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Trodelvy® (sacituzumab govitecan) Stability of Unopened Vials After Single and Multiple Temperature Excursions

This document is in response to your request for extended storage and stability information of Trodelvy® (sacituzumab govitecan [SG]) unopened vials after single and multiple temperature excursions. This document does not intend to offer an opinion regarding the clinical relevance of these data or the advisability of storing or administering any drug in a manner inconsistent with its approved labeling. Trodelvy® (SG) should be stored according to the product label.

The full indication, important safety information, and boxed warnings for neutropenia and diarrhea are available at: www.gilead.com/-/media/files/pdfs/medicines/oncology/trodelvy/trodelvy_pi.

Relevant Product Labeling[1]

How Supplied/Storage and Handling

Store SG vials in a refrigerator at 2°C to 8°C (36–46°F) in the original carton to protect from light until time of reconstitution. Do not freeze.

Alternative Storage and Stability Information[2]

The tables below summarize available data from in-house studies regarding the storage of unopened SG vials in varying conditions after single (Table 1) and multiple (Table 2) temperature excursions. The “acceptable duration” refers to the stability of unopened SG vials in the specified packaging and storage conditions, but it does not endorse alternative packaging or use beyond the expiration date stated on the original packaging.

Table 1. Summary of Single Temperature Excursion and Duration for SG Lyophilized Powder[2]

Storage Condition	Package Type	Acceptable Duration
25°±2°C (77°±3.6°F)/60±5% relative humidity	Unopened vial	22 days
-20°C (-4°F)	Unopened vial	72 hours

Table 2. Summary of Multiple Temperature Excursions and Durations for SG Lyophilized Powder[2]

Storage Condition	Package Type	Acceptable Duration
-20°C to 25°C (-4°F to 77°F)/ 60±5% relative humidity	Unopened vial	**Multiple Excursions[a]:** • Low extreme: Up to 3 excursions of 24 hours as low as -20°C (-4°F) **And/or** • High extreme: Up to 3 excursions of 24 hours as high as 25°C (77°F)/ 60±5% relative humidity

[a]Stability data support a total of 6 temperature excursions outside approved storage with a maximum of 3 excursions at each temperature extreme for the same vial. Excursions should not exceed a maximum of 72 hours at either the higher or lower temperature extreme.

Please note that in-house stability studies have not evaluated the stability of unopened SG vials that have been exposed to light.

References

1. TRODELVY® Gilead Sciences Inc. Trodelvy (sacituzumab govitecan-hziy) for injection, for intravenous use. U.S. Prescribing Information. Foster City, CA.
2. Gilead Sciences Inc. Data on File

Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Trodelvy US Prescribing Information available at: www.gilead.com/-/media/files/pdfs/medicines/oncology/trodelvy/trodelvy_pi.

Follow-Up

For any additional questions, please contact Trodelvy Medical Information at:

☎1-888-983-4668 or www.askgileadmedical.com

Adverse Event Reporting

Please report all adverse events to:

Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or www.gilead.com/utility/contact/report-an-adverse-event

FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or www.accessdata.fda.gov/scripts/medwatch

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