

To Whom It May Concern

Basel, 03 May 2023

HERCEPTIN® 600 mg Solution for Injection (Ro 45-2317/F07)

Dear Sir/Madam,

Please find the information about the stability of Herceptin below.

Unopened vial

Shelf life is 21 months, Store in a refrigerator (2°C – 8°C). Do not freeze. Keep the vial in the outer carton in order to protect from light. Once removed from the refrigerator Herceptin subcutaneous formulation must be administered within 6 hours and should not be kept above 30°C.

Physico-chemical stability of the drug in vial after first withdraw of concentrate from the vial

Not applicable. Herceptin 600 mg Solution for Injection is for single-use only. As Herceptin does not contain any antimicrobial-preservative, from a microbiological point of view, the medicine should be used immediately. If the medicine is not used immediately, it should be reconstituted under controlled and validated aseptic conditions. After transferring the solution to the syringe, it is recommended to protect the needle in order to avoid the drying of the solution in the needle, thereby reducing the quality of the medicine. The hypodermic injection needle must be attached to the syringe immediately prior to administration followed by volume adjustment to 5 mL. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

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

Once transferred from the vial to the syringe the medicinal product is physically and chemically stable for 28 days at 2°C – 8°C and for 6 hours (cumulative time in the vial and the syringe) at ambient temperature (max. 30°C) in diffused daylight.

As Herceptin does not contain any antimicrobial-preservative, from a microbiological point of view, the medicine should be used immediately.

On behalf of Roche Registration GmbH,

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Pharma Technical Regulatory

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