Package leaflet: Information for the patient

Trodelvy 180 mg powder for concentrate for solution for infusion
sacituzumab govitecan

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side affects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start receiving this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Trodelvy is and what it is used for

Trodelvy is a cancer medicine that contains the active substance sacituzumab govitecan.

Trodelvy is used to treat a type of breast cancer in adults called triple-negative breast cancer (TNBC). Trodelvy should only be used after patients have tried at least two other treatments for their cancer, including at least one of them for a locally advanced cancer or metastasised cancer.

Trodelvy is used to treat a type of breast cancer in adults called hormone receptor -positive (HR+), human epidermal growth factor receptor 2 -negative (HER2-) breast cancer. Trodelvy should only be used after patients have tried a treatment including a hormonal anticancer treatment and at least two additional other treatments for a locally advanced cancer or metastasised cancer.

Talk to your doctor or nurse if you have any questions about how Trodelvy works or why this medicine has been prescribed for you.

2. What you need to know before you are given Trodelvy

You **must not be given** Trodelvy if you are **allergic** to **sacituzumab govitecan,** to any of the other **ingredients** of this medicine (listed in section 6), or if you are allergic to irinotecan. If you think you may be allergic, ask your doctor for advice.

Warnings and precautions

Seek urgent medical attention if you notice any of the following serious side effects whilst being given or after you are given Trodelvy:

Neutropenia
This is a condition where you have too few neutrophils in your blood after receiving Trodelvy, resulting in increased risk of infections. These infections can be severe, life-threatening and may lead

to death, mainly early on in treatment. **Seek urgent medical attention** if you have the following signs and symptoms that may be due to having too few neutrophils (including infections):

- a fever (a temperature of 38.5°C or higher)
- chills or sweating
- sore throat, sores in the mouth, or a toothache
- stomach pain
- pain near the anus or sores around the anus
- pain or burning when urinating, or urinating often
- diarrhoea
- a cough or shortness of breath.

Your doctor will take blood samples to monitor neutrophils and may give a medicine to help prevent low neutrophil count while being treated with TRODELVY. You will not be given Trodelvy if the absolute neutrophil count is below a certain level on Day 1 or Day 8 of any cycle.

If your neutrophil count is too low, your doctor may need to lower your dose of TRODELVY, give you a medicine to treat low neutrophil count, or in some cases may stop TRODELVY.

Fever

Seek urgent medical attention if you have the following signs and symptoms:

- a temperature of 38.5°C or higher
- sweating

Diarrhoea

Seek urgent medical attention if you suffer from severe diarrhoea, whilst receiving Trodelvy (for example, black or bloody stools; symptoms of dehydration such as lightheadedness, dizziness, or faintness; inability to take fluids by mouth due to nausea or vomiting; or inability to get diarrhoea under control within 24 hours).

Contact your doctor or nurse the first time that you get diarrhoea. Your Trodelvy treatment will be postponed until your diarrhoea has improved.

You will be given loperamide to treat your diarrhoea, as long as you do not have an infection. If appropriate, you may also be given fluids into your veins (intravenously). Your doctor may also give you medicine, such as atropine, to help with stomach cramps, diarrhoea, and excessive saliva in mouth before your next treatment infusion. Your diarrhoea can lead to dehydration and sudden kidney damage. Talk to your doctor if you experience dark-coloured urine or decreased urine volume.

Allergic and Infusion related reactions (reactions related to your infusion of the medicine)

These reactions can be severe and life-threatening and can emerge when receiving Trodelvy.

Seek urgent medical attention if you have the following signs and symptoms of allergic and infusion related reactions:

- itching
- outbreak of swollen, pale red bumps or plaques (wheals) on the skin that appear suddenly
- fever
- a sudden attack of severe shivering accompanied by a feeling of coldness
- excessive sweating
- breathing difficulties and wheezing
- chest pain, heart palpitations.

You may be given some medicine before Trodelvy is administered to help relieve the symptoms. During each infusion of Trodelvy and for 30 minutes after, you will be closely monitored for these signs and symptoms of infusion-related reactions. Your doctor will slow down the infusion rate or stop it if you develop a serious infusion-related reaction.

Please let your doctor, pharmacist or nurse know if you have previously experienced any problems after receiving infusions, such as dizziness, feeling of fainting, difficulty breathing, breathlessness, swelling or skin rash, swelling of your face, lips, tongue, or throat, chills or shaking chills (rigors), and fever.

Nausea and vomiting
Seek urgent medical attention if you suffer from uncontrolled nausea or vomiting whilst receiving Trodelvy.
Your doctor will give you anti-sickness medicines before and after Trodelvy is administered to help relieve nausea and vomiting. You will not be given Trodelvy if you have severe nausea and vomiting and will only be given Trodelvy when the symptoms have been controlled.

Talk to your doctor or nurse before you are given Trodelvy if you:
- have liver problems
- have kidney problems
- are female and of child-bearing age (see 'Pregnancy, Breast-feeding and Fertility')
- are taking medicines to treat other conditions (see 'Other medicines and Trodelvy')
- have experienced any problems after receiving any infusions in the past
- have been told you carry a gene for uridine diphosphate-glucuronosyl transferase 1A1 (UGT1A1)*28

Some patients are genetically more likely to have certain side effects from Trodelvy. If you have the UGT1A1*28 gene, you are more likely to develop low white blood cell count (neutropenia), a fever while your white blood cell count is low, low level of red blood cell count (anaemia). You may also be more likely to develop other side effects after being given Trodelvy than those who do not have the gene.

See section 4. for a list of all the side effects related to Trodelvy.

Children and adolescents
Trodelvy must not be given to children under 18 years of age because there is no information about its use in this age group.

Other medicines and Trodelvy
Tell your doctor if you are taking, have recently taken or might take **any other medicines, including herbal medicines** while receiving Trodelvy. This is because Trodelvy or the other medicines may not work as well as expected or you may be more likely to get a side effect.

This includes in particular:
- **propofol**, given as an anesthetic in surgery.
- **ketoconazole**, used to treat fungal infections.
- **tyrosine kinase inhibitors** used to treat cancer (medicines ending in nib).
- **carbamazepine** or **phenytoin** used to treat epilepsy.
- **rifampicin** used to treat tuberculosis.
- **protease inhibitor antivirals** used to treat HIV.

Pregnancy
Tell your doctor immediately if you are pregnant, think you may be pregnant or are planning to have a baby**.** Trodelvy must not be given if you are pregnant.

Male and female contraception
Women must use effective contraception during treatment with Trodelvy, and for 6 months after the last dose of Trodelvy.
Men with female partners who can become pregnant **must use effective contraception** during treatment and for 3 months after the last dose of Trodelvy.

Breast-feeding
Do not breast-feed during treatment with Trodelvy and for 1 month after the last dose. It is unknown whether this medicine passes into breast milk.

Driving and using machines
You may experience side effects of Trodelvy that may affect your ability to drive and use machines. You should therefore be cautious when driving, using tools or operating machines after being given Trodelvy.

3. How you will be given Trodelvy

Trodelvy will only be given to you by your doctor or a nurse experienced in using anti-cancer therapies.
It is important that the doctor specialising in your care has confirmed you can take this medicine by carrying out a blood test prior to treatment.

Medicines given before Trodelvy treatment
You will be given some medicines before receiving Trodelvy to help with side effects, such as nausea and vomiting and influsion-related reactions.

How much you will be given
The dose you are given will depend on your weight. Your doctor will weigh you and will determine the dose you should receive.

Frequency of administration
You should usually receive Trodelvy twice every 3 weeks on Days 1 and 8 of a 21-day treatment cycle.

How you will be given your medicine
A doctor or nurse will put the medicine into your bloodstream via an intravenous infusion (a drip into your vein).

First infusion: you will be given your first infusion of Trodelvy over 3 hours. Your doctor or nurse will monitor you for signs and symptoms of infusion-related reactions both during the infusion and 30 minutes after.

Second and subsequent infusions: you will be given the other infusions over 1 to 2 hours, if your first infusion was uneventful. Your doctor or nurse will monitor you during and 30 minutes after your infusion.

Infusion-related reactions
Your doctor will slow down the infusion rate of Trodelvy if you develop an infusion-related reaction. The medicine will be stopped if the infusion reaction is life-threatening. See section 2.

Dose of medicine when experiencing some side-effects
Your doctor may adjust the dose or stop Trodelvy if you experience certain side effects. See section 4.

If you are given more Trodelvy than you should
Since the infusion is given to you by your doctor or other appropriately trained staff, an overdose is unlikely. If you inadvertently receive too much medicine, your doctor will monitor you and give you additional supportive care to prevent and treat side effects.

If a dose of Trodelvy is missed
If you forget or miss your appointment, contact your doctor or your treatment centre to make another appointment as soon as possible.

If you stop treatment with Trodelvy
You should not stop the therapy early without talking with your doctor first.

The therapy for breast cancer with Trodelvy usually requires a number of treatments. The number of

infusions that you receive will depend on how you are responding to treatment. Therefore, you should continue to take Trodelvy even if you see your symptoms improve until your doctor recommends that Trodelvy should be stopped.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

Seek urgent medical attention if you get any of the following serious side effects:

Very common
(may affect more than 1 in 10 people)

- **Diarrhoea. Seek urgent medical attention if you have** the following signs and symptoms:
  - black or bloody stools
  - symptoms of dehydration such as lightheadedness, dizziness, or faintness
  - inability to take fluids by mouth due to nausea or vomiting
  - inability to get diarrhoea under control within 24 hours.

- **Hypersensitivity reactions (including infusion-related reactions)** which may cause the following signs and symptoms:
  - swollen lips, tongue, eyes, throat or face
  - swelling or a raised, itchy, red skin rash
  - outbreak of swollen, pale red bumps or plaques (wheals) on the skin that appear suddenly
  - fever
  - a sudden attack of severe shivering accompanied by a feeling of coldness
  - excessive sweating
  - wheezing, chest or throat tightness, shortness of breath, dizziness, feeling of fainting, breathlessness
  - chest pain, heart palpitations.

Common
(may affect up to 1 in 10 people)

- **Low neutrophil count with fever,** which may cause the following signs and symptoms:
  - a fever, which is a temperature of 38.5°C or higher: this is called febrile neutropenia
  - chills or sweating
  - sore throat, sores in the mouth, or a toothache
  - stomach pain
  - pain or burning when urinating, or urinating often
  - diarrhoea
  - a cough or shortness of breath.

- **Pneumonia (Lung infection)** which may cause the following signs and symptoms:
  - cough, which may produce greenish, yellow or even bloody mucus
  - fever, sweating and shaking chills
  - shortness of breath
  - rapid, shallow breathing
  - sharp or stabbing chest pain that gets worse when you breathe deeply or cough
  - loss of appetite, low energy, and fatigue

Other possible side effects
Other side effects are listed below. If any of these become severe or serious, tell your doctor immediately.

Very common
(may affect more than 1 in 10 people)
- burning sensation during urination and frequent, and urgent need to urinate
- shortness of breath, cough, sore throat, headache, and sneezing
- looking pale and feeling tired (may be symptoms of low level of red blood cells (anaemia))
- low level of white blood cells (lymphocytes or leukocytes)
- nausea (feeling sick)
- vomiting (being sick)
- loss of appetite
- low blood level of potassium or magnesium
- trouble sleeping
- feeling dizzy
- shortness of breath
- constipation; stomach pain
- hair loss; rash; general itching
- back pain; joint pain
- tiredness

Common
(may affect up to 1 in 10 people)
- shiver, fever, general discomfort, pale or discolored skin, shortness of breath due to infection in bloodstream by bacteria (sepsis)
- infection of the lungs (pneumonia)
- blocked nose, pain in your face, runny nose, wheezing, cough (may be symptoms of bronchitis)
- hacking cough which may bring up clear, yellow-grey or greenish phlegm
- low number of platelets, which may lead to bleeding and brusing (thrombocytopenia)
- high blood level of glucose
- decreased water in the body
- low blood level of phosphate, calcium or sodium
- change in your sense of taste
- low blood pressure
- nose bleeding; cough reflex triggered by the drip down of mucus in the back of your throat
- inflammation of the large bowel (colitis)
- inflamed and sore mouth; pain in upper stomach area; heartburn; bloated stomach
- darkening of the skin; rash; acne-like skin problem; dry skin
- excess protein in urine
- dehydration
- chills, pain
- weight loss
- increase in enzymes called alkaline phosphatase or lactate dehydrogenase, abnormal blood tests related to coagulation

Uncommon
(may affect up to 1 in 100 people)
- inflammation of the small intestine (enteritis)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Trodelvy

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the vial label and carton after EXP. The expiry date refers to the last day of that month that the medicine can be used.

Store in a refrigerator (2°C to 8°C). Do not freeze.
Keep the vial in the outer carton in order to protect from light.

Once reconstituted, the infusion bag containing Trodelvy solution can be stored in a refrigerator at 2°C to 8°C for up to 24 hours protected from light.

Do not use this medicine if you notice the reconstituted solution is cloudy or discoloured.

Trodelvy is a cytotoxic drug. Applicable special handling and disposal procedures must be followed.

Do not throw away any medicines via wastewater. The hospital pharmacist will throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Trodelvy contains
- The active substance is sacituzumab govitecan
- The other ingredients are 2-(*N*-morpholino)ethane sulfonic acid (MES), polysorbate 80 and trehalose dihydrate.

What Trodelvy looks like and contents of the pack
The medicine is an off-white to yellowish powder. It comes as 50 mL clear glass single-dose vials, with a rubber stopper and crimp-sealed with an aluminum flip-off cap. Each pack contains 1 vial.

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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Other sources of information

Detailed information on this medicine is available on the website of the Medicines and Healthcare Regulatory Agency (MHRA) https://www.gov.uk/guidance/find-product-information-about-medicines and other websites https://www.medicines.org.uk/emc/.

The following information is intended for healthcare professionals only:

Trodelvy is a cytotoxic drug. Applicable special handling and disposal procedures have to be followed.

Reconstitution

- The product should be prepared in a hospital aseptic unit.
- Calculate the required dose (mg) of Trodelvy based on the patient's body weight.
- Using a sterile syringe, slowly inject 20 mL of sodium chloride 0.9% solution for injection, into each 180 mg Trodelvy vial. The resulting concentration will be 10 mg/mL.
- The product should only be reconstituted with 0.9% sodium chloride.
- Gently swirl vials and allow to dissolve for up to 15 minutes. Do not shake. The product should be inspected visually for particulate matter and discoloration prior to administration. The solution should be free of visible particulates, clear and yellow. Do not use the reconstituted solution if it is cloudy or discoloured.
- Use immediately to prepare a diluted Trodelvy solution for infusion.

Dilution

- Calculate the required volume of the reconstituted Trodelvy solution needed to obtain the appropriate dose according to patient's body weight. Withdraw this amount from the vial(s) using a syringe. Discard any unused portion remaining in the vial(s).
- Adjust the volume in the infusion bag as needed with sodium chloride 0.9% solution for injection, to obtain a concentration of 1.1 mg/mL to 3.4 mg/mL (the total volume should not exceed 500 mL). For patients whose body weight exceeds 170 kg, divide the total dosage of Trodelvy equally between two 500 mL infusion bags and infuse sequentially via slow infusion.
- Slowly inject the required volume of reconstituted Trodelvy solution into a polyvinyl chloride, polyolefin (polypropylene and/or polyethylene), or ethylene vinyl acetate infusion bag to minimise foaming. Do not shake the contents.
- Only sodium chloride 0.9% solution for injection should be used since the stability of the reconstituted product has not been determined with other infusion-based solutions. Use the diluted solution in the infusion bag immediately. If not used immediately, the infusion bag containing Trodelvy solution can be stored refrigerated at 2°C to 8°C for up to 24 hours protected from light. After refrigeration, administer diluted solution at room temperature up to 25°C within 8 hours (including infusion time).

Do not freeze or shake.

Administration

- Administer Trodelvy as an intravenous infusion. Protect infusion bag from light.
- An infusion pump may be used.
- Do not mix Trodelvy, or administer as an infusion, with other medicinal products.
- Upon completion of the infusion, flush the intravenous line with 20 mL sodium chloride 0.9% solution for injection.

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.