

To Whom It May Concern

Basel, 20 October 2023

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.

Vial (unopened)

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.

Diluted medicinal product

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.

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,

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Christelle Laroche

Pharma Technical Regulatory



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