



## To Whom It May Concern

Basel , 23 May 2022

### **TECENTRIQ® 1200 mg concentrate for solution for infusion**

Dear Sir/Madam,

Please find the information about the stability of Tecentriq below.

#### **Vial (unopened)**

Shelf life is 3 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**

Tecentriq does not contain any antimicrobial preservative or bacteriostatic agents and should be prepared by a healthcare professional using aseptic technique to ensure the sterility of prepared solutions. Do not shake. Use a sterile needle and syringe to prepare Tecentriq. The release of Tecentriq in the environment should be minimised. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Aseptic preparation, handling and storage:

Aseptic handling must be ensured when preparing the infusion. Preparation should be:

- performed under aseptic conditions by trained personnel in accordance with good practice rules especially with respect to the aseptic preparation of parenteral products.
- prepared in a laminar flow hood or biological safety cabinet using standard precautions for the safe handling of intravenous agents.
- followed by adequate storage of the prepared solution for intravenous infusion to ensure maintenance of the aseptic conditions

#### **Diluted medicinal product**

Chemical and physical in-use stability has been demonstrated for up to 24 hours at  $\leq 30^{\circ}\text{C}$  and for up to 30 days at  $2^{\circ}\text{C}$  to  $8^{\circ}\text{C}$  from the time of preparation. From a microbiological point of view, the prepared solution for infusion 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  $2^{\circ}\text{C}$  to  $8^{\circ}\text{C}$  or 8 hours at ambient temperature ( $\leq 25^{\circ}\text{C}$ ), unless dilution has taken place in controlled and validated aseptic conditions.

On behalf of Roche Registration GmbH,

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