GILEAD | Medical Information

Trodelvy® (sacituzumab govitecan-hziy) Protection From Light

This document is in response to your request for information regarding protecting Trodelvy® (sacituzumab govitecan-hziy [SG]) from light. Please refer to the attached US FDA-approved prescribing information for the approved label indication and important safety information. This information is provided in response to your inquiry and is not intended to serve as medical advice.

All handling, use, and storage of SG should comply with institutional guidelines and follow the clinical judgment of the managing healthcare professional. Please note, Gilead cannot support the use of SG if exposed to conditions not consistent with the US FDA-approved prescribing information.

Some data may be outside of the US FDA-approved prescribing information. In providing this data, Gilead Sciences, Inc. is not making any representation as to its clinical relevance or to the use of any Gilead product(s). For information about the approved conditions of use of any Gilead drug product, please consult the FDA-approved prescribing information.

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]

Preparation and Administration

Dilution

If not used immediately, the infusion bag containing SG solution can be stored refrigerated at 2°C to 8°C (36–46°F) for up to 24 hours protected from light. After refrigeration, administer diluted solution at room temperature up to 25°C (77°F) within 8 hours (including infusion time).

Administration

Administer SG as an IV infusion. Protect infusion bag from light. The infusion bag should be covered during administration to the patient until dosing is complete. It is not necessary to cover the infusion tubing or to use light-protective tubing during the infusion.

How supplied/storage and handling

Store 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.

Additional Data on SG and Protection From Light[2]

SG is photosensitive with main impacts observed in aggregation parameters (ie, percent high molecular weight [%HMW]). The vials, as well as reconstituted/diluted product in the infusion bag, must be protected from direct light during storage and use.

Exposure to light should be kept to a minimum at all times, including during drug transfer, preparation (reconstitution and dilution), and throughout the IV administration process.

While working in the hood during reconstitution and dilution, it is preferred that the room lighting remain on. Any fluorescent light in the hood (directly on top of the material) should remain off if practical; however, hood lighting is acceptable during reconstitution.

The infusion bag should be covered during administration and until dosing is complete.

It is not necessary to cover the infusion tubing or to use light-sensitive tubing during the infusion.

Impact of Light Exposure on Diluted SG

In a light protection study, diluted SG drug product (3.4 mg/ml) was exposed to ambient lighting conditions during preparation, incubation, and administration and compared to a light protected preparation under the same conditions.[2]

After dose preparation, the bags were kept at room temperature for 1 hour before being infused for a total of 3 hours into a collection bottle. After 1 hour, a steady increase in aggregation by %HMW was observed for the preparation without light protection, with a %HMW increase of 0.9% recorded after 3 hours of infusion; the arm protected from light, however, demonstrated an increase of 0.1% %HMW.[2]

Further assessments related to product quality parameters were not performed as part of this study, and no further data are currently available.

In general, aggregates may have an impact on the efficacy and safety of a therapeutic drug in terms of differences in potency and the potential for immunogenic adverse events.[2,3]

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.
3. Ratanji KD, Derrick JP, Dearman RJ, Kimber I. Immunogenicity of therapeutic proteins: influence of aggregation. *J Immunotoxicol.* 2014;11(2):99-109.

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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