



# TRODELVY<sup>®</sup> (sacituzumab govitecan-hziy)

## Should I take premedication before receiving TRODELVY?

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](https://www.gilead.com/-/media/files/pdfs/medicines/oncology/trodelvy/trodelvy_patient_pi.pdf)

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### The short answer<sup>1</sup>

TRODELVY can cause serious side effects.



Nausea and vomiting can be severe.



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

Before each dose of TRODELVY, you will receive medicines, which are called premedication, to help prevent infusion-related reactions, and nausea and vomiting.

More detailed information regarding premedication that is recommended for people receiving TRODELVY is provided below.

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## What is the most important information I should know about TRODELVY?<sup>1</sup>

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.

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## Who is TRODELVY for?<sup>1</sup>

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

- with the medicine pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph when your TNBC cannot be removed by surgery and the tumors test positive for PD-L1

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.

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## What is important for me to know about allergic and infusion-related reactions?<sup>1</sup>

**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

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## What is important for me to know about nausea and vomiting?<sup>1</sup>



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.

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## What is premedication?<sup>1</sup>

Some medicines are recommended before each dose of TRODELVY to help prevent infusion-related reactions, and nausea and vomiting. These are called premedication, or medicines that you take before your treatment with TRODELVY.

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## Do I need to take any premedication before receiving TRODELVY?<sup>1</sup>

The following medicines are recommended before each dose of TRODELVY to help prevent nausea and vomiting or infusion-related reactions.

### **Nausea and Vomiting:**



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.

### **Infusion-related reactions:**



Before each dose of TRODELVY, you will receive medicines to help prevent infusion-related reactions. These may include medicines to reduce fever (antipyretics), histamine blockers (antihistamines), and if you have experienced infusion-related reactions before, you may be given medicines that help to reduce inflammation (corticosteroids).

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## **How often do I need to take premedication?<sup>1</sup>**

It is recommended that you take your premedication before each dose of TRODELVY to help prevent infusion-related reactions or nausea and vomiting. Your healthcare provider may decide when to give you premedication depending on your experience before, during, or after your treatment with TRODELVY.

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## **Can I take premedication for other side effects?**

Not all side effects can be prevented with premedication. Talk to your healthcare provider to discuss potential options to help manage other side effects.

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## **What should I know before starting TRODELVY?<sup>1</sup>**

**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.

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.

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## What should I watch out for during or after my TRODELVY infusion?<sup>1</sup>



You will be monitored for side effects during and for at least 30 minutes after you receive each infusion of TRODELVY.



Your healthcare provider may slow down or temporarily stop your infusion of TRODELVY if you have an infusion-related reaction or permanently stop TRODELVY if you have a life-threatening infusion-related reaction.

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

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

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.

## Glossary

- **Allergic reaction:** happens when your body's immune system overreacts to something and causes symptoms such as rash, hives, swelling, and trouble breathing.
- **Antihistamines:** medicines that help reduce or stop allergy symptoms.
- **Antipyretics:** medicines that help prevent or lower a fever.
- **Corticosteroids:** medicines that help reduce inflammation (swelling, redness, and pain).
- **Diarrhea:** loose or watery stools.
- **Febrile neutropenia:** a fever while a person has low levels of neutrophils, which may indicate an infection.
- **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.
- **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.
- **Intravenous (IV):** into the vein.
- **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:** 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.

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## References

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

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## 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](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

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](http://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](http://www.accessdata.fda.gov/scripts/medwatch)

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