



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	166009	CARVEDILOL-DRLA carvedilol 3.125mg 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 3.125mg 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 3.125mg tablet bottle

Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	Yellow, round, film coated tablets debossed with 'R' on one side and "252" on other side.

Active Ingredients

carvedilol	3.125 mg
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Other Ingredients (Excipients)



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

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