TRODELVY®
sacituzumab govitecan-hziy
180 mg for injection

NURSING CONSIDERATIONS

Developing a Plan For Select Side Effects

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.

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.

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

Set expectations with your patients

Before patients start TRODELVY, have a conversation with them to:

- ☐ Discuss the efficacy and safety results from the clinical trials for TRODELVY
- ☐ Review the mechanism of action of TRODELVY and how it may be different from their previous treatments
- ☐ Share available resources, including information about psychosocial support throughout treatment (ie, social worker, behavioral health, pastoral care, advocacy groups, etc)
- ☐ Review their medical history and any previous treatments or side effects they may have experienced

Develop a side effect management plan

Prior to each dose of TRODELVY, talk with your patients about:

- ☐ Any side effects they may have experienced with previous doses of TRODELVY if applicable
- ☐ Potential serious and common side effects, including signs and symptoms, onset, and how long symptoms may last
- ☐ When to contact you or another healthcare provider if they experience certain side effects
- ☐ Medications that may be prescribed for use before or during treatment to help manage certain side effects
- ☐ Roles and expectations for patients and caregivers, including the importance of open and honest communication

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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.

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.

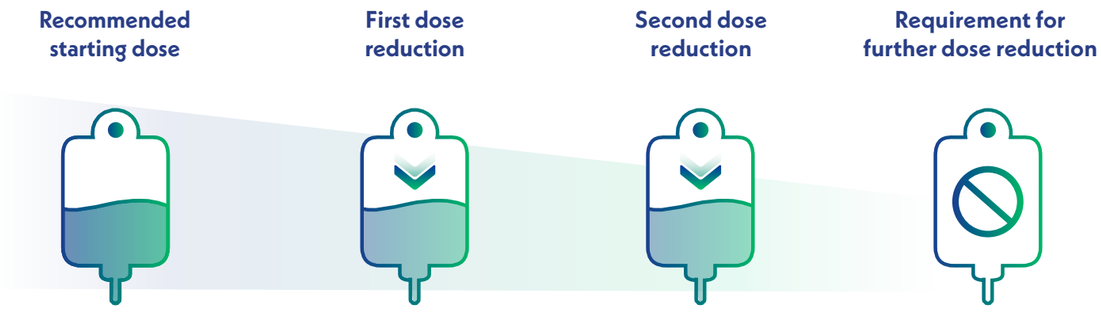
Please see full Important Safety Information throughout, and click to see full Prescribing Information, including BOXED WARNING.

Dose modifications for adverse reactions[1]

- Management of adverse reactions may require temporary interruption, dose reduction, or treatment discontinuation of TRODELVY as described below
- Do not reescalate the TRODELVY dose after a dose reduction for adverse reactions has been made

Adverse reactions	Severity	Dose modification
Neutropenia	Grade 3-4 neutropenia (absolute neutrophil count [ANC] <1000/mm^3) or febrile neutropenia	• Withhold TRODELVY until ANC ≥1500/mm^3 for Day 1 dose or ANC ≥1000/mm^3 for Day 8 dose • Administer G-CSF during treatment as clinically indicated • Reduce 1 dose level for each occurrence of febrile neutropenia or prolonged Grade 3-4 neutropenia, or discontinue according to the dose reduction levels information below
Nausea/Vomiting/ Diarrhea	Grade 3-4 nausea, vomiting or diarrhea that is not controlled with antiemetics or antidiarrheal agents	• Withhold TRODELVY until resolved to ≤Grade 1 • Reduce 1 dose level with each occurrence, or discontinue according to the dose reduction levels information below
Infusion-Related Reaction	Grade 1-3 infusion-related reactions	Slow infusion rate or interrupt the infusion
	Grade 4 infusion-related reactions	Discontinue TRODELVY
Other Toxicities	Other Grade 3-4 toxicities of any duration despite optimal medical management	• Withhold TRODELVY until resolved to ≤Grade 1 • Reduce 1 dose level with each occurrence or discontinue according to the dose reduction levels information below

Dose reduction levels[1]



ANC, absolute neutrophil count; G-CSF=granulocyte colony-stimulating factor.

Considerations for managing select side effects[1]

Help manage certain adverse reactions with appropriate medications and/or by modifying, withholding, or discontinuing doses of TRODELVY.[1]

	Be Aware	Prepare	Monitor and Manage
Neutropenia	**Severe, life-threatening, or fatal neutropenia can occur as early as the first cycle of treatment. Primary prophylaxis with G-CSF is recommended for all patients at an increased risk of febrile neutropenia.** ☐ Consider factors such as insurance coverage and short- vs long-acting formulations when using G-CSF with the treatment of TRODELVY	☐ Develop a proactive plan for neutropenia management and discuss with patients ☐ Primary prophylaxis with G-CSF is recommended as early as the first cycle for all patients at increased risk for febrile neutropenia, including older patients, patients with previous neutropenia, poor performance status, organ dysfunction, or multiple comorbidities ☐ If required, begin prior authorization process for G-CSF if you haven't already	☐ Monitor blood cell counts periodically during treatment ☐ Withhold TRODELVY for absolute neutrophil count below 1500/mm^3 on Day 1 of any cycle or neutrophil count below 1000/mm^3 on Day 8 of any cycle, or for neutropenic fever ☐ Initiate anti-infective treatment in patients with febrile neutropenia without delay ☐ If patients did not receive primary prophylaxis with G-CSF and experience neutropenia, administer G-CSF during treatment as clinically indicated ☐ Reducing, interrupting, or discontinuing doses of TRODELVY may be required. **Please see page 3 for specific dose modifications for adverse reactions**
Diarrhea	**TRODELVY can cause severe diarrhea.** ☐ Identify patients who have had prior excessive cholinergic response (eg, abdominal cramping, diarrhea, salivation, etc) ☐ Document patient baselines for bowel movements	☐ Develop a proactive plan for diarrhea management ☐ Appropriate premedication (eg, atropine) may be used for patients who have exhibited an excessive cholinergic response to treatment with TRODELVY	☐ If diarrhea occurs, evaluate for infectious causes. If no infectious cause is found, promptly initiate 4 mg of loperamide followed by 2 mg with each episode of diarrhea (up to 16 mg/day). Discontinue loperamide 12 hours after diarrhea resolves ☐ Additional supportive measures such as fluid and electrolyte substitution may be employed as needed ☐ Withhold TRODELVY for Grade 3-4 diarrhea at the time of scheduled treatment administration and resume when resolved to ≤Grade 1 ☐ Modifying, withholding, or discontinuing doses of TRODELVY may be required. **Please see page 3 for specific dose modifications for adverse reactions**
Hypersensitivity & Infusion-Related Reactions	**Serious hypersensitivity reactions including life-threatening anaphylactic reactions have occurred with TRODELVY treatment. Severe signs and symptoms included cardiac arrest, hypotension, wheezing, angioedema, swelling, pneumonitis, and skin reactions.** ☐ Identify patients who have had prior infusion-related reactions	☐ Order and premedicate with antipyretics and H1 and H2 blockers prior to infusion ☐ Corticosteroids may be used for patients who had prior infusion reactions ☐ Have medications and emergency equipment immediately available to treat infusion-related reactions, including anaphylaxis	☐ Closely monitor patients during and for at least 30 minutes after infusion is complete ☐ Slow or interrupt the infusion rate of TRODELVY if the patient develops a Grade 1-3 infusion-related reaction ☐ Instruct patients to self-monitor and immediately report symptoms during or within 24 hours after their infusion ☐ Permanently discontinue TRODELVY for Grade 4 infusion-related reactions
Nausea & Vomiting	**TRODELVY is emetogenic, or a substance that may cause nausea and/or vomiting in some patients, and can cause severe nausea and vomiting.[1,2]** ☐ Identify patients who have had prior nausea and vomiting	☐ Order and premedicate for the prevention of CINV with a 2- or 3-drug combination (eg, dexamethasone with either a 5-HT3 receptor antagonist or an NK_1 receptor antagonist) as well as other drugs as needed ☐ Provide take-home medications with clear instructions for prevention and treatment of delayed nausea and vomiting	☐ Additional antiemetics and other supportive measures may also be employed as clinically indicated ☐ Withhold TRODELVY for Grade 3 nausea or Grade 3-4 vomiting at the time of scheduled treatment administration and resume with additional supportive measures when resolved to ≤Grade 1 ☐ Modifying, withholding, or discontinuing doses of TRODELVY may be required. **Please see page 3 for specific dose modifications for adverse reactions**

5-HT3=5-hydroxytryptamine 3 receptor; CINV=chemotherapy-induced nausea and vomiting; G-CSF=granulocyte colony-stimulating factor; H1=histamine receptor 1; H2=histamine receptor 2; NK_1=neurokinin 1.

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

These are not all the possible side effects of TRODELVY. Information provided does not constitute the provision of medical advice and should not substitute for clinical decision-making.

For resources to help you support your patients, visit TRODELVYhcp.com.

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.

References: 1. TRODELVY. Prescribing Information. Gilead Sciences, Inc.; March 2025. **2.** National Cancer Institute. Emetogenic. National Institutes of Health. Accessed April 22, 2025. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/emetogenic

GILEAD

TRODELVY®
sacituzumab govitecan-hziy
180 mg for injection