applicable

Chemical and physical in-use stability of the reconstituted solution has been demonstrated for up to 24 hours at 2°C to 8°C. From a microbiological point of view, the product should be used immediately. If not used immediately, the reconstituted vials can be stored for up to 24 hours at 2°C to 8°C, provided it was reconstituted under controlled and validated aseptic conditions, and must be discarded thereafter.

Physico-chemical stability of the drug after preparation of solution for injection

The reconstituted Kadcyla solution diluted in infusion bags containing sodium chloride 9 mg/ml (0.9%) solution for infusion, or sodium chloride 4.5 mg/ml (0.45%) solution for infusion, is stable for up to 24 hours at 2°C to 8°C, provided it was prepared under controlled and validated aseptic conditions. Particulates may be observed on storage if diluted in 0.9% sodium chloride (see section 6.6 Annex: Summary of Product Characteristics). The use of 0.20 or 0.22 micron in-line polyethersulfone (PES) filter is required for the infusion when the concentrate for infusion is diluted with sodium chloride 9 mg/mL (0.9%) solution for infusion.

Roche Registration GmbH

Emil-Barell-Straße 1
D-79639 Grenzach-Wyhlen
Germany
Telefon +49 7624 14 2892
Telefax +49 7624 1015

Sitz der Gesellschaft:
Grenzach-Wyhlen
Registergericht:
Freiburg HRB 717155

Geschäftsführung:
Dr. Julia Wagle
USt-IdNr.: DE314809599

The reconstituted product contains no preservative and is intended for single use only. Discard any unused portion. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

On behalf of Roche Registration GmbH,

ppa.



Dr. Holger Raviol

Pharma Technical Regulatory

ppa.



Dr. Andreas Emmendoerffer

Pharma Technical Regulatory

Roche Registration GmbH

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