

TO WHOM IT MAY CONCERN

Basel , 25 August 2022

Polivy 30 mg powder for concentrate for solution for infusion **Polivy 140 mg powder for concentrate for solution for infusion**

Dear Sir/Madam,
Please find the information about the stability of Polivy below

Vial (unopened)

Shelf life: 30 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.

After opening a vial / after first puncture

Not applicable. Polivy is for single-use only. Any unused product or waste material should be disposed of in accordance with local requirements.

Reconstituted solution

From a microbiological point of view, the reconstituted 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 refrigerated (2 °C - 8 °C), unless reconstitution has taken place in controlled and validated aseptic conditions. Chemical and physical in-use stability of the reconstituted solution has been demonstrated for up to 72 hours refrigerated (2 °C - 8 °C) and up to 24 hours at room temperature (9 °C - 25 °C).

Diluted solution

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 refrigerated (2 °C - 8 °C), unless dilution has taken place in controlled and validated aseptic conditions. Chemical and physical stability of the prepared solution for infusion has been demonstrated for the durations listed in Table 7. The diluted solution must be discarded if storage time exceeds the limits specified in Table 7.

Table 7. Durations for which chemical and physical stability of the prepared solution for infusion have been demonstrated

Diluent used to prepare solution for infusion	Solution for infusion storage conditions¹
Sodium chloride 9 mg/mL (0.9%)	Up to 72 hours refrigerated (2 °C - 8 °C) or up to 4 hours at room temperature (9 °C - 25 °C)
Sodium chloride 4.5 mg/mL (0.45%)	Up to 72 hours refrigerated (2 °C - 8 °C) or up to 8 hours at room temperature (9 °C - 25 °C)
5% Glucose	Up to 72 hours refrigerated (2 °C - 8 °C) or up to 8 hours at room temperature (9 °C - 25 °C)

¹To ensure product stability, do not exceed specified storage durations.



On behalf of Roche Registration GmbH,

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Christelle Laroche
Pharma Technical Regulatory

ppa.

A handwritten signature in blue ink, appearing to read "H. Zauwiler", with a long horizontal flourish extending to the right.

Dr. Markus Boutellier
Pharma Technical Regulatory

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