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 partry to manufacturer 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

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

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Active Ingredients	
doxazosin mesilate	**2.43 mg**