



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

Product Type	Single Medicine Product	Effective date	18/03/2019
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Permitted Indications

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

Pack Size	Poison Schedule
28 Tablets	(S4) Prescription Only Medicine

Components

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

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification White to off white round, biconvex, film coated tablets debossed 'B 50' on one side and plain on other side.

Active Ingredients

bicalutamide 50 mg

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