



TRODELVY[®] (sacituzumab govitecan-hziy)

What are the possible side effects of TRODELVY when used alone?

This information is provided in response to your question. It is not treatment advice on how to use TRODELVY. Please discuss this question and others you have about your medical condition or treatment with your healthcare provider.

Download the **TRODELVY Patient Information** for more details, including approved use(s) and important warnings: https://www.gilead.com/-/media/files/pdfs/medicines/oncology/trodelvy/trodelvy_patient_pi.pdf

The short answer¹

The most common side effects of TRODELVY when used alone include:

- Decreased white blood cell counts
- Decreased red blood cell counts
- Nausea
- Diarrhea
- Feeling tired or weak
- Hair loss
- Increased sugar levels (glucose) in the blood
- Constipation
- Vomiting
- Decreased protein levels (albumin) in the blood
- Increased alkaline phosphatase levels in the blood
- Decreased appetite
- Stomach pain
- Decreased creatinine clearance
- Decreased magnesium and potassium levels in the blood

TRODELVY can cause **serious side effects** including:



Low white blood cell counts, also known as neutropenia, can be severe and lead to infections that can be life-threatening or cause death as early as the first cycle of treatment



Loose or watery stools, also known as diarrhea. Severe diarrhea can lead to loss of too much body fluid (dehydration) and kidney problems.



Nausea and vomiting can be severe.



TRODELVY can cause serious or life-threatening allergic and infusion-related reactions.



TRODELVY may cause fertility problems in females, which could affect your ability to have a baby. Talk to your healthcare provider if fertility is a concern for you.

These are not all the possible side effects of TRODELVY. Talk to your healthcare provider for medical advice about side effects.

What is the most important information I should know about TRODELVY?¹

Some medicines have important warnings that are designed to alert you of serious or life-threatening risks that come with taking the medicine.

TRODELVY has an important warning for: Severe diarrhea and severe, life-threatening, or low white blood cell count (neutropenia) that can cause death, as early as the first treatment cycle.

Your healthcare provider should check your blood cell counts during treatment with TRODELVY and may give a medicine to help prevent low white blood cell count starting in the first cycle of treatment if you have an increased risk for developing low white blood cell count with a fever, also known as febrile neutropenia.

Your healthcare provider should monitor you for diarrhea and give you medicine as needed to help control your diarrhea. If you lose too much body fluid, your healthcare provider may need to give you fluids and electrolytes to replace body

salts. If you develop diarrhea during treatment with TRODELVY, your healthcare provider should check to see if diarrhea may be caused by an infection.

If you develop serious side effects, your healthcare provider may treat you with certain medicines, delay treatment, lower your dose, or permanently stop treatment with TRODELVY.

Who is TRODELVY for?¹

TRODELVY is a prescription medicine used in adults to treat:

- a type of cancer called **triple-negative breast cancer (TNBC)** which is estrogen and progesterone hormone receptor (HR)-negative and human epidermal growth factor receptor 2 (HER2)-negative that has spread to nearby tissues (locally advanced) or to other parts of the body (metastatic)

As the first treatment:

- alone when your TNBC cannot be removed by surgery and you are not a candidate for PD-1 or PD-L1 inhibitor-based therapy

As the second or later treatment:

- after you have received 2 or more prior therapies throughout the body (systemic) for TNBC that cannot be removed by surgery and at least 1 of the therapies was for metastatic TNBC.
- a type of cancer called **hormone receptor (HR) positive and human epidermal growth factor receptor 2 (HER2) negative breast cancer** that has spread to nearby tissues (locally advanced) or to other parts of the body (metastatic)
 - when your HR-positive, HER2-negative breast cancer cannot be removed by surgery and you have received hormonal-based therapy and at least 2 more therapies throughout the body (systemic) for metastatic breast cancer

It is not known if TRODELVY is safe and effective in people with moderate or severe liver problems or in children.

What should I know before starting TRODELVY?¹

Do not receive TRODELVY if you have had a severe allergic reaction to TRODELVY. Ask your healthcare provider if you are not sure.

Before receiving TRODELVY, tell your healthcare provider about all of your medical conditions, including if you have been told that you carry a gene for uridine diphosphate-glucuronosyl transferase 1A1 (UGT1A1)*28. People who carry this gene have an increased risk of getting side effects with TRODELVY, especially low white blood cell counts, a fever while your white blood cell count is low, and low red blood cell counts.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Certain medicines may affect the way TRODELVY works and may increase your risk of side effects.

What are the common side effects?¹

The most common side effects of TRODELVY when used alone include:

- Decreased white blood cell counts
- Decreased red blood cell counts
- Nausea
- Diarrhea
- Feeling tired or weak
- Hair loss
- Increased sugar levels (glucose) in the blood
- Constipation
- Vomiting
- Decreased protein levels (albumin) in the blood
- Increased alkaline phosphatase levels in the blood

- Decreased appetite
- Stomach pain
- Decreased creatinine clearance
- Decreased magnesium and potassium levels in the blood

What are the serious side effects?¹



If you develop serious side effects, your healthcare provider may treat you with certain medicines, delay treatment, lower your dose, or permanently stop treatment with TRODELVY.

What is important for me to know about neutropenia?

Low white blood cell counts can be severe and lead to infections that can be life-threatening or cause death as early as the first cycle of treatment.



Your healthcare provider should check your blood cell counts during treatment with TRODELVY and may give a medicine to help prevent low blood cell count starting in the first cycle of treatment if you have an increased risk for developing low white blood cell count with a fever (febrile neutropenia).

Tell your healthcare provider right away if you develop any of the following signs of infection during treatment with TRODELVY:



- Fever
- Chills
- Cough
- Shortness of breath
- Burning or pain when you urinate

What is important for me to know about diarrhea?



Severe diarrhea can lead to loss of too much body fluid (dehydration) and kidney problems.



Your healthcare provider should monitor you for diarrhea and give you medicine as needed to help control your diarrhea. If you lose too much body fluid, your healthcare provider may need to give you fluids and electrolytes to replace body salts.



If you develop diarrhea during treatment with TRODELVY, your healthcare provider should check to see if diarrhea may be caused by an infection.

Tell your healthcare provider right away:



- the first time that you get diarrhea during treatment with TRODELVY
- if you develop black or bloody stools
- if you develop symptoms of losing too much body fluid and body salts, such as lightheadedness, dizziness or faintness
- if you cannot take fluids by mouth due to nausea or vomiting
- if you cannot get your diarrhea under control within 24 hours

What is important for me to know about allergic and infusion-related reactions?

Do not receive TRODELVY if you have had a severe allergic reaction to TRODELVY. Ask your healthcare provider if you are not sure.



TRODELVY can cause serious or life-threatening allergic and infusion-related reactions. These reactions are more common within 24 hours of receiving TRODELVY.

Tell your healthcare provider right away if you get any of the following symptoms of an allergic or infusion-related reaction during or at any time after your TRODELVY infusion:



- swelling of your face, lips, tongue, or throat
- hives
- skin rash, itching, or flushing of your skin
- fever
- difficulty breathing or wheezing
- lightheadedness, dizziness, feeling faint or passing out

- chills or shaking chills (rigors)
- chest pain

What is important for me to know about nausea and vomiting?



Nausea and vomiting can be severe. Before each dose of TRODELVY, you will receive medicines to help prevent nausea and vomiting. You should be given medicines to take home with you, along with instructions about how to take them to help prevent and treat any nausea and vomiting after you receive TRODELVY.



Tell your healthcare provider right away if you develop nausea or vomiting that is not controlled with the medicines prescribed for you.

Can I take TRODELVY if I am pregnant?¹



Before receiving TRODELVY, tell your healthcare provider if you are pregnant or plan to become pregnant. TRODELVY can harm your unborn baby. Your healthcare provider should check to see if you are pregnant before you start receiving TRODELVY.



Females who can become pregnant should use effective birth control during treatment and for 6 months after your last dose of TRODELVY. Talk to your healthcare provider about birth control choices that may be right for you during this time. Tell your healthcare provider right away if you become pregnant during treatment with TRODELVY.

Males with a female partner who can become pregnant should use effective birth control during treatment and for 3 months after your last dose of TRODELVY.

Glossary

- **Allergic reaction:** happens when your body's immune system overreacts to something and causes symptoms such as rash, hives, swelling, and trouble breathing.
- **Dehydration:** occurs when you use or lose more fluid than you take in, and your body doesn't have enough water and other fluids to carry out its normal functions.
- **Diarrhea:** loose or watery stools.
- **Hormonal-based therapy:** a type of medicine that works by blocking or changing hormones in your body. It is often used to treat certain cancers, like some breast cancers, that rely on hormones to grow.
- **Febrile neutropenia:** a fever while a person has low levels of neutrophils, which may indicate an infection.
- **Fertility problems:** having difficulty getting pregnant or staying pregnant, even after trying for a while.
- **Hormone receptor (HR):** a hormone is a substance made by a gland in your body. A receptor is a protein found inside or on the surface of a cell. When hormones attach (bind) to specific receptors, it causes changes within the cell. There are 2 types of hormone receptors, estrogen and progesterone.
- **Human epidermal growth factor receptor (HER2):** HER2 is a protein that can affect cell growth. A receptor is a protein found inside or on the surface of a cell. When proteins attach (bind) to specific receptors, it causes changes within the cell.
- **Infusion:** slow injection of a substance/medicine into the body.
- **Infusion-related reaction:** reaction during or following infusion of a medicine.
- **Locally advanced:** cancer that has spread to nearby tissues
- **Metastatic:** spread of cancer from the place where it started to other parts of the body.
- **Nausea:** feeling sick to the stomach; stomach discomfort and the sensation of wanting to vomit.
- **Neutropenia:** low levels of neutrophils, a type of white blood cell.
- **PD-L1:** PD-L1 is a protein that is present on some people's tumors, and that can be targeted by specific medications called anti-PD-1 or anti-PD-L1 treatments.
- **Triple negative breast cancer (TNBC):** a type of breast cancer that does not use hormones or HER2 protein to grow.
- **White blood cells:** part of your immune system that help protect you from infections, germs, and other harmful invaders. A low number can reduce your ability to fight infections.

References

1. TRODELVY® Gilead Sciences Inc. Trodelvy (sacituzumab govitecan-hziy) for injection, for intravenous use. U.S. Prescribing Information. Foster City, CA.

More information about TRODELVY

If you would like more detailed information about TRODELVY, please visit:

https://www.gilead.com/-/media/files/pdfs/medicines/oncology/trodelvy/trodelvy_pi.pdf

This is the US FDA-approved Prescribing Information, including the Patient Labeling, for TRODELVY. It will tell you about the uses, warnings, and other important safety information about TRODELVY.

Important note

Gilead Sciences, Inc. is providing this letter in response to your unsolicited request for medical information. Some of the information included in this letter may not be covered in the US FDA-approved Prescribing Information for TRODELVY. Gilead Sciences, Inc. does not intend this letter to be used as medical advice and does not promote use of TRODELVY in a way that has not been approved by the FDA. Please discuss this question and others you may have about your medical condition or treatment with your healthcare provider.

Follow-Up

For any additional questions, please contact Gilead Medical Information at:

☎ 1-866-MEDI-GSI (1-866-633-4474) or 🌐 <https://www.patient.askgileadmedical.com/>

Reporting side effects

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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