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]

Your healthcare provider will give you TRODELVY by intravenous infusion, a type of injection into a vein. It is given 1 time each week, on **Day 1** and on **Day 8** of a 21-day treatment cycle.

Before each dose of TRODELVY, you will receive medicines to help prevent you from feeling sick and being sick, also known as nausea and vomiting, and to prevent infusion-related reactions.

Your healthcare provider will monitor you for side effects and 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 medication.

TRODELVY has an important warning for: Severe or life-threatening low white blood cell count (neutropenia) and severe diarrhea. 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 medicine 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 called **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 hormone (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.

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

Your healthcare provider will give you TRODELVY by intravenous infusion, a type of injection into a vein.

It is 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 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 side effect, or permanently stop TRODELVY if you have a life-threatening infusion-related side effect.

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

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.

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Your healthcare provider may decrease your dose of TRODELVY, delay treatment, or permanently stop TRODELVY if you experience certain side effects.

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

Talk to your healthcare provider as soon as you experience 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. In some cases, your healthcare provider may decide to stop your TRODELVY treatment.

Glossary

Clinical trial: a study in people that may help to find out how well a medicine works or how safe it is.

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-related reaction: reaction during or following infusion of a drug.

Triple-negative breast cancer: breast cancer that does not use hormones or HER2 protein to grow.

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

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