GILEAD | Medical Information

Trodelvy® (sacituzumab govitecan-hziy) Preparation for Administration

This document is in response to your request for information regarding the preparation for administration 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]

Please note that the reconstitution and dilution instructions provided in the SG US FDA-approved prescribing information should be followed. Gilead cannot support the use of SG under circumstances where reconstitution and/or dilution are not consistent with the US FDA-approved prescribing information.

Dosage and Administration

Recommended dosage

The recommended dosage of SG as a single agent or in combination with pembrolizumab is 10 mg/kg administered as an IV infusion on Days 1 and 8 of each 21-day cycle. Continue SG until disease progression or unacceptable toxicity. Do not administer SG at doses >10 mg/kg.

Preparation and administration

Reconstitution

- SG is a hazardous drug. Follow applicable special handling and disposal procedures.
- Calculate the required dose (mg) of SG based on the patient's current body weight.
- 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.**
- Gently swirl vials and allow to dissolve for up to 15 minutes. **Do not shake**. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. The solution should be free of visible particulates, clear and yellow. Do not use the reconstituted solution if it is cloudy or discolored.
- Use reconstituted SG immediately to prepare a diluted SG infusion solution.

Dilution

- Calculate the required amount of the reconstituted SG solution needed to obtain the appropriate dose according to the patient's body weight.
- Determine the final volume of the infusion solution to deliver the appropriate dose at an SG concentration range of 1.1 mg/mL 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).
- To minimize foaming, slowly inject the calculated amount of reconstituted SG solution into the infusion bag. Do not shake the contents.
- 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). **Do not freeze or shake**.

How Supplied/Storage and Handling

SG for injection is a sterile, off-white to yellowish lyophilized powder in a single-dose vial. Each SG vial is individually boxed in a carton:

- NDC 55135-132-01 contains one 180 mg vial

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.

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

Additional Preparation for Administration Information[2]

Table 1 presents an example of SG dose preparation for a sample patient for illustration purposes only. All handling, use, and storage of SG should comply with institutional guidelines and follow the clinical judgment of the managing healthcare professional. Clinical professional judgement and local practices/Institutional guidelines regarding safety precautions should be used.

Table 1. Sample SG Dose Calculations for 10 mg/kg Dosing[2a]

Preparation for 10 mg/kg Dosing			
	Action	**Example**	**Result**
Step 1	Calculate total dose	Patient is 58 kg: 58 kg × 10 mg/kg	580 mg dose
Step 2	Calculate the number of vials to request	580 mg ÷ 200 mg/vial[b] =2.9 vials (round up)	Maximum of three vials are needed[b]

Preparation for 10 mg/kg Dosing			
	Action	**Example**	**Result**
Step 3	Reconstitute the required number of vials by adding 20 mL 0.9% sodium chloride injection, USP into each vial. Gently swirl. Do not shake	Add 20 mL into each of the three vials	Approximately 20 mL of reconstituted SG in each vial, with a final concentration of 10 mg/mL
Step 4	Calculate the required volume (mL) of reconstituted SG needed to equal the required dose	580 mg dose ÷ 10 mg/mL	58 mL
Step 5	Select the appropriate volume of 0.9% sodium chloride infusion bag needed to maintain a final concentration range of 1.1–3.4 mg/mL	250 mL or 500 mL bag can be used for a 580 mg dose (both within 1.1–3.4 mg/mL concentration)	250 mL infusion bag is selected
Step 6[c]	Withdraw the volume from the 0.9% sodium chloride infusion bag equivalent to the volume of reconstituted SG that is to be added	Remove 58 mL from 250 mL 0.9% sodium chloride infusion bag	192 mL 0.9% sodium chloride is remaining in the infusion bag
Step 7	Slowly transfer the calculated amount of reconstituted SG into the infusion bag and gently mix. Do not shake	Withdraw 58 mL of SG solution from the three vials and add it to the 192 mL 0.9% sodium chloride infusion bag	**Result:** 250 mL total volume in the infusion bag
Step 8	**QC check**: Verify that the final concentration is within the required range of 1.1–3.4 mg/mL	**Calculate:** 580 mg ÷ 250 mL (dose divided by total volume of infusion bag)	**Final concentration**: 2.32 mg/mL

Abbreviation: QC=quality control; USP=United States Pharmacopeia.
[a]Sample SG preparation and dose calculation for a 58 kg patient using a reconstituted 10 mg/mL vial and a 250 mL infusion bag.
[b]Please note: There is 200 mg SG in each vial. Following reconstitution per the Pharmacy Manual, each vial contains 20 mL of a 10 mg/mL SG solution. If a site is in receipt of 180 mg SG labeled product and is not permitted by local procedures to extract more than the labeled minimum extractable quantity of 180 mg (equal to 18 mL of reconstituted solution) from the vial, then the calculation to determine the required number of vials must be performed using 180 mg SG per vial.
[c]This step is not required as long as the infusion bag can hold the additional volume and the final concentration of SG is within the required range of 1.1–3.4 mg/mL.

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 https://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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