TRODELVY®
sacituzumab govitecan-hziy
180 mg for injection

TRODELVY Reconstitution, Dilution, and Administration Guide

TRODELVY for injection is a sterile, off-white to yellowish lyophilized powder in a single dose vial.

Each TRODELVY 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°F to 46°F) in the original carton to protect from light until time of reconstitution. Do not freeze

INDICATIONS

TRODELVY® (sacituzumab govitecan-hziy) is a Trop-2-directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of adult patients with:

- Unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who have received two or more prior systemic therapies, at least one of them for metastatic disease.
- Unresectable locally advanced or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+ or IHC 2+/ISH−) breast cancer who have received endocrine-based therapy and at least two additional systemic therapies in the metastatic setting.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: NEUTROPENIA AND DIARRHEA

- **TRODELVY can cause severe, life-threatening, or fatal neutropenia. Withhold TRODELVY for absolute neutrophil count below 1500/mm^3 or neutropenic fever. Monitor blood cell counts periodically during treatment. Primary prophylaxis with G-CSF is recommended for all patients at increased risk of febrile neutropenia. Initiate anti-infective treatment in patients with febrile neutropenia without delay.**
- **TRODELVY can cause severe diarrhea. Monitor patients with diarrhea and give fluid and electrolytes as needed. At the onset of diarrhea, evaluate for infectious causes and, if negative, promptly initiate loperamide. If severe diarrhea occurs, withhold TRODELVY until resolved to ≤Grade 1 and reduce subsequent doses.**

CONTRAINDICATIONS

- Severe hypersensitivity reaction to TRODELVY.

Please see full Important Safety Information throughout, and click to see full Prescribing Information, including BOXED WARNING.

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Recommended preparation for TRODELVY[1]

The recommended dose is a 10 mg/kg IV infusion on Days 1 and 8 of 21-day treatment cycles until disease progression or unacceptable toxicity

All handling, use, and storage of TRODELVY 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.

See page 5 for an example calculation

Reconstitution[1]

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

1

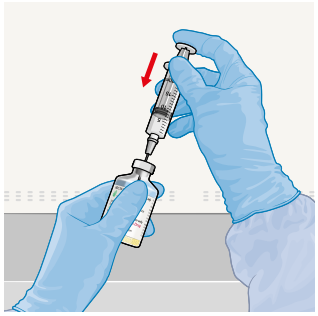
Calculate the required dose of TRODELVY

a. Calculate the required dose (mg) of TRODELVY based on the patient's current body weight.

- Ensure the patient's body weight is in kg for calculations (1 kg = 2.205 lbs)

b. Determine the number of vials needed. Each vial contains 180 mg.

2



Reconstitute the vials

a. Using a sterile syringe, **slowly inject 20 mL of 0.9% Sodium Chloride Injection, USP, into each 180 mg TRODELVY 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

b. 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**

c. Use immediately to prepare a diluted TRODELVY infusion solution.

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Dilution[1]

3

Calculate the required amount of reconstituted TRODELVY and infusion solution needed for dilution

a. Calculate the required amount of the reconstituted TRODELVY solution needed to obtain the appropriate dose according to the patient's body weight.

- After reconstitution in step 2, each vial has a concentration of 10mg/mL

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

- For the infusion solution, only use 0.9% Sodium Chloride Injection, USP, since the stability of the reconstituted TRODELVY solution has not been determined with other infusion-based solutions
- Use a polyvinyl chloride, polypropylene/ polyethylene, polyolefin, or ethylene vinyl acetate infusion bag

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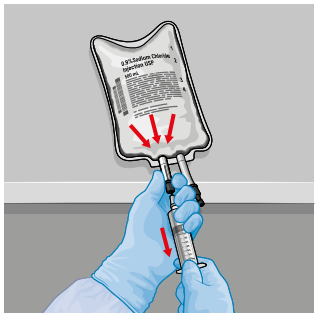
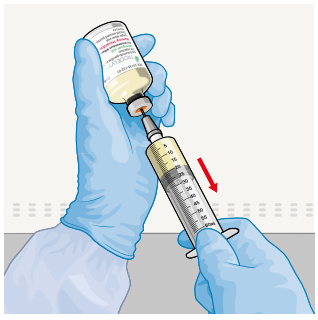


Prepare the diluent bag

- **Withdraw and discard** the volume of 0.9% Sodium Chloride Injection, USP, from the final infusion bag that is necessary to achieve the indicated TRODELVY concentration following the addition of the calculated amount of reconstituted TRODELVY solution

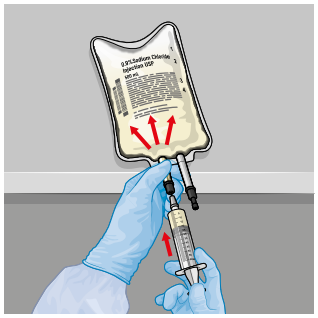
5



Withdraw the required dose of reconstituted TRODELVY

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

6



Add the reconstituted solution to the final IV bag

a. Slowly inject the calculated amount of reconstituted TRODELVY solution **into the infusion bag** to minimize foaming. **Do not shake the contents.**

b. Verify final concentration is within range of 1.1 mg/mL to 3.4 mg/mL.

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USP=United States Pharmacopoeia.

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Administration[1]

- Administer TRODELVY as an intravenous 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
- An infusion pump may be used
- Do not mix TRODELVY, 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

If not used immediately[1]

- The infusion bag containing TRODELVY solution can be stored refrigerated at 2°C to 8°C (36°F to 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).** Protect from light
- Do not freeze or shake

Scan the QR code to download the Product Order Form for complete TRODELVY ordering information.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

Neutropenia: Severe, life-threatening, or fatal neutropenia can occur as early as the first cycle of treatment and may require dose modification. Neutropenia occurred in 64% of patients treated with TRODELVY. Grade 3-4 neutropenia occurred in 49% of patients. Febrile neutropenia occurred in 6%. Neutropenic colitis occurred in 1.4%. Primary prophylaxis with G-CSF is recommended starting in the first cycle of treatment in all patients at increased risk of febrile neutropenia, including older patients, patients with previous neutropenia, poor performance status, organ dysfunction, or multiple comorbidities. Monitor absolute neutrophil count (ANC) during treatment. Withhold TRODELVY for ANC below 1500/mm^3 on Day 1 of any cycle or below 1000/mm^3 on Day 8 of any cycle. Withhold TRODELVY for neutropenic fever. Treat neutropenia with G-CSF and administer prophylaxis in subsequent cycles as clinically indicated or indicated in Table 2 of USPI.

Diarrhea: Diarrhea occurred in 64% of all patients treated with TRODELVY. Grade 3-4 diarrhea occurred in 11% of patients. One patient had intestinal perforation following diarrhea. Diarrhea that led to dehydration and subsequent acute kidney injury occurred in 0.7% of all patients. Withhold TRODELVY for Grade 3-4 diarrhea and resume when resolved to ≤Grade 1. At onset, evaluate for infectious causes and if negative, promptly initiate loperamide, 4 mg initially followed by 2 mg with every episode of diarrhea for a maximum of 16 mg daily. Discontinue loperamide 12 hours after diarrhea resolves. Additional supportive measures (e.g., fluid and electrolyte substitution) may also be employed as clinically indicated. Patients who exhibit an excessive cholinergic response to treatment can receive appropriate premedication (e.g., atropine) for subsequent treatments.

Hypersensitivity and Infusion-Related Reactions: TRODELVY can cause serious hypersensitivity reactions including life-threatening anaphylactic reactions. Severe signs and symptoms included cardiac arrest, hypotension, wheezing, angioedema, swelling, pneumonitis, and skin reactions. Hypersensitivity reactions within 24 hours of dosing occurred in 35% of patients. Grade 3-4 hypersensitivity occurred in 2% of patients. The incidence of hypersensitivity reactions leading to permanent discontinuation of TRODELVY was 0.2%. The incidence of anaphylactic reactions was 0.2%. Pre-infusion medication is recommended. Have medications and emergency equipment to treat such reactions available for immediate use. Observe patients closely for hypersensitivity and infusion-related reactions during each infusion and for at least 30 minutes after completion of each infusion. Permanently discontinue TRODELVY for Grade 4 infusion-related reactions.

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Example TRODELVY calculations[1]

The sample calculations are based on a 154-lb (70-kg) patient prescribed TRODELVY at the recommended dose of 10 mg/kg.

	Action	Example	Result
Reconstitution			
Step 1a	Calculate the total dose of TRODELVY based on the patient's weight in kg (1 kg = 2.205 lbs)	154 lbs ÷ 2.205 ≈ 70 kg 70 kg x 10 mg/kg = 700 mg	700 mg of TRODELVY
Step 1b	Determine the number of vials needed	700 mg ÷ 180 mg per vial	4 vials needed
Step 2	Reconstitute the vials by adding 20 mL of normal saline into each vial	Add 20 mL to each of the 4 vials	Each vial contains 20 mL of the 10 mg/mL reconstituted TRODELVY solution
Dilution			
Step 3a	Calculate the required volume (number of mLs needed) of reconstituted TRODELVY solution for the required dose calculated in step 1a	700 mg ÷ 10 mg/mL	70 mL of reconstituted TRODELVY solution
Step 3b	Select an infusion bag with the appropriate volume to deliver the required dose at a concentration of 1.1 mg/mL to 3.4 mg/mL	700 mg ÷ 250 mL normal saline = 2.8 mg/mL (within 1.1-3.4 mg/mL ratio)	250 mL infusion bag selected
Step 4	Withdraw volume from the infusion bag equivalent to the volume of reconstituted TRODELVY solution to be added	250 mL - 70 mL	180 mL normal saline remaining in the infusion bag
Step 5	Withdraw the calculated dose of reconstituted TRODELVY from the vials	Withdraw 70 mL of reconstituted TRODELVY	
Step 6a	Transfer the TRODELVY solution into the infusion bag	70 mL TRODELVY solution + 180 mL normal saline	250 mL total volume in infusion bag
Step 6b	Verify the final concentration is within the range of 1.1-3.4 mg/mL	700 mg ÷ 250 mL = 2.8 mg/mL	Final concentration of reconstituted TRODELVY solution is within the range

IMPORTANT SAFETY INFORMATION (cont'd)
WARNINGS AND PRECAUTIONS (cont'd)

Nausea and Vomiting: TRODELVY is emetogenic and can cause severe nausea and vomiting. Nausea occurred in 64% of all patients treated with TRODELVY and Grade 3-4 nausea occurred in 3% of these patients. Vomiting occurred in 35% of patients and Grade 3-4 vomiting occurred in 2% of these patients. Premedicate with a two or three drug combination regimen (e.g., dexamethasone with either a 5-HT3 receptor antagonist or an NK_1 receptor antagonist as well as other drugs as indicated) for prevention of chemotherapy-induced nausea and vomiting (CINV). Withhold TRODELVY doses for Grade 3 nausea or Grade 3-4 vomiting and resume with additional supportive measures when resolved to Grade ≤1. Additional antiemetics and other supportive measures may also be employed as clinically indicated. All patients should be given take-home medications with clear instructions for prevention and treatment of nausea and vomiting.

IMPORTANT SAFETY INFORMATION (cont'd)
WARNINGS AND PRECAUTIONS (cont'd)

Increased Risk of Adverse Reactions in Patients with Reduced UGT1A1 Activity: Patients homozygous for the uridine diphosphate-glucuronosyl transferase 1A1 (UGT1A1)*28 allele are at increased risk for neutropenia, febrile neutropenia, and anemia and may be at increased risk for other adverse reactions with TRODELVY. The incidence of Grade 3-4 neutropenia was 58% in patients homozygous for the UGT1A1*28, 49% in patients heterozygous for the UGT1A1*28 allele, and 43% in patients homozygous for the wild-type allele. The incidence of Grade 3-4 anemia was 21% in patients homozygous for the UGT1A1*28 allele, 10% in patients heterozygous for the UGT1A1*28 allele, and 9% in patients homozygous for the wild-type allele. Closely monitor patients with known reduced UGT1A1 activity for adverse reactions. Withhold or permanently discontinue TRODELVY based on clinical assessment of the onset, duration and severity of the observed adverse reactions in patients with evidence of acute early-onset or unusually severe adverse reactions, which may indicate reduced UGT1A1 function.

Embryo-Fetal Toxicity: Based on its mechanism of action, TRODELVY can cause teratogenicity and/or embryo-fetal lethality when administered to a pregnant woman. TRODELVY contains a genotoxic component, SN-38, and targets rapidly dividing cells. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with TRODELVY and for 6 months after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with TRODELVY and for 3 months after the last dose.

ADVERSE REACTIONS

In the pooled safety population, the most common (≥ 25%) adverse reactions including laboratory abnormalities were decreased leukocyte count (84%), decreased neutrophil count (75%), decreased hemoglobin (69%), diarrhea (64%), nausea (64%), decreased lymphocyte count (63%), fatigue (51%), alopecia (45%), constipation (37%), increased glucose (37%), decreased albumin (35%), vomiting (35%), decreased appetite (30%), decreased creatinine clearance (28%), increased alkaline phosphatase (28%), decreased magnesium (27%), decreased potassium (26%), and decreased sodium (26%).

In the ASCENT study (locally advanced or metastatic triple-negative breast cancer), the most common adverse reactions (incidence ≥25%) were fatigue, diarrhea, nausea, alopecia, constipation, vomiting, abdominal pain, and decreased appetite. The most frequent serious adverse reactions (SAR) (>1%) were neutropenia (7%), diarrhea (4%), and pneumonia (3%). SAR were reported in 27% of patients, and 5% discontinued therapy due to adverse reactions. The most common Grade 3-4 lab abnormalities (incidence ≥25%) in the ASCENT study were reduced neutrophils, leukocytes, and lymphocytes.

In the TROPiCS-02 study (locally advanced or metastatic HR-positive, HER2-negative breast cancer), the most common adverse reactions (incidence ≥25%) were diarrhea, fatigue, nausea, alopecia, and constipation. The most frequent serious adverse reactions (SAR) (>1%) were diarrhea (5%), febrile neutropenia (4%), neutropenia (3%), abdominal pain, colitis, neutropenic colitis, pneumonia, and vomiting (each 2%). SAR were reported in 28% of patients, and 6% discontinued therapy due to adverse reactions. The most common Grade 3-4 lab abnormalities (incidence ≥25%) in the TROPiCS-02 study were reduced neutrophils and leukocytes.

DRUG INTERACTIONS

UGT1A1 Inhibitors: Concomitant administration of TRODELVY with inhibitors of UGT1A1 may increase the incidence of adverse reactions due to potential increase in systemic exposure to SN-38. Avoid administering UGT1A1 inhibitors with TRODELVY.

UGT1A1 Inducers: Exposure to SN-38 may be reduced in patients concomitantly receiving UGT1A1 enzyme inducers. Avoid administering UGT1A1 inducers with TRODELVY.

Please see full Important Safety Information throughout, and click to see full Prescribing Information, including BOXED WARNING.

Reference: 1. TRODELVY. Prescribing information. Gilead Sciences, Inc.; March 2025.

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