

TRODELVY® (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

The short answer¹

TRODELVY can cause serious side effects.



Nausea and vomiting are common with TRODELVY and can sometimes be severe.



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

To prevent these side effects, some medicines, which are called premedication, are recommended to be taken before each dose of TRODELVY.

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

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 lifethreatening 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
- o 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 is important for me to know about allergic and infusion-related reactions?¹

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 infusionrelated 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, also called rigors

What is important for me to know about nausea and vomiting?¹



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.

What is premedication?¹

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

Do I need to take any premedication before receiving TRODELVY?¹

The following medicines are recommended before each dose of TRODELVY to help prevent nausea and vomiting or infusion 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 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 reactions before, you may be given medicines that help to reduce inflammation (corticosteroids).

How often do I need to take premedication?¹

It is recommended that you take premedication before each dose of TRODELVY to help prevent infusion 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.

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.

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.

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 should I watch out for during or after my TRODELVY infusion?¹



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 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)

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.

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.
- 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.
- **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.
- 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: \$\mathbb{2} 1-888-983-4668 or \$\sqrt{0}\$ 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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