

TRODELVY[®] (troh-DELL-vee)
(sacituzumab govitecan-hziy) for injection, for intravenous use

MOST IMPORTANT INFORMATION ABOUT TRODELVY

TRODELVY can cause serious side effects, including:

- **Low white blood cell count (neutropenia)** which is common and can sometimes be severe and lead to infections that can be life-threatening or cause death. Your healthcare provider should check your blood cell counts during treatment. If your white blood cell count is too low, your healthcare provider may need to lower your dose, give you a medicine to help prevent low blood cell count with future doses of TRODELVY, or in some cases may stop TRODELVY. Your healthcare provider may need to give you antibiotic medicines if you develop fever while your white blood cell count is low. **Call your healthcare provider right away if you develop any of the following signs of infection:**

- fever
- cough
- burning or pain when you urinate
- chills
- shortness of breath

- **Severe diarrhea.** Diarrhea is common and can 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 it. 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 it may be caused by an infection. Your healthcare provider may decrease your dose or 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 dehydration, 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

ABOUT TRODELVY

TRODELVY is a prescription medicine used to treat adults with:

- 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 other parts of the body (metastatic) or cannot be removed by surgery, **and** who have previously received two or more prior treatments, including at least one treatment for metastatic disease.
- HR-positive and HER2-negative breast cancer that has spread to other parts of the body or cannot be removed by surgery, **and** who previously received endocrine therapy **and** at least two additional treatments for metastatic disease.
- bladder cancer and cancers of the urinary tract that have spread or cannot be removed by surgery. TRODELVY may be used if you have received a platinum-containing chemotherapy medicine **and** also received an immunotherapy medicine.

It is not known if TRODELVY is safe and effective in people with moderate or severe liver problems or in children.

Do NOT receive TRODELVY if you have had a severe allergic reaction to TRODELVY. Ask your healthcare provider if you are not sure.

POSSIBLE SIDE EFFECTS OF TRODELVY

TRODELVY can also cause serious side effects, including:

- **Allergic and infusion-related reactions** which can be serious and life-threatening. Tell your healthcare provider or nurse right away if you get any of the following symptoms during an infusion or within 24 hours after:
 - 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)

IMPORTANT FACTS

This is only a brief summary of important information about TRODELVY and does not replace talking to your healthcare provider about your condition and your treatment.

POSSIBLE SIDE EFFECTS OF TRODELVY (cont'd)

- **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 along with medicines to take home with instructions about how to take them. 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 or stop TRODELVY if your nausea and vomiting is severe and cannot be controlled with anti-nausea medicines.

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 enzyme called alkaline phosphatase in the blood (test for liver or bone problems), and decreased levels of magnesium, potassium, and sodium in the blood.

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.

Before and during treatment with TRODELVY, your healthcare provider will need to do tests to monitor your health. Tell your healthcare provider right away if you have any new symptoms while taking TRODELVY.

These are not all of the possible side effects of TRODELVY. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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 UGT1A1*28, which can increase your risk of getting side effects with TRODELVY, especially low white blood cell counts, with or without a fever, and low red blood cell counts.
- have liver problems.
- 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 your 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 your last dose of TRODELVY.
- are breastfeeding or plan to breastfeed. It is not known if TRODELVY passes into your breastmilk and can harm your baby. Do not breastfeed during treatment and for 1 month after your last dose of TRODELVY.

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.

HOW TO RECEIVE TRODELVY

- Your healthcare provider will give you TRODELVY into your vein through an intravenous (IV) line.
- TRODELVY is given 1 time each week, on Day 1 and on Day 8 of a 21-day treatment cycle.
- You will receive the first dose over 3 hours; if well-tolerated, future doses may be given over 1 to 2 hours.
- Before each dose, 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 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 stay on treatment.

GET MORE INFORMATION

This is only a brief summary of important information about TRODELVY. Talk to your healthcare provider or pharmacist to learn more.

To learn more, go to TRODELVY.com or call 1-844-TRODELVY (1-844-876-3358)