



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 259990 ASTZOL anastrozole 1 mg 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 23/12/2015
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. ASTZOL anastrozole 1 mg film-coated tablet blister pack

Product Type	Single Medicine Product	Effective date	16/04/2019
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Permitted Indications

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

Early breast cancer: . Adjuvant treatment of early breast cancer in postmenopausal women with oestrogen/progesterone-receptor-positive disease. .
 Advanced breast cancer: . First line treatment of advanced breast cancer in postmenopausal women with oestrogen/progesterone-receptor-positive disease. . Treatment of advanced breast cancer in postmenopausal women with disease progression following tamoxifen therapy. Patients with oestrogen-receptor-negative disease and patients who have not responded to previous tamoxifen therapy rarely respond to anastrozole.

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	Not recorded

Pack Size/Poison information

Pack Size

30 Tablets

Poison Schedule

(S4) Prescription Only Medicine

Components

1. ASTZOL anastrozole 1 mg film-coated tablet blister pack

Dosage Form

Tablet, film coated

Route of Administration

Oral

Visual Identification

White to off white, round, biconvex, film-coated tablet debossed with "AHI" on one side and plain on other side

Active Ingredients

anastrozole 1 mg

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