

To Whom It May Concern

Basel, 27 January 2025

GAZYVARO® (obinutuzumab) Vials 1000 mg/40 mL (Ro 507-2759/F06)

Vial (unopened)

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.

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

Not applicable. The withdraw of all 40 mL of concentrate from the vial have to be diluted in polyvinyl chloride (PVC) or non-PVC polyolefin infusion bags containing sodium chloride 9 mg/mL (0.9%) solution for injection. Gazyvaro is for intravenous use. It should be given as an intravenous infusion through a dedicated line after dilution.

Gazyvaro infusions should not be administered as an intravenous push or bolus.

Gazyvaro should be prepared by a healthcare professional using aseptic technique. Do not shake the vial. Use a sterile needle and syringe to prepare Gazyvaro. The bag should be gently inverted to mix the solution in order to avoid excessive foaming. The diluted solution should not be shaken or frozen. Parenteral medicinal products should be inspected visually for particulates and discoloration prior to administration.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

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

After dilution, chemical and physical stability have been demonstrated in sodium chloride 9 mg/mL (0.9%) solution for injection at concentrations of 0.4 mg/mL to 20 mg/mL for 24 hours at 2°C to 8°C followed by 48 hours (including infusion time) at $\leq 30^{\circ}\text{C}$.

From a microbiological point of view, the prepared infusion solution 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-8°C, unless dilution has taken place in controlled and validated aseptic conditions.

On behalf of Roche Registration GmbH,

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