



TRODELVY®
sacituzumab govitecan-hziy
180 mg for injection

NURSING CONSIDERATIONS

Developing a Plan for Select Adverse Reactions

INDICATIONS

TRODELVY® (sacituzumab govitecan-hziy) is a Trop-2-directed antibody and topoisomerase inhibitor conjugate indicated in adult patients:

Locally Advanced or Metastatic Triple-Negative Breast Cancer

First Line

- As a single agent for the first-line treatment of unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who are not candidates for PD-1 or PD-L1 inhibitor-based therapy
- In combination with pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph for the first-line treatment of unresectable locally advanced or mTNBC whose tumors express PD-L1 [Combined Positive Score (CPS ≥10)] as determined by an FDA-authorized test

Second Line or Later

- For the treatment of unresectable locally advanced or mTNBC who have received two or more prior systemic therapies, at least one of them for metastatic disease.

Locally Advanced or Metastatic HR-positive, HER2-negative Breast Cancer

- For the treatment of 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/mm³ 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 48% 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/mm³ on Day 1 of any cycle or below 1000/mm³ 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 62% of all patients treated with TRODELVY. Grade 3-4 diarrhea occurred in 10% of patients. One patient had intestinal perforation following diarrhea. Diarrhea that led to dehydration and subsequent acute kidney injury occurred in 0.6% 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 (eg, fluid and electrolyte replacement) may also be employed as clinically indicated. Patients who exhibit an excessive cholinergic response to treatment can receive appropriate premedication (eg, 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, and skin reactions. Hypersensitivity reactions occurred in 28% of patients with 13% occurring within 24 hours of dosage. Grade 3-4 hypersensitivity occurred in 1.5% of patients with 0.4% of these occurring within 24 hours of dosage. The incidence of hypersensitivity reactions leading to permanent discontinuation of TRODELVY was 0.4%. The incidence of anaphylactic reaction was <0.1%. Pre-infusion medication is recommended. Have medications and emergency equipment to treat such reactions available for immediate use. Closely monitor patients 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.

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 set expectations

- ☐ Discuss the efficacy and safety results from the clinical trials
- ☐ Review the mechanism of action of TRODELVY and how it may be different from previous treatments they may have received
- ☐ 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 adverse reactions they may have experienced

Develop an adverse reaction management plan

Some patients may be hesitant to report adverse reactions, so it is important to talk about:

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

Initiate¹

Start TRODELVY at 10 mg/kg^a

- The recommended dosage of TRODELVY as a single agent or in combination with pembrolizumab is 10 mg/kg as an intravenous infusion on Days 1 and 8 of each 21-day cycle until disease progression or unacceptable toxicity (see Section 2 of the USPI for more information on dosing)

Patient Selection for Combination Therapy (in PD-[L]1-positive 1L mTNBC)^b

- Select patients for treatment of unresectable locally advanced or mTNBC with TRODELVY in combination with pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph, based on the tumor expression of PD-L1 as confirmed by an FDA-authorized test^c
- When TRODELVY is administered in combination with pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph, discontinue pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph after approximately 24 months

^aDo not administer TRODELVY at doses greater than 10 mg/kg. Do NOT substitute TRODELVY for or use with other drugs containing irinotecan or its active metabolite SN-38. Administer as an intravenous infusion.

^bRefer to the Prescribing Information for pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph for the recommended dosing.

^cInformation on FDA-authorized tests is available at <http://www.fda.gov/companiondiagnostics>.

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 63% of all patients treated with TRODELVY, and Grade 3-4 nausea occurred in 3% of these patients. Vomiting occurred in 33% of patients, and Grade 3-4 vomiting occurred in 2% of these patients. Premedicate with a two- or three-drug combination regimen (eg, dexamethasone with either a 5-HT3 receptor antagonist or an NK1 receptor antagonist, as well as other drugs as indicated) for prevention of chemotherapy-induced nausea and vomiting. 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**.

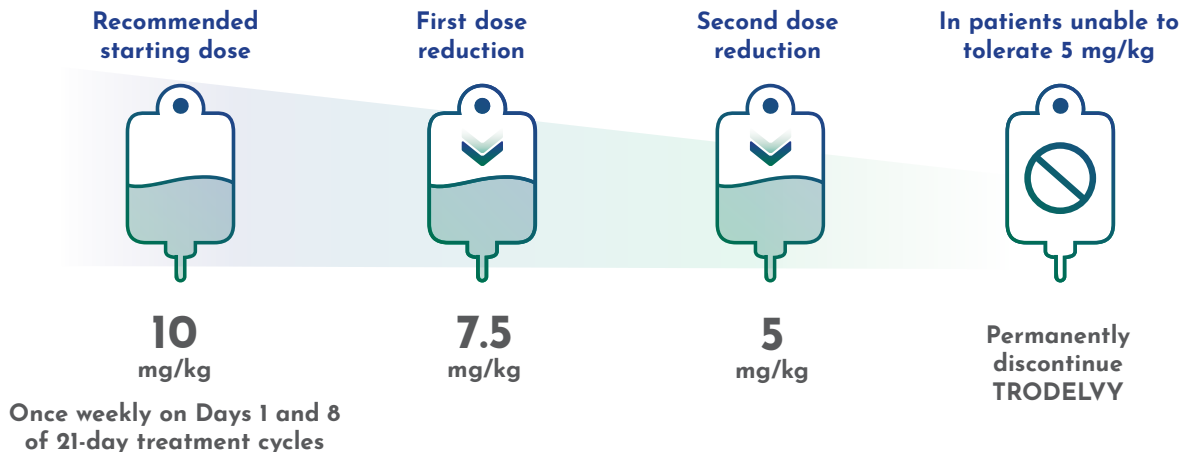


Dose modifications for adverse reactions¹

Management of adverse reactions may require temporary interruption, dose reduction, or permanent discontinuation of TRODELVY.

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/mm³ for Day 1 dose or ANC ≥1000/mm³ 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 permanently discontinue according to the dosage 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 permanently discontinue according to the dosage 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	Permanently 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 permanently discontinue according to the dosage reduction levels information below

Dosage reduction levels for TRODELVY¹



Note: Do not reescalate the TRODELVY dose after a dose reduction for adverse reactions has been made.

When administering TRODELVY in combination with pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph, interrupt or discontinue one or both drugs of the combination or reduce the dose of TRODELVY to manage adverse reactions as appropriate. Refer to the Prescribing Information for pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph for recommendations on dosage interruption or discontinuation due to adverse reactions.

1L= first line; ANC=absolute neutrophil count; G-CSF=granulocyte colony-stimulating factor; mTNBC=metastatic triple-negative breast cancer; PD-(L)1=PD-1 or PD-L1; USPI=United States Prescribing Information.

Considerations for managing select adverse reactions¹

Help manage certain adverse reactions with appropriate medications and/or by interrupting, reducing, or permanently discontinuing doses of TRODELVY!

	Be Aware	Prepare	Monitor and Manage
 Neutropenia	TRODELVY can cause severe, life-threatening, or fatal neutropenia as early as the first cycle of treatment. Primary prophylaxis with G-CSF is recommended in the TRODELVY USPI 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 TRODELVY ☐ Identify patients who may have an increased risk of febrile neutropenia	☐ Develop a proactive plan for neutropenia management and discuss with patients ☐ 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 ☐ 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/mm³ on Day 1 of any cycle or absolute neutrophil count below 1000/mm³ 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 ☐ Interrupting, reducing, or permanently 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 Considerations for diarrhea with TRODELVY in combination with pembrolizumab² Pembrolizumab can cause immune-mediated colitis, which may be severe or fatal, and may present with diarrhea. For recommendations for management of adverse reactions of pembrolizumab, refer to the Prescribing Information for pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph.	☐ 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 replacement 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 ☐ Interrupting, reducing, or permanently discontinuing doses of TRODELVY may be required. Please see page 3 for specific dose modifications for adverse reactions
 Hypersensitivity & 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, and skin reactions. ☐ Identify patients who have had prior infusion-related reactions TRODELVY is contraindicated in patients who have experienced a severe hypersensitivity reaction to TRODELVY.	☐ 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 and after their infusion ☐ Permanently discontinue TRODELVY for Grade 4 infusion-related reactions
 Nausea & Vomiting	TRODELVY is emetogenic and can cause severe nausea and vomiting. ☐ Identify patients who have had prior nausea and vomiting	☐ Order and premedicate for the prevention of CINV with a 2- or 3-drug combination regimen (eg, dexamethasone with either a 5-HT₃ receptor antagonist or an NK₁ 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 ☐ Interrupting, reducing, or permanently 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; NK₁=neurokinin 1; USPI=United States Prescribing Information.

When administering TRODELVY in combination with pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph, interrupt or discontinue one or both drugs of the combination or reduce the dose of TRODELVY to manage adverse reactions as appropriate. Refer to the Prescribing Information for pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph for recommendations on dosage interruption or discontinuation due to adverse reactions.¹

Please see full Important Safety Information throughout, and click to see full [Prescribing Information](#), including **BOXED WARNING**.

These are not all the possible adverse reactions 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 57% in patients homozygous for the UGT1A1*28 allele, 48% in patients heterozygous for the UGT1A1*28 allele, and 41% in patients homozygous for the wild-type allele. The incidence of Grade 3-4 anemia was 17% in patients homozygous for the UGT1A1*28 allele, 9% in patients heterozygous for the UGT1A1*28 allele, and 8% 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 of TRODELVY as a single agent, the most common ($\geq 25\%$) adverse reactions, including laboratory abnormalities, were decreased leukocyte count (83%), decreased neutrophil count (77%), decreased hemoglobin (71%), nausea (63%), diarrhea (62%), decreased lymphocyte count (60%), fatigue (59%), alopecia (47%), increased glucose (40%), constipation (37%), vomiting (33%), decreased albumin (32%), increased alkaline phosphatase (30%), decreased appetite (28%), abdominal pain (27%), decreased creatinine clearance (27%), decreased magnesium and potassium (26% each).

In the safety population of TRODELVY in combination with pembrolizumab, the most common ($\geq 25\%$) adverse reactions, including laboratory abnormalities, were decreased neutrophil count and hemoglobin (86% each), decreased leukocyte count (84%), diarrhea (72%), nausea (68%), decreased lymphocyte count (61%), fatigue (58%), alopecia (52%), increased alkaline phosphatase and glucose (50% each), increased alanine aminotransferase (47%), constipation (41%), increased aspartate aminotransferase (40%), rash (37%), decreased potassium (35%), increased lactate dehydrogenase (34%), vomiting (29%), abdominal pain, headache, and increased eosinophils (26% each), and decreased albumin (25%).

In the ASCENT-03 study (single agent in previously untreated, unresectable locally advanced or mTNBC), the most common adverse reactions (incidence $\geq 25\%$) were nausea, diarrhea, alopecia, fatigue, constipation, and vomiting. The most frequent serious adverse reactions (SAR) ($> 2\%$) were diarrhea, febrile neutropenia, and neutropenia (3.6% each), and pneumonia (2.9%). SAR occurred in 26% of patients, and 3.6% permanently discontinued TRODELVY

due to adverse reactions. Fatal adverse reactions occurred in 2.5% of patients and included sepsis (1.1%), and acute respiratory failure, neutropenic colitis, pneumonia, and septic shock (0.4% each). The most common Grade 3-4 lab abnormalities (incidence $\geq 25\%$) were decreased neutrophils and leukocytes.

In the ASCENT-04 study (in combination with pembrolizumab in previously untreated, unresectable locally advanced or mTNBC whose tumors express PD-L1), the most common adverse reactions (incidence $\geq 25\%$) were diarrhea, nausea, fatigue, alopecia, constipation, rash, vomiting, abdominal pain, and headache. The most frequent SAR ($\geq 2\%$) were febrile neutropenia (7%), neutropenia (6%), diarrhea (5%), and fatigue and pneumonia (2.3% each). SAR occurred in 38% of patients, and 7% permanently discontinued TRODELVY due to adverse reactions. Fatal adverse reactions occurred in 3.2% of patients and included death (unknown cause) (0.9%) and completed suicide, neutropenic sepsis, sepsis, pneumonia, and pulmonary embolism (0.5% each). The most common Grade 3-4 lab abnormalities (incidence $\geq 25\%$) were decreased neutrophils and leukocytes.

In the ASCENT study (previously treated locally advanced or mTNBC), the most common adverse reactions (incidence $\geq 25\%$) were fatigue, diarrhea, nausea, alopecia, constipation, vomiting, abdominal pain, and decreased appetite. The most frequent SAR ($> 1\%$) were neutropenia (7%), diarrhea (4%), and pneumonia (3%). SAR occurred in 27% of patients, and 5% permanently discontinued TRODELVY due to adverse reactions. Fatal adverse reactions occurred in 1.2% of patients and included respiratory failure (0.8%) and pneumonia (0.4%). The most common Grade 3-4 lab abnormalities (incidence $\geq 25\%$) were decreased neutrophils, leukocytes, and lymphocytes.

In the TROPiCS-02 study (locally advanced or metastatic HR+/HER2- breast cancer), the most common adverse reactions (incidence $\geq 25\%$) were diarrhea, fatigue, nausea, alopecia, and constipation. The most frequent SAR ($> 1\%$) were diarrhea (5%), febrile neutropenia (4.1%), neutropenia (3%), abdominal pain (2.2%), neutropenic colitis and vomiting (1.9% each), and colitis and pneumonia (1.5% each). SAR occurred in 28% of patients, and 6% permanently discontinued TRODELVY due to adverse reactions. Fatal adverse reactions occurred in 2.2% of patients and included arrhythmia, COVID-19 pneumonia, pneumonia, nervous system disorder, pulmonary embolism, and septic shock (0.4% each). The most common Grade 3-4 lab abnormalities (incidence $\geq 25\%$) were decreased neutrophils and leukocytes.

DRUG INTERACTIONS

UGT1A1 Inhibitors: Avoid administering UGT1A1 inhibitors with TRODELVY. SN-38 is a UGT1A1 substrate. 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.

UGT1A1 Inducers: Avoid administering UGT1A1 inducers with TRODELVY. SN-38 is a UGT1A1 substrate. Concomitant administration of TRODELVY with inducers of UGT1A1 may reduce exposure to SN-38.

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.; 2026. 2. KEYTRUDA. Prescribing Information. Merck & Co., Inc.; June 2026.



TRODELVY, the TRODELVY logo, GILEAD, and the GILEAD logo are trademarks of Gilead Sciences, Inc., or its related companies. All other marks are the property of their respective owners.

© 2026 Gilead Sciences, Inc. All rights reserved. US-TROP-2475 09/26



TRODELVY®
sacituzumab govitecan-hziy
180 mg for injection