

To Whom It May Concern

Basel, 27 January 2025

PERJETA® (pertuzumab) Vials 420 mg/14 mL

Dear Sir/Madam,

Please find the information about the stability of Perjeta below.

Unopened vial

Shelf life is 2 years. Store in a refrigerator (2°C-8°C). Do not freeze. Keep the vial in the outer carton in order to protect from light.

After opening a vial / after first puncture – not applicable

Perjeta does not contain any antimicrobial preservative. Therefore, care must be taken to ensure the sterility of the prepared solution for infusion and should be prepared by a healthcare professional. Perjeta is for single use only and is administered intravenously by infusion. The vial must not be shaken. 14 ml of Perjeta concentrate should be withdrawn from the vial using a sterile needle and syringe and diluted into a 250 ml PVC or non-PVC polyolefin infusion bag of sodium chloride 9 mg/ml (0.9%) solution for infusion. Stability of the solution prepared for the infusion – according to description “Diluted medicinal product”. Parenteral medicinal products should be inspected visually for particulates and discoloration prior to administration. If particulates or discoloration are observed, the solution should not be used. Once the infusion is prepared it should be administered immediately. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

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Dr. Julia Wagle
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Diluted medicinal product

Chemical and physical in-use stability has been demonstrated for 24 hours at 30°C and up to 30 days at 2°C to 8°C protected from light. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2°C to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

On behalf of Roche Registration GmbH,

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Dr. Holger Raviol

Pharma Technical Regulatory

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