MabThera In-Use Storage and Stability in Various Diluents

This article responds to your request for information on the in-use storage and stability of MabThera® (rituximab) in various intravenous diluent bags.

Please refer to the stability information provided in the local label. Any deviation from this information is considered off-label and any treatment decisions based on such deviations are the full responsibility of the prescribing physician.

Recommendation for storage and stability of prepared Mabthera solution with approved diluents

If diluting Mabthera in 0.9% aqueous normal saline solution (NS)

Follow asceptic technique when diluting Mabthera in 0.9% aqueous solution. Prepared Mabthera IV solution can be stored for 30 days at 2ºC to 8°C and 24 hours at room temperature.[1]

If diluting Mabthera in dextrose 5% in water (D5W)

Follow aspect technique when diluting MabThera in 5% aqueous dextrose solution. Prepared MabThera IV solution can be stored for 24 hours at 2ºC to 8°C plus an additional 12 hours at room temperature.[1]

In-use storage and stability consideration

Mabthera does not contain any anti-microbial preservative.[1] Therefore it is recommended that the prepared infusion solution be administered immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and should not be longer than 24 hours at 2ºC to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

Non-approved diluents for preparing Mabthera IV solution

Roche only performed in-use stability studies with 0.9% NS and D5W solutions.[2] Evaluation of MabThera prepared with other IV diluents have not been performed; therefore, we cannot provide any recommendations on the storage and stability of prepared MabThera IV solution in any other IV diluents. This includes but is not limited to

- lactated ringers
- hypotonic IV solutions (e.g. 0.45% NaCl, 1/2NS), and
- hypertonic IV solutions (e.g. Dextrose 10% in water, D10W).

References

1. Roche Internal Regulatory Document (Accessed on 14 Jul 2023).
2. Roche Internal Communication. (Accessed on 14 Jul 2023).