



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

**Public Summary**

**Summary for ARTG Entry:** 262931 VALGANCICLOVIR AN valganciclovir (as hydrochloride) 450 mg film coated tablet bottle

**ARTG entry for** Medicine Registered  
**Sponsor** Juno Pharmaceuticals Pty Ltd  
**Postal Address** Level 2 6 Bond Street, South Yarra, VIC, 3141  
 Australia  
**ARTG Start Date** 20/09/2016  
**Product category** Medicine  
**Status** Active  
**Approval area** Drug Safety Evaluation Branch

**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. VALGANCICLOVIR AN valganciclovir (as hydrochloride) 450 mg film coated tablet bottle**

<b>Product Type</b>	Single Medicine Product	<b>Effective date</b>	27/09/2017
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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**

VALGANCICLOVIR AN is indicated for the treatment of cytomegalovirus (CMV) retinitis in adult patients with acquired immunodeficiency syndrome (AIDS). VALGANCICLOVIR AN is indicated for the prophylaxis of CMV disease in adult and paediatric solid organ transplantation (SOT) patients who are at risk.

**Warnings**

See Product Information and Consumer Medicine Information for this product

**Additional Product information**

**Container information**

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	HDPE	24 Months	Store below 25 degrees Celsius	Child resistant closure	Not recorded

**Pack Size/Poison information**

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

**Components**

**1. VALGANCICLOVIR AN valganciclovir (as hydrochloride) 450 mg film coated tablet bottle**

<b>Dosage Form</b>	Tablet, film coated
<b>Route of Administration</b>	Oral
<b>Visual Identification</b>	Pink oval tablet with "450" on one side and plain on the reverse

**Active Ingredients**

<b>Valganciclovir hydrochloride</b>	<b>496.3 mg</b>
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