



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 281353 ESTAMANE exemestane 25mg 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 9/02/2017
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. ESTAMANE exemestane 25mg tablet blister pack

Product Type	Single Medicine Product	Effective date	23/05/2017
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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

Exemestane is indicated for the sequential adjuvant treatment of oestrogen receptor-positive early breast cancer in post-menopausal women who have received prior adjuvant tamoxifen therapy. . Exemestane is indicated for the treatment of oestrogen receptor-positive advanced breast cancer in women with natural or induced postmenopausal status whose disease has progressed following anti-oestrogen therapy.

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	30 Months	Store below 25 degrees Celsius	Not recorded	Store in a Dry Place

Pack Size/Poison information

Pack Size
 90 Tablets
 15 Tablets
 30 Tablets

Poison Schedule
 (S4) Prescription Only Medicine
 (S4) Prescription Only Medicine
 (S4) Prescription Only Medicine

Components

1. ESTAMANE exemestane 25mg tablet blister pack

Dosage Form

Tablet, film coated

Route of Administration

Oral

Visual Identification

White to off-white, round, biconvex film-coated tablets debossed with 'E25' on one side and plain on the other.

Active Ingredients

Exemestane **25 mg**

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