



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

**Public Summary**

<b>Summary for ARTG Entry:</b>	353081	TRODELVY sacituzumab govitecan 180 mg powder for injection vial
<b>ARTG entry for</b>	Medicine Registered	
<b>Sponsor</b>	Gilead Sciences Pty Ltd	
<b>Postal Address</b>	Level 6 / 417 St Kilda Road, MELBOURNE, VIC, 3004 Australia	
<b>ARTG Start Date</b>	6/09/2021	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	Drug Safety Evaluation Branch	



**Medicine under additional monitoring**

**Conditions**

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

**Products**

**1 . TRODELVY sacituzumab govitecan 180 mg powder for injection vial**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	6/09/2021
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**Permitted Indications**

No Permitted Indications included on Record

**Indication Requirements**

No Indication Requirements included on Record

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

TRODELVY is indicated for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who have received at least two prior systemic therapies, including at least one prior therapy for locally advanced or metastatic disease.

**Warnings**

See Product Information and Consumer Medicine Information for this product

**Additional Product information**

*This product is included in the Black Triangle Scheme*

**Container information**

Type	Material	Life Time	Temperature	Closure	Conditions
Vial	Glass Type I Clear	3 Years	Store at 2 to 8 degrees Celsius	Not recorded	Do not Freeze Refrigerate Protect from Light

**Pack Size/Poison information**

<b>Pack Size</b>	<b>Poison Schedule</b>
1 vial	(S4) Prescription Only Medicine

**Components**

**1 . TRODELVY sacituzumab govitecan 180 mg powder for injection vial**

<b>Dosage Form</b>	Injection, powder for
<b>Route of Administration</b>	Intravenous Infusion
<b>Visual Identification</b>	Off-white to yellowish lyophilised powder.

**Active Ingredients**

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sacituzumab govitecan

180 mg

**Other Ingredients (Excipients)**

2-N-morpholinoethanesulfonic acid monohydrate

polysorbate 80

trehalose dihydrate

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