



TRODELVY® (sacituzumab govitecan-hziy)

What are the possible side effects?

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 include:

- Decreased white blood cell (leukocyte and lymphocyte) and red blood cell counts
- Feeling tired or weak
- Hair loss
- Constipation
- Increased sugar levels in the blood
- Decreased protein levels (albumin) in the blood
- Decreased appetite
- Changes in kidney function test
- Increased levels of an enzyme called alkaline phosphatase in the blood (test for liver or bone problems)
- Decreased levels of magnesium, potassium, and sodium in the blood

TRODELVY can cause **serious side effects** including



Low levels of white blood cells, also known as neutropenia, are common and can sometimes 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, are common and can sometimes be severe.



Nausea and vomiting are common, and can sometimes 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 that can occur when taking 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 or life-threatening low white blood cell count (neutropenia) as early as the first treatment cycle.

Your healthcare provider should check your blood cell counts during treatment. You may receive a medicine 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 during treatment with TRODELVY and check to see if it is caused by an infection. You may receive a medicine to help control your diarrhea.

If your white blood cell count is too low or your diarrhea is severe and cannot be controlled with medicines, your healthcare provider may lower your dose of TRODELVY, delay your treatment, or permanently stop treatment.

Who is TRODELVY for?¹

TRODELVY is a prescription medication used to treat adults with:

- a type of breast 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**.

TRODELVY may be used:

- when your breast cancer has spread to other parts of the body (metastatic) or cannot be removed by surgery, and
 - if you previously received two or more prior treatments, including at least one treatment for metastatic disease.
- a type of breast cancer that is **HR-positive and HER2-negative (HR+/HER2-)**.

TRODELVY may be used:

- when your breast cancer has spread to other parts of the body or cannot be removed by surgery, and
- if you previously received endocrine therapy and at least two additional treatments for metastatic disease.

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.

What are the common side effects?¹

The most common side effects of TRODELVY include:

- Decreased white blood cell (leukocyte and lymphocyte) and red blood cell counts
- Feeling tired or weak
- Hair loss
- Constipation
- Increased sugar levels in the blood
- Decreased protein levels (albumin) in the blood
- Decreased appetite
- Changes in kidney function test
- Increased levels of an enzyme called alkaline phosphatase in the blood (test for liver or bone problems)
- Decreased levels of magnesium, potassium, and sodium in the blood

What are the serious side effects?¹

What is important for me to know about neutropenia?

Low levels of white blood cells, also known as neutropenia, are common with TRODELVY and can sometimes 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).



If your white blood cell count is too low, your healthcare provider may need to delay treatment or lower your dose of TRODELVY, give you a medicine to treat low blood cell count, or in some cases may permanently stop TRODELVY.



Your healthcare provider may need to give you antibiotic medicines if you develop a fever while your white blood cell level is low.

Call 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?



Diarrhea is common with TRODELVY and can also be severe. 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 the diarrhea may be caused by an infection
- may decrease your dose, delay treatment, or permanently stop TRODELVY if your diarrhea is severe and cannot be controlled with anti-diarrheal medicines

Call your healthcare provider right away:



- the first time that you get diarrhea during treatment with TRODELVY
- if you have black or bloody stools
- if you have symptoms of losing too much body fluid and body salts, such as lightheadedness, dizziness or faintness
- if you are unable to take fluids by mouth due to nausea or vomiting
- if you are not able to 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.

Tell your healthcare provider or nurse right away if you get any of the following symptoms of an allergic or infusion-related reaction during your infusion of TRODELVY or within 24 hours after you receive a dose of TRODELVY:



- 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 pass out
- chills or shaking chills (rigors)

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



Nausea and vomiting are common with TRODELVY and can sometimes 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.

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



Your healthcare provider may decide to decrease your dose, delay treatment, or permanently stop TRODELVY if your nausea and vomiting is severe and cannot be controlled with anti-nausea medicines.

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 their 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 their 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.
- **Antibiotic:** a type of medicine that fights infections caused by bacteria.
- **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.
- **Endocrine hormone 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.
- **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.
- **Nausea:** feeling sick to the stomach; stomach discomfort and the sensation of wanting to vomit.
- **Metastatic:** spread of cancer from the place where it started to other parts of the body.
- **Neutropenia:** low levels of neutrophils, a type of white blood cell.
- **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 Trodelvy Medical Information at:

☎ 1-888-983-4668 or 🌐 <https://www.patient.askgileadmedical.com/>

Reporting side effects

Gilead Sciences, Inc. is providing this letter in response to your unsolicited request for medical information. It is not promotional. It is intended for a US audience 18 years or older.

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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