GILEAD | Medical Information

Trodelvy® (sacituzumab govitecan-hziy) Use of an Alternative Solution for Reconstitution and Dilution

This document is in response to your request for information regarding the use of an alternative solution for the reconstitution and dilution of Trodelvy® (sacituzumab govitecan-hziy [SG]).

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]

Dosage and Administration

Preparation and administration

Reconstitution

SG is a hazardous drug. Follow applicable special handling and disposal procedures.

Using a sterile syringe, slowly inject 20 mL of 0.9% sodium chloride injection, USP, into each 180 mg SG vial. Each vial contains overfill to compensate for liquid loss during preparation and after reconstitution, the total resulting volume delivers a concentration of 10 mg/mL.

Dilution

Determine the final volume of the infusion solution to deliver the appropriate dose at a concentration range of 1.1 to 3.4 mg/mL.

Use 0.9% sodium chloride injection, USP only since the stability of the reconstituted SG solution has not been determined with other infusion-based solutions. Use a polyvinyl chloride, polypropylene/polyethylene, polyolefin, or ethylene vinyl acetate infusion bag.

Withdraw and discard the volume of 0.9% sodium chloride injection, USP from the final infusion bag that is necessary to achieve the indicated SG concentration following the addition of the calculated amount of reconstituted SG solution.

Withdraw the calculated amount of the reconstituted SG solution from the vial(s) using a syringe. Discard any unused portion remaining in the vial(s).

Please refer to the attached US FDA-approved Prescribing Information for additional details pertaining to the reconstitution and dilution of SG.

Additional Information

No information is available regarding the use of alternative solutions for the reconstitution and/or dilution of SG.

Gilead cannot provide alternative recommendations or suggestions for reconstitution/dilution solutions, outside of those recommended in the US FDA-approved Prescribing Information.

Gilead cannot recommend the use of SG under circumstances where reconstitution and/or dilution is carried out in a manner that is not consistent with the US FDA-approved Prescribing Information.

References

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

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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