

Public Summary

Summary for ARTG Entry: 32637 CARDURAN Doxazosin 2mg (as mesilate) tablet blister pack

ARTG entry for Medicine Registered
Sponsor Pfizer Australia Pty Ltd
Postal Address 38-42 Wharf Road, WEST RYDE, NSW, 2114
 Australia
ARTG Start Date 26/05/1992
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 February 1992, other than condition No. 8 and condition No. 9.

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 February 1992, other than condition No. 11.

Except where the sponsor has been contracted by an overseas party to manufacture the goods and that party will be responsible for placing the goods on the market in countries other than Australia, the sponsor must have and shall retain, while the goods remain listed, evidence necessary to substantiate and support the accuracy of the indications in relation to the listed goods, and upon the request of the Head, Office of Prescription Medicines Authorisation Branch, Therapeutic Goods Administration, shall produce such evidence to this officer.

The conditions applying to these goods when they are exported from Australia are given below:

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. CARDURAN 2mg tablet**

Product Type	Single Medicine Product	Effective date	29/09/2016																								
Warnings See Product Information and Consumer Medicine Information for this product Standard Indications Specific Indications Hypertension: CARDURAN is indicated for the treatment of mild to moderate hypertension. It can be used as a single antihypertensive agent or in combination with a thiazide diuretic or a beta-blocking agent. There is limited experience with CARDURAN in combination with angiotensin converting enzyme inhibitors or calcium channel blockers. Benign Prostatic Hyperplasia: CARDURAN is indicated for the relief of manifestations of mild to moderate benign prostatic hyperplasia. Additional Product information Container information <table border="1"> <thead> <tr> <th>Type</th> <th>Material</th> <th>Life Time</th> <th>Temperature</th> <th>Closure</th> <th>Conditions</th> </tr> </thead> <tbody> <tr> <td>Blister Pack</td> <td>PVC/PE/PVDC/Al</td> <td>2 Years</td> <td>Store below 30 degrees Celsius</td> <td>Not recorded</td> <td>Not recorded</td> </tr> </tbody> </table> Pack Size/Poison information <table border="1"> <thead> <tr> <th>Pack Size</th> <th>Poison Schedule</th> </tr> </thead> <tbody> <tr> <td>100(E)</td> <td>(S4) Prescription Only Medicine</td> </tr> <tr> <td>30</td> <td>(S4) Prescription Only Medicine</td> </tr> <tr> <td>28(E)</td> <td>(S4) Prescription Only Medicine</td> </tr> <tr> <td>28 tablets</td> <td>(S4) Prescription Only Medicine</td> </tr> <tr> <td>10</td> <td>(S4) Prescription Only Medicine</td> </tr> </tbody> </table> Components 1. Medicine Component Dosage Form Tablet, uncoated Route of Administration Oral Visual Identification A white capsule shaped biconvex flat sided tablet being 9mm long, 4.5mm wide and 2.8mm thick with 'PFIZER' on one side & 'CN' breakline '2' on other				Type	Material	Life Time	Temperature	Closure	Conditions	Blister Pack	PVC/PE/PVDC/Al	2 Years	Store below 30 degrees Celsius	Not recorded	Not recorded	Pack Size	Poison Schedule	100(E)	(S4) Prescription Only Medicine	30	(S4) Prescription Only Medicine	28(E)	(S4) Prescription Only Medicine	28 tablets	(S4) Prescription Only Medicine	10	(S4) Prescription Only Medicine
Type	Material	Life Time	Temperature	Closure	Conditions																						
Blister Pack	PVC/PE/PVDC/Al	2 Years	Store below 30 degrees Celsius	Not recorded	Not recorded																						
Pack Size	Poison Schedule																										
100(E)	(S4) Prescription Only Medicine																										
30	(S4) Prescription Only Medicine																										
28(E)	(S4) Prescription Only Medicine																										
28 tablets	(S4) Prescription Only Medicine																										
10	(S4) Prescription Only Medicine																										

Warnings

See Product Information and Consumer Medicine Information for this product

Standard Indications**Specific Indications**

Hypertension: CARDURAN is indicated for the treatment of mild to moderate hypertension. It can be used as a single antihypertensive agent or in combination with a thiazide diuretic or a beta-blocking agent. There is limited experience with CARDURAN in combination with angiotensin converting enzyme inhibitors or calcium channel blockers. Benign Prostatic Hyperplasia: CARDURAN is indicated for the relief of manifestations of mild to moderate benign prostatic hyperplasia.

Additional Product information**Container information**

Type	Material	Life Time	Temperature	Closure	Conditions
Blister Pack	PVC/PE/PVDC/Al	2 Years	Store below 30 degrees Celsius	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
100(E)	(S4) Prescription Only Medicine
30	(S4) Prescription Only Medicine
28(E)	(S4) Prescription Only Medicine
28 tablets	(S4) Prescription Only Medicine
10	(S4) Prescription Only Medicine

Components**1. Medicine Component**

Dosage Form Tablet, uncoated

Route of Administration Oral

Visual Identification A white capsule shaped biconvex flat sided tablet being 9mm long, 4.5mm wide and 2.8mm thick with 'PFIZER' on one side & 'CN' breakline '2' on other

Active Ingredients

doxazosin mesilate

2.43 mg

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary