



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	355870	PADCEV enfortumab vedotin 20 mg powder for injection vial
ARTG entry for	Medicine Registered	
Sponsor	Astellas Pharma Australia Pty Ltd	
Postal Address	Level 2 / 2 Banfield Road, MACQUARIE PARK, NSW, 2113 Australia	
ARTG Start Date	7/07/2022	
Product Category	Medicine	
Status	Active	
Approval Area	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 . PADCEV enfortumab vedotin 20 mg powder for injection vial

Product Type	Single Medicine Product	Effective Date	21/05/2024
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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

PADCEV as monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer who have previously received a platinum-containing chemotherapy and a programmed death receptor-1 or programmed death-ligand-1 inhibitor.

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	36 Months	Store at 2 to 8 degrees Celsius	Neither child resistant closure nor restricted flow insert	Refrigerate Do not Freeze

Pack Size/Poison information

Pack Size	Poison Schedule
1 vial	(S4) Prescription Only Medicine

Components

1 . PADCEV enfortumab vedotin 20 mg powder for injection vial

Dosage Form	Injection, powder for
Route of Administration	Intravenous Infusion
Visual Identification	Powder for injection vial. White to off-white lyophilized powder.

Active Ingredients

enfortumab vedotin	20 mg
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Other Ingredients (Excipients)

histidine hydrochloride monohydrate

histidine

polysorbate 20

trehalose dihydrate

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