

For adults with bladder cancer and cancers of the urinary tract that have spread (metastatic) or cannot be removed by surgery, and who have received a platinum-containing chemotherapy medicine and also received an immunotherapy medicine.

TRODELVY is approved based on medical studies that measured how many patients responded and how long they responded. Continued approval may depend on benefit demonstrated in additional medical studies.

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

FREQUENTLY ASKED QUESTIONS ABOUT TRODELVY

Not actual patients.

IMPORTANT SAFETY INFORMATION

TRODELVY can cause serious side effects, including low white blood cell count and diarrhea:

- **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, chills, cough, shortness of breath, or burning or pain when you urinate.
- **Severe diarrhea.** Diarrhea is common and can be severe. 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 (dehydration), your healthcare

provider may need to give you fluids and electrolytes to replace body salts. If diarrhea happens later in your treatment, your healthcare provider may check you 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; or if you are not able to get your diarrhea under control within 24 hours.

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

Please see full Important Safety Information on pages 12–13. Please see [Important Facts about TRODELVY](#), including Important Warning.

Learn more at [TRODELVY.com](https://www.trodelvy.com)



TRODELVY™
sacituzumab govitecan-hziy
180 mg for injection

TREATMENT INFORMATION

What is TRODELVY?

TRODELVY® (sacituzumab govitecan-hziy) is a prescription medicine used to treat adults with bladder cancer and cancers of the urinary tract that have spread (metastatic) or cannot be removed by surgery, and who have received a platinum-containing chemotherapy medicine and also received an immunotherapy medicine.

TRODELVY is approved based on medical studies that measured how many patients responded and how long they responded. Continued approval may depend on benefit demonstrated in additional medical studies.

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How is TRODELVY thought to work?

TRODELVY is a type of drug called an antibody-drug conjugate, or ADC for short. Unlike traditional chemotherapy, ADCs contain 3 parts: an antibody, an anti-cancer drug, and a linker. The antibody looks for a specific protein, in this case Trop-2, which is found to be overexpressed in many cancers, including bladder cancer. The anti-cancer drug kills cancer cells once they're found. The linker connects the anti-cancer drug to the antibody.

Scientists discovered that patients with metastatic bladder cancer have tumor cells that more often contain the Trop-2 protein. TRODELVY binds to cells with Trop-2.

Information from laboratory studies suggest that this is how TRODELVY works. The clinical benefit of these observations is unknown.

How is TRODELVY given?

You will receive TRODELVY from your healthcare provider as an infusion into your vein. Each treatment cycle is 21 days. Doses are given once a week for 2 weeks, on Day 1 and Day 8, followed by 1 week off.

- 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 reactions, and reduce or prevent 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. Your healthcare provide may temporarily reduce the dose of TRODELVY to help manage side effects. In certain instances, permanent discontinuation may be recommended
- You and your healthcare provider will decide how long you will continue to receive TRODELVY

What are some of the things that need to be done before I am given TRODELVY?

Before your first infusion, you may be given medicines such as antihistamines or corticosteroids. You may also receive a fever reducer. These medicines can help prevent reactions to the infusion. You may also be given medicine to help prevent nausea and vomiting.

On Day 1 and Day 8, you may have a short physical exam to check your blood pressure, pulse, breathing, and temperature. Your weight will also be measured to find the right dose of TRODELVY. An intravenous (IV) tube will be put in your vein and a blood sample may be taken.

How often will I receive TRODELVY?

TRODELVY is an IV infusion. It is given once a week for 2 weeks, on Day 1 and Day 8, followed by 1 week off. Each treatment cycle is 3 weeks, which means treatment cycles repeat every 21 days.

How long will I be on TRODELVY?

You and your healthcare provider will decide how many treatment cycles you receive. This may be based on factors such as whether your tumor has responded to treatment or your body's ability to tolerate treatment.

Will TRODELVY affect other medical conditions I may have?

TRODELVY may affect your body in different ways.

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 uridine diphosphate-glucuronosyl transferase 1A1 (UGT1A1)*28. People who carry this gene have an increased risk of getting side effects with TRODELVY, especially a fever while your white blood cell count is low, 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
- 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.

Tell your healthcare provider right away if you or your partner become pregnant during treatment with TRODELVY. Please see Important Safety Information on page 10 or Important Facts, located in brochure pocket, for more information on the use of birth control during and after TRODELVY treatment.

Notes

IMPORTANT SAFETY INFORMATION (cont'd)

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 your infusion of TRODELVY 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; or chills or shaking chills (rigors).

Please see full Important Safety Information on pages 12–13. Please see Important Facts about TRODELVY, including Important Warning.

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SIDE EFFECTS

What are the possible side effects of TRODELVY?

TRODELVY can cause **serious side effects**, including:



Low white blood cell count (neutropenia). Low white blood cell counts are common with TRODELVY and can sometimes be severe and lead to infections that can be life-threatening or cause death. Call your healthcare provider right away if you develop any of the following signs of infection during treatment with TRODELVY: fever, chills, cough, shortness of breath, burning or pain when you urinate.



Severe diarrhea. Diarrhea is common with TRODELVY and can also be severe. 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 losing too much body fluid (dehydration) and body salts, such as lightheadedness, dizziness or faintness; if you are unable to take fluids by mouth due to nausea or vomiting; or if you are not able to get your diarrhea under control within 24 hours.



Allergic and infusion-related reactions. Serious allergic reactions can happen during treatment with TRODELVY, including life-threatening allergic reactions, and infusion-related 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; or chills or shaking chills (rigors).



Nausea and vomiting. 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 or stop TRODELVY if your nausea and vomiting is severe and cannot be controlled with anti-nausea medicines.

Most common side effects. The most common side effects of TRODELVY include feeling tired or weak, hair loss, decreased red blood cell count, constipation, decreased appetite, rash, and stomach-area (abdominal) pain or discomfort.

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 may report side effects to FDA at 1-800-1088.

Notes

Can I take a break during the infusion if I start feeling unwell?

If you start to feel unwell, alert the nurse or other healthcare team member immediately. They will discuss your options with you.

Will I experience hair loss?

TRODELVY is likely to cause hair loss, even for patients who have not lost hair before. This may happen soon after starting treatment.

Are there things I can do to help with certain side effects?

Yes, your healthcare provider will discuss medications you may take before, during, or after treatment to help manage certain side effects. These may include medication to help prevent nausea and vomiting and antidiarrheal medication. Your healthcare provider may recommend treatments for other side effects as well. Granulocyte colony-stimulating factor (G-CSF) was used in 44% of patients who received TRODELVY. Your healthcare provider may determine which side effects require reducing your dose and which side effects may require interrupting your treatment or permanently discontinuing TRODELVY.

There may also be small lifestyle changes you can make to help manage some side effects. Tips to help manage side effects at home are provided on the following pages. Be sure to consult your healthcare provider first and discuss any side effects that you may have.

You may report side effects to FDA at 1-800-FDA-1088.



Not an actual patient.

Please see full Important Safety Information on pages 12–13.
Please see Important Facts about TRODELVY, including Important Warning.

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SIDE EFFECT MANAGEMENT AND TIPS

Some side effects of TRODELVY are similar to those you may have experienced while taking chemotherapy for bladder cancer, and the severity is different for everyone. Contact your healthcare provider if you experience any side effects that require immediate attention and support.

The most common side effects seen during clinical trials with TRODELVY were: nausea, diarrhea, feeling tired or weak (fatigue), decreased white blood cell count (neutropenia), hair loss (alopecia), decreased red blood cell count (anemia), vomiting, constipation, decreased appetite, rash, and abdominal pain.

Decreased white blood cell count (neutropenia)

TRODELVY may lower your neutrophils, a type of white blood cell. This can put you at higher risk of infection. Your healthcare provider should check your blood cell counts during treatment with TRODELVY. If your white blood cell count is too low, your healthcare provider may need to lower your dose of TRODELVY, 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.

Some tips that may help:

- Wash your hands often with soap and warm water
- Avoid large crowds and stay away from people who are sick
- Thoroughly wash raw fruits and vegetables before eating them

Diarrhea

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 (dehydration) your healthcare provider may need to give you fluids and electrolytes to replace body salts. If diarrhea happens later in your treatment, your healthcare provider may check you to see if the diarrhea 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.

Some tips that may help:

- Slowly sip cool, clear liquids throughout the day to stay hydrated
- Eat frequent, small meals that are bland and low-fiber such as bananas, white rice, and toast
- Avoid alcohol, caffeine, greasy or spicy foods, and limit dairy products and raw vegetables

Nausea and vomiting

Your healthcare provider may provide medications to help prevent nausea and vomiting. Follow the directions he or she gives you.

Some tips that may help:

- Eat 5 to 6 small meals or snacks a day rather than 3 large meals
 - Eat bland foods, such as toast and crackers
 - Try eating small amounts of foods that are high in calories
- Slowly sip cool, clear liquids such as ginger ale, apple juice, broth, or tea throughout the day to stay hydrated
- Try to take deep, slow breaths or get fresh air when you begin to feel sick
- If you are vomiting, ice chips or frozen juice chips may help you take in fluids more easily

Feeling tired or weak (fatigue)

It's common for treatment to leave you feeling tired and weak.

Some tips that may help:

- Plan time to relax and rest, and create a schedule that works for you
- Take short naps, and try to get 7 to 8 hours of sleep each night
- Try to stay active, but talk with your healthcare provider before starting a new exercise routine
- Drink plenty of water and eat well
- Reduce stress by trying meditation, yoga, reading, or keeping a diary

Hair loss (alopecia)

Hair loss is common with treatment.

Some tips that may help:

- If you are considering a wig, buying it before treatment begins can help you match it to the color and style of your hair
- Check to see if your insurance company will cover the cost for a wig (cranial prosthesis)
- Wear a hair net at night or sleep on a satin pillowcase to keep hair from coming out in clumps
- Protect your scalp from the sun by using sunscreen, and wear a hat or scarf outside
- The effectiveness and safety of cooling caps is still being researched. If you are curious about this option, talk to your healthcare provider. Also, ask if the treatment center has experience in using cooling caps and how successful they have been

Decreased red blood cell count (anemia)

A low red blood cell count can be common with treatment. This can leave you feeling tired and weak.

Some tips that may help:

- Limit activities and get plenty of rest
- Take short naps, and try to get 7 to 8 hours of sleep each night
- Eat a well-balanced diet that includes proteins (such as meat, fish, eggs, dairy, and nuts), and drink plenty of water

TREATMENT DAYS

How long does a TRODELVY infusion take?

Your first infusion will take approximately 3 hours. After that, if prior treatment was well tolerated, your healthcare provider may decide to reduce your infusion time to 1 to 2 hours.

What would be helpful for me to know on my treatment days?

Treatment days can be exhausting. Here are a few tips to consider:

- If you think you will feel too tired to drive, arrange for transportation to and from the infusion center
- Bring things to pass the time. Books, audio books, and magazines are great choices. Headphones and a tablet or phone for music, shows, movies, or podcasts can be helpful
- Consider downloading a meditation app
- Wear comfortable clothing and bring a blanket in case you start to feel cold
- Until you know how TRODELVY will affect you, consider asking someone to be home to help you on treatment days. Once you have had a few treatments, you can have a better sense of how you will feel and what kind of help you may or may not need on treatment days

Will I need to have a port for my infusion?

You do not need to have a port inserted to receive treatment with TRODELVY. However, if you already have a port, it can be used for the infusion.

A port can help reduce the number of times a nurse needs to insert a needle into your vein. This can be helpful if your veins are small or damaged.

IMPORTANT SAFETY INFORMATION *(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.

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. (See next page for more.)

What should I expect on treatment days?

Your healthcare provider may recommend the following on treatment days:

1 PRE-INFUSION

You may be given medicines before your infusion to help prevent infusion reactions, including a fever reducer, antihistamines, or corticosteroids. Your healthcare provider may also give you medicine to help reduce or prevent nausea or vomiting.

2 INFUSION

Your first infusion of TRODELVY will take approximately 3 hours. Your healthcare provider will observe you during the infusion and for at least 30 minutes afterward. After that, if prior treatment was well tolerated, your infusions with TRODELVY may take 1 to 2 hours.

3 OBSERVATION

After each infusion, your healthcare provider will watch you for reactions for at least 30 minutes. If you experience any side effects while taking TRODELVY, tell your healthcare provider right away. Please read the Important Safety Information on pages 12 and 13 of this brochure.

How can my healthcare provider and I tell if the treatment is working?

Your healthcare provider will tell how well your treatment is working by doing different exams or tests. Ask your healthcare provider to explain the results to you and discuss if your treatment is working.

Keep in mind that side effects do not tell you if the treatment is, or is not, working.

Notes

Tell your healthcare provider about any side effects that bother you or do not go away. Call your healthcare provider for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

ACCESS SERVICES

What if I need help paying for TRODELVY?

TRODELVY ACCESS SUPPORT can help you determine your benefits and coverage for TRODELVY and provide support throughout your treatment journey.



Open your camera and point your smart device at the QR code to open [TRODELVY.com](https://trodelvy.com)

Reimbursement support services include:

- Benefits and coverage
- Out-of-pocket cost assessment
- Patient support programs
- Alternate assistance options

The TRODELVY Savings Program can provide financial assistance toward the cost of TRODELVY.

TRODELVY ACCESS SUPPORT:

Phone: 1-844-TRODELVY (1-844-876-3358)
Monday–Friday, 9 AM – 7 PM ET
Fax: 1-833-851-4344

Please visit [TRODELVY.com](https://trodelvy.com) for more information.

IMPORTANT SAFETY INFORMATION *(cont'd)*

Before receiving TRODELVY, tell your healthcare provider about all of your medical conditions, including if you: *(cont'd)*

- 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. 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.
 - 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.
 - 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.
 - Tell your healthcare provider right away if you or your partner become pregnant during treatment with 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.

SUPPORT GROUPS

What support groups are available for patients with advanced bladder cancer?

There are additional resources that may be helpful to patients, families, and caregivers dealing with bladder cancer. The following resources are not controlled or owned by Gilead Sciences, Inc (Gilead). Gilead is not responsible for their content.

Bladder Cancer Advocacy Network (BCAN): Connect with a community of patients, caregivers, survivors, advocates, and medical and research professionals dedicated to helping people with bladder cancer.
bcan.org

American Cancer Society: Find local cancer support programs and resources.
cancer.org/treatment/support-programs-and-services.html

Cancer Support Community: Access information, support, and other resources.
cancersupportcommunity.org/bladder-cancer

IMPORTANT SAFETY INFORMATION *(cont'd)*

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.

The most common side effects of TRODELVY include feeling tired or weak, hair loss, decreased red blood cell count, constipation, decreased appetite, rash, and stomach-area (abdominal) pain or discomfort.

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.

Please see full Important Safety Information on pages 12–13.
Please see [Important Facts about TRODELVY](#), including **Important Warning.**



IMPORTANT SAFETY INFORMATION

WHAT IS TRODELVY?

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- **Severe diarrhea.** Diarrhea is common and can be severe. 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 (dehydration), your healthcare provider may need to give you fluids and electrolytes to replace body salts. If diarrhea happens later in your treatment, your healthcare provider may check you 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; or if you are not able to get your diarrhea under control within 24 hours.

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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 your infusion of TRODELVY 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; or chills or shaking chills (rigors).

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.

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. 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.
 - 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.
 - 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.
 - Tell your healthcare provider right away if you or your partner become pregnant during treatment with 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.

The most common side effects of TRODELVY include feeling tired or weak, hair loss, decreased red blood cell count, constipation, decreased appetite, rash, and stomach-area (abdominal) pain or discomfort.

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.

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Not actual patients.

Learn more at TRODELVY.com

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 - **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; or if you are not able to get your diarrhea under control within 24 hours.

Please see full Important Safety Information on pages 12–13. Please see [Important Facts](#) about TRODELVY, including Important Warning.



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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 feeling tired or weak, hair loss, decreased red blood cell count, constipation, decreased appetite, rash, and stomach-area (abdominal) pain or discomfort.

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.

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. 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 (dehydration) your healthcare provider may need to give you fluids and electrolytes to replace body salts. If diarrhea happens later in your treatment, your healthcare provider may check you 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:

- breast cancer that is estrogen and progesterone hormone receptor (HR) negative, and human epidermal growth factor receptor 2 (HER2)-negative (also called triple-negative breast cancer) 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.
- 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)

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.
 - 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.
 - Tell your healthcare provider right away if you or your partner become pregnant during treatment with 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 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)