

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)** can be severe and lead to infections that can be life-threatening or cause death as early as the first cycle of treatment. Your healthcare provider should check your blood cell counts during treatment and may give a medicine to help prevent neutropenia starting in the first cycle of treatment if you have an increased risk for developing low white blood cell count with a fever (febrile neutropenia). **Tell 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** 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.
 - **Tell your healthcare provider right away:**
 - the first time that you get diarrhea during treatment with TRODELVY
 - if you develop black or bloody stools
 - if you develop symptoms of dehydration, such as lightheadedness, dizziness or faintness
 - if you cannot take fluids by mouth due to nausea or vomiting
 - if you cannot get your diarrhea under control within 24 hours

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.

ABOUT TRODELVY

TRODELVY[®] (sacituzumab govitecan-hziy) is a prescription medicine used in adults to treat:

- Triple-Negative Breast Cancer (TNBC) that cannot be removed by surgery (unresectable) and has spread to nearby tissues (locally advanced) or other parts of the body (metastatic).
 - As the first treatment:
 - alone when 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 the tumors test positive for PD-L1.
 - As the second or later treatment, after you received 2 or more prior therapies throughout the body (systemic) and at least 1 of the therapies was for metastatic TNBC.
- Hormone Receptor (HR) positive, Human Epidermal Growth Factor Receptor 2 (HER2) negative breast cancer that cannot be removed by surgery (unresectable) and has spread to nearby tissues (locally advanced) or other parts of the body (metastatic), and you 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 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** can be serious or life-threatening. 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 during your or at any time after 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

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

The most common side effects of TRODELVY when used alone include decreased white blood cell and red blood cell counts, nausea, diarrhea, feeling tired or weak, hair loss, increased sugar levels (glucose) in the blood, constipation, vomiting, decreased protein levels (albumin) in the blood, increased alkaline phosphatase in the blood, decreased appetite, stomach pain, decreased creatinine clearance, and decreased magnesium and potassium levels in the blood.

The most common side effects of TRODELVY when used with pembrolizumab include decreased white blood cell and red blood cell counts, diarrhea, nausea, feeling tired or weak, hair loss, increased alkaline phosphatase, sugar (glucose), and liver enzyme levels in the blood, constipation, rash, decreased potassium levels in the blood, increased lactate dehydrogenase levels in the blood, vomiting, stomach pain, headache, increased eosinophil levels in the blood, and decreased protein levels (albumin) 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.

These are not all of the possible side effects of TRODELVY. Call your doctor for medical advice about side effects. You are encouraged to report side effects to the 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. It is not known if TRODELVY is safe in people with moderate or severe 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 and may increase your risk of side effects.

HOW TO RECEIVE TRODELVY

- 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.
- 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).