



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

**Public Summary**

**Summary for ARTG Entry:** 273904 BICALIDE bicalutamide 50mg film-coated tablet blister pack

**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** 20/07/2016  
**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. BICALIDE bicalutamide 50mg film-coated tablet blister pack**

<b>Product Type</b>	Single Medicine Product	<b>Effective date</b>	29/05/2017
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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**

Treatment of advanced prostate cancer in combination with LHRH agonist therapy. Prevention of disease flare associated with the use of LHRH agonists.

**Warnings**

See Product Information and Consumer Medicine Information for this product

**Additional Product information**

**Container information**

Type	Material	Life Time	Temperature	Closure	Conditions
Blister Pack	PVC/PVDC/Al	36 Months	Store below 25 degrees Celsius	Not recorded	Protect from Moisture

**Pack Size/Poison information**

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

**Components**

**1. BICALIDE bicalutamide 50mg film-coated tablet blister pack**

<b>Dosage Form</b>	Tablet, film coated
<b>Route of Administration</b>	Oral
<b>Visual Identification</b>	White to off white round, biconvex, film coated tablets debossed 'B 50' on one side and plain on other side.

**Active Ingredients**

<b>Bicalutamide</b>	<b>50 mg</b>
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