



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 166014 CARVEDILOL-DRLA carvedilol 12.5mg tablet bottle

ARTG entry for	Medicine Registered
Sponsor	Dr Reddys Laboratories Australia Pty Ltd
Postal Address	Suite 3 Level 3 390 St Kilda Road, Melbourne, VIC, 3004 Australia
ARTG Start Date	23/03/2011
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 . CARVEDILOL-DRLA carvedilol 12.5mg tablet bottle

Product Type	Single Medicine Product	Effective Date	23/03/2011
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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

CARVEDILOL-DRLA is indicated for the treatment of hypertension. Data have not been provided to support the use of this drug in renovascular disease. CARVEDILOL-DRLA is indicated for the treatment of patients with symptomatic mild to severe (NYHA Class II - IV) congestive heart failure (CHF) as an adjunct to conventional treatments (e.g. diuretics, digoxin, ACE inhibitors and vasodilators).

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	HDPE	2 Years	Store below 25 degrees Celsius	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
100 tablet	(S4) Prescription Only Medicine
500 tablet	(S4) Prescription Only Medicine

Components

1 . carvedilol 12.5mg tablet bottle

Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	White, round, film coated tablets debossed with 'R' on one side and "254" on other side.

Active Ingredients

carvedilol	12.5 mg
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Other Ingredients (Excipients)

Public Summary



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colloidal anhydrous silica
crospovidone
hypromellose
lactose monohydrate
macrogol 400
magnesium stearate
polysorbate 80
povidone
purified water
titanium dioxide

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