

# TRODELVY®

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

### 1. Why am I being given TRODELVY?

TRODELVY contains the active ingredient sacituzumab govitecan. TRODELVY is used to treat adults with a type of breast cancer known as triple-negative breast cancer, that has spread to other parts of the body or cannot be removed by surgery, and that has previously been treated with at least two therapies for breast cancer. TRODELVY is also used to treat adults with a type of breast cancer known as hormone receptor (HR)-positive and human epidermal growth factor 2 (HER2)-negative, that has previously been treated by endocrine therapy (including a CDK 4/6 inhibitor) and at least two additional other therapies for locally advanced or metastasised cancer. For more information, see Section [1. Why am I being given TRODELVY?](#) in the full CMI.

### 2. What should I know before I receive TRODELVY?

Do not use if you have ever had an allergic reaction to TRODELVY or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I receive TRODELVY?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with TRODELVY and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How am I given TRODELVY?

TRODELVY is prepared by a healthcare professional and will be given to you in a hospital or clinic by a doctor or nurse. Your doctor will give you TRODELVY into your vein through an intravenous (IV) line. You will receive TRODELVY once per week, on Day 1 and on Day 8 of a 21-day treatment cycle. Your doctor will decide how long you will continue to receive TRODELVY.

More instructions can be found in Section [4. How am I given TRODELVY?](#) in the full CMI.

### 5. What should I know while receiving TRODELVY?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist, pharmacist, or surgeon you visit that you are using TRODELVY.</li><li>• Tell your doctor right away if you develop fever, chills or feel unwell, severe diarrhoea, have black or bloody stools, experience signs of an allergic reaction, become pregnant or think you may be pregnant.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop your TRODELVY treatment or miss any doctor's appointments without talking to your doctor first.</li><li>• Do not take any other medicines without first telling your doctor or consulting with a pharmacist.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• TRODELVY may cause tiredness in some people. If you feel tired, weak or dizzy, do not drive or use machines until symptoms stop.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Tell your doctor if you drink alcohol. The effects of alcohol on this medicine were not assessed as part of its registration.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• TRODELVY will be stored in the pharmacy or on the hospital ward in a refrigerator at a temperature between 2°C and 8°C.</li></ul>

For more information, see Section [5. What should I know while receiving TRODELVY?](#) in the full CMI.

### 6. Are there any side effects?

The most common side effects you may feel while receiving TRODELVY include diarrhoea, nausea, constipation, vomiting, hair loss, and feeling tired. Serious side effects can include infections caused by a low white blood cell count. Call your doctor right away if you experience fever, chills, cough, shortness of breath, or burning or pain when you urinate. Other serious side effects can include allergic reactions and severe diarrhoea or vomiting that causes you to become dehydrated. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

# TRODELVY®

**Active ingredient:** *sacituzumab govitecan* (Sah-see-TOO-zoo-mab GOH-vih-TEE-kan)

## Consumer Medicine Information (CMI)

This leaflet provides important information about using TRODELVY. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using TRODELVY.**

Where to find information in this leaflet:

- [1. Why am I being given TRODELVY?](#)
- [2. What should I know before I receive TRODELVY?](#)
- [3. What if I am taking other medicines?](#)
- [4. How am I given TRODELVY?](#)
- [5. What should I know while receiving TRODELVY?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I being given TRODELVY?

TRODELVY contains the active ingredient **sacituzumab govitecan**.

TRODELVY belongs to a group of medicines known as anti-neoplastic (anti-cancer) agents. There are different classes of anti-cancer agents.

TRODELVY is designed to work differently to traditional anti-cancer agents (e.g., chemotherapy).

TRODELVY is made up of three components:

- a monoclonal antibody that recognises and attaches to certain cancer cells, and
- a substance intended to kill cancer cells, and
- a linker that links the antibody to the substance.

TRODELVY is designed to target and deliver the anti-cancer substance directly to certain cancer cells to stop the growth and spread of the cancer.

TRODELVY is used to treat adults with:

- a type of breast cancer that is oestrogen and progesterone hormone receptor (HR) negative, and human epidermal growth factor receptor 2 (HER2)-negative (also called triple-negative breast cancer), and
  - has spread to other parts of the body or cannot be removed by surgery, and
  - has previously been treated with at least two therapies for breast cancer.
- a type of breast cancer that is HR positive and HER2-negative. TRODELVY may be used:

- if you previously have received endocrine therapy (including a CDK 4/6 inhibitor) and
- if you previously have received at least two additional systemic therapies for locally advanced or metastatic disease.

## 2. What should I know before I receive TRODELVY?

### Warnings

**Do not use TRODELVY if:**

- you are allergic to sacituzumab govitecan, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

**Check with your doctor if you:**

- have any other medical conditions, including:
  - liver problems
  - if you have been told you carry a gene for uridine diphosphate-glucuronosyl transferase 1A1 (UGT1A1)\*28
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. [Are there any side effects?](#)

### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

TRODELVY may cause harm to your unborn baby. You should not become pregnant during treatment with TRODELVY.

If you are a female who can become pregnant:

- Your doctor should do a pregnancy test before you start treatment with TRODELVY.
- You should use effective birth control (contraception) during treatment, and for 6 months after your last dose of TRODELVY.

If you are a male with a female partner who can become pregnant:

- You should use effective birth control during treatment, and for 3 months after your last dose of TRODELVY.

Talk to your doctor if you are breastfeeding or intend to breastfeed. You must not breastfeed during treatment with TRODELVY, and for 1 month after your last dose.

TRODELVY may cause fertility problems in females, which could affect your ability to have a baby. Talk to your doctor if fertility is a concern for you.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with TRODELVY and affect how it works.**

**Medicines that may increase the effect of TRODELVY include:**

- Medicines that work by inhibiting an enzyme known as UGT1A1, such as atazanavir sulfate.

**Medicines that may reduce the effect of TRODELVY include:**

- Medicines that work by inducing an enzyme known as UGT1A1, such as efavirenz, fosamprenavir/ritonavir, tipranavir/ritonavir, and rifampicin.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect TRODELVY.**

### 4. How am I given TRODELVY?

**How much is given**

- TRODELVY is prepared by a healthcare professional and will be given to you in a hospital or clinic by a doctor or nurse.
- Your doctor will give you TRODELVY into your vein through an intravenous (IV) line.
- You will receive TRODELVY once per week, on Day 1 and on Day 8 of a 21-day treatment cycle.
- 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 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 doctor 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 doctor will decide how long you will continue to receive TRODELVY.

**If you miss a dose of TRODELVY**

As TRODELVY is given to you under the supervision of your doctor, you are unlikely to miss a dose. However, if you forget or miss your appointment to receive TRODELVY,

make another appointment as soon as possible. Do not wait until your next planned appointment. Your doctor will decide when you should be given your next dose of TRODELVY.

**If you are given too much TRODELVY**

As TRODELVY is given to you under the supervision of your doctor, you are unlikely to be given too much. However, if you experience any side effects after receiving TRODELVY, tell your doctor or nurse immediately.

### 5. What should I know while receiving TRODELVY?

**Things you should do**

**Keep all your doctor's appointments so that your progress can be checked.**

**Tell your doctor or pharmacist if you feel like your condition is worsening or have new side effects while you are receiving TRODELVY.**

**Call your doctor straight away if you:**

- Develop any signs of infection, including fever, chills, cough, shortness of breath or a burning or pain when you urinate
- Experience diarrhoea that lasts longer than 24 hours, or makes you feel like you are losing too much body fluid (e.g., light-headedness, dizziness, faintness)
- Have black or bloody stools
- Experience signs of an allergic reaction, such as swelling on the face, difficulty breathing, skin rash, chills, fever or dizziness
- Become pregnant or think you may be pregnant.

Remind any doctor, dentist or pharmacist you visit that you are being given TRODELVY. If you are going to have surgery, tell the surgeon or anaesthetist that you are being given TRODELVY.

**Things you should not do**

- Do not stop your TRODELVY treatment or miss any doctor's appointments without talking to your doctor first.
- Do not take any other medicines, whether they require a prescription or not, without first telling your doctor or consulting with a pharmacist.

**TRODELVY may affect your fertility**

Talk to your doctor if you are planning on having children.

**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.

Your doctor should check your blood cell counts during treatment with TRODELVY. If your white blood cell count is too low, your doctor 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 doctor may need to give you antibiotic medicines if you develop fever while your white blood cell count is low.

**Call your doctor right away or go straight to the Emergency Department at your nearest hospital 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.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how TRODELVY affects you.**

TRODELVY may cause tiredness in some people. If you feel tired, weak or dizzy, do not drive or use machines until symptoms stop.

### Drinking alcohol

Discuss alcohol use with your doctor.

### Looking after your medicine

TRODELVY will be stored in the pharmacy or on the hospital ward in a refrigerator at a temperature between 2°C and 8°C.

### Getting rid of any unwanted medicine

Your doctor, nurse or pharmacist will dispose of any left-over medicine.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<p><b>Stomach or bowel-related:</b></p> <ul style="list-style-type: none"> <li>• Diarrhoea</li> <li>• Nausea</li> <li>• Vomiting</li> <li>• Loss of appetite</li> <li>• Constipation</li> <li>• Stomach pain</li> </ul> <p><b>General body-related</b></p> <ul style="list-style-type: none"> <li>• Feeling tired</li> <li>• Feeling weak or low in energy</li> <li>• Dizziness or light-headedness</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<ul style="list-style-type: none"> <li>• Hair loss</li> <li>• Cold hands and feet</li> <li>• Bleeding or bruising easily</li> </ul> <p><b>Blood test-related:</b></p> <ul style="list-style-type: none"> <li>• Lower white blood cell count</li> <li>• Lower red blood cell count</li> <li>• Lower platelet count</li> </ul>	
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### Serious side effects

Serious side effects	What to do
<p><b>Allergic reaction:</b></p> <ul style="list-style-type: none"> <li>• Swelling of face, lips, tongue or throat</li> <li>• Difficulty breathing or wheezing</li> <li>• Skin rash or reddening of skin</li> <li>• Hives</li> <li>• Dizziness or light-headedness</li> <li>• Chills or shaking</li> <li>• Fever</li> </ul> <p><b>Infection related to low white blood cell count (neutropenia):</b></p> <ul style="list-style-type: none"> <li>• Fever</li> <li>• Chills</li> <li>• Cough</li> <li>• Shortness of breath or pain when taking a deep breath</li> <li>• Burning or pain when you urinate</li> <li>• Infection of the lungs (pneumonia)</li> </ul> <p><b>Stomach or bowel-related:</b></p> <ul style="list-style-type: none"> <li>• Severe diarrhoea; <ul style="list-style-type: none"> <li>• if you have black or bloody stools</li> <li>• if you have symptoms of losing too much body fluid (dehydration) such as light-headedness, dizziness or faintness</li> </ul> </li> <li>• if you have nausea or vomiting that stops you from drinking fluids</li> <li>• if you are not able to get your diarrhoea under control within 24 hours</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side

effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What TRODELVY contains

<b>Active ingredient (main ingredient)</b>	Sacituzumab govitecan
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• 2-N-morpholinoethanesulfonic acid monohydrate</li><li>• Polysorbate 80</li><li>• Trehalose dihydrate</li></ul>

**Do not take this medicine if you are allergic to any of these ingredients.**

### What TRODELVY looks like

TRODELVY is an off-white to yellowish powder which is dissolved in a solution of sodium chloride before it is given. After dissolving, the TRODELVY solution is clear and yellow.

Each TRODELVY carton contains 1 vial (AUST R 353081).

### Who distributes TRODELVY

#### Australia

Gilead Sciences Pty Ltd  
Level 28, 385 Bourke Street  
Melbourne, Victoria 3000

#### New Zealand

c/o Tompkins Wake  
Level 17, 88 Shortland Street  
Auckland, 1010

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