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GILEAD | Medical Information

# TRODELVY® (sacituzumab govitecan-hziy)

# How is it given?

**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 answer[1]

If you are receiving TRODELVY on its own, your healthcare provider will give it by an infusion into the vein, also called intravenous or IV therapy. TRODELVY is usually given 1 time each week, on **Day 1** and on **Day 8** of a 21-day treatment cycle.

If you are receiving TRODELVY with pembrolizumab, your healthcare provider will give you TRODELVY into your vein through an intravenous (IV) line. TRODELVY is usually given 1 time each week, on Day 1 and on Day 8 of a 21-day treatment cycle. Your healthcare provider can give you more information about pembrolizumab.

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

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.

Your healthcare provider will decide how long you will continue to receive TRODELVY.

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

Some medications 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



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- 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.

# How is TRODELVY given and for how long?[1]

## Trodelvy given alone



Your healthcare provider will give you TRODELVY into your vein through an intravenous (IV) line.

TRODELVY is usually given 1 time each week, on **Day 1** and on **Day 8** of a 21-day treatment cycle.






Your healthcare provider will calculate your dose based on your current body weight in kilograms (kg). **The dose is 10 mg for every kilogram** of



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body weight. A kilogram is a measure of weight, 1 kg is equal to 2.2 pounds (lb).

You will receive the first dose of TRODELVY over 3 hours. If you tolerate the first dose well, future doses may be given over 1 to 2 hours.

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

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.

Your healthcare provider will decide how long you will continue to receive TRODELVY.

## TRODELVY given with pembrolizumab

If you are receiving TRODELVY with pembrolizumab, your healthcare provider will give them separately. Your healthcare provider can give you more information about pembrolizumab.

TRODELVY is usually given 1 time each week, on **Day 1** and on **Day 8** of a 21-day cycle.




## Can TRODELVY be given at a different dose or schedule?

The recommended dose and schedule of TRODELVY treatment are based on clinical trial results which showed that 10 mg for every kg of body weight, given by intravenous infusion, on Day 1 and on Day 8 of a 21-day treatment cycle, provided the best balance of efficacy (how well a medicine works) and side effects.

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. Gilead is unable to provide you with an alternative dose or



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treatment schedule. Please discuss this question and others you have your healthcare provider.

## Can my dose of TRODELVY be adjusted if I have side effects?[1]

Tell your healthcare provider right away if you develop any side effects while receiving TRODELVY.

If needed, your healthcare team will decide when and how much to adjust your dose of TRODELVY based on the side effects you may experience. They will order any relevant tests and may give you medicines to help control your side effects. 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

- **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-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
- **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



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- **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. Patient 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

## Data Privacy

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