



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	46043	SORBIDIN isosorbide dinitrate 10mg tablet bottle
<b>ARTG entry for</b>	Medicine Registered	
<b>Sponsor</b>	Alphapharm Pty Ltd	
<b>Postal Address</b>	PO Box R1462, ROYAL EXCHANGE, NSW, 1225 Australia	
<b>ARTG Start Date</b>	10/08/1993	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	Non-Prescription Medicines	

### 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 . SORBIDIN isosorbide dinitrate 10mg tablet bottle

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	27/10/2010
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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

Treatment of angina pectoris (classic effort associated angina, chronic stable angina, vasospastic angina, variant angina, unstable angina and angina decubitus) and myocardial ischaemia due to ischaemic heart disease. The tablets are not intended to abort the acute anginal episode, but are useful in the prophylactic treatment of angina pectoris and myocardial ischaemic heart disease. An aid in the management of left ventricular failure, either alone or as part of the syndrome of congestive heart failure.

#### Warnings

No Warnings included on Record

#### Additional Product information

#### Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	Not recorded	3 Years	Store below 30 degrees Celsius	Not recorded	Not recorded

#### Pack Size/Poison information

<b>Pack Size</b>	<b>Poison Schedule</b>
100	(S3) Pharmacist Only Medicine

#### Components

1 .

<b>Dosage Form</b>	Tablet, uncoated
<b>Route of Administration</b>	Oral
<b>Visual Identification</b>	8mm normal convex white tablet marked "IS/10" on one side, " " on the reverse.

#### Active Ingredients

<b>diluted isosorbide dinitrate</b>	<b>25 mg</b>
Equivalent: isosorbide dinitrate	10 mg

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**Other Ingredients (Excipients)**

**lactose**

**magnesium stearate**

**microcrystalline cellulose**

**pregelatinised maize starch**

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