Trodelvy® (sacituzumab govitecan-hziy) Type of Infusion Bag and Ancillary Infusion Equipment

This document is in response to your request for information regarding the compatibility of infusion bag materials and ancillary infusion equipment with 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. Do not shake.

Dilution

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.

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 2ºC to 8ºC (36–46ºF) for up to 24 hours protected from light. After refrigeration, administer diluted solution at room temperature up to 25ºC (77ºF) within 8 hours (including infusion time).

Administration

Protect the 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.

An infusion pump may be used.

Do not mix SG, or administer as an infusion, with other medicinal products.

Upon completion of the infusion, flush the intravenous line with 20 mL 0.9% sodium chloride injection, USP.

Additional Information on Infusion Bags and Ancillary Infusion Equipment[2]

Gilead is unable to provide specific recommendations or suggestions regarding infusion bag type or ancillary infusion equipment, including selection/use of IV tubing, in-line filters, closed system transfer devices (CSTDs), or any other infusion system device or equipment. The conduct of the infusion must be patient specific and determined as appropriate by the managing physician. All handling, use, and storage of SG should comply with local guidelines and be determined by the clinical judgment of the managing healthcare professional.

Material Compatibility

0.9% Sodium Chloride infusion bags should only be used since the stability of the reconstituted product has not been determined with other infusion-based solutions.

SG is compatible with the following materials of construction:

- 0.9% Sodium Chloride infusion bags made of:
  - Polyvinyl chloride (PVC)
  - Polyolefin (polypropylene and/or polyethylene)
  - Ethylene vinyl acetate (EVA)
- Acrylonitrile butadiene styrene (ABS)
- Delrin or Polyoxymethylene (POM)
- Fluorinate Ethylene Propylene (FEP)
- Methyl methacrylate acrylonitrile butadiene styrene (MABS)
- Polyamide (PA)
- Polybutylene terephthalate (PBT)
- Polycarbonate (PC)
- Polyethersulfone (PES)
- Polyethylene (PE)
- Polyisoprene (PI)
- Polypropylene (PP)
- Polytetrafluoroethylene (PTFE)
- Polyurethane (PU)
- PVC with Di(2-ethylhexyl) phthalate (DEHP) and without DEHP (Trioctyl trimellitate [TOTM])
- Stainless steel
- Thermoplastic elastomer (TPE)
- Titanium

CSTD

SG is compatible with the following CSTD:

- PhaSeal™
- PhaSeal™ Optima
- SmartSite™/Texium™
- Equashield®
- OnGuard®
- Cyto-set®
- Mini-Spike® Chemo
- ChemoClave®
- ChemoLock™
- Safety Device for Bolus or Drugs Preparation (4010-S), High Speed Spike with Safety Valve (REF: 4038), Mini Spike Multi-Collection with Hydrophobic Filter and Safety Valve (REF: 4047), Micro Spike Multi-Collection with Hydrophobic Filter and Safety Valve (REF: 4048); these CSTDs are made by BTC Medical groups.

Use with In-Line filters

Use of an IV set with in-line filter is not mandatory for SG administration. If an IV set with in-line filter is required to be used as per site procedures, SG is compatible with 0.2 µm PES filters.

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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