



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

## Public Summary

**Summary for ARTG Entry:** 169504 SALPRAZ HEARTBURN RELIEF pantoprazole (as sodium sesquihydrate) 20 mg enteric coated tablet blister pack

**ARTG entry for** Medicine Registered  
**Sponsor** Alphapharm Pty Ltd  
**Postal Address** PO Box R1462, ROYAL EXCHANGE, NSW, 1225  
Australia  
**ARTG Start Date** 1/03/2010  
**Product Category** Medicine  
**Status** Active  
**Approval Area** 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. SALPRAZ HEARTBURN RELIEF pantoprazole (as sodium sesquihydrate) 20 mg enteric coated tablet blister pack

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	1/03/2010
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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

For symptomatic relief of heartburn, acid regurgitation and other symptoms associated with gastroesophageal reflux disease (GORD).

#### Warnings

No Warnings included on Record

#### Additional Product information

#### Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Blister Pack	Al/Al	30 Months	Store below 25 degrees Celsius	Neither child resistant closure nor restricted flow insert	Not recorded

#### Pack Size/Poison information

Pack Size	Poison Schedule
14	(S3) Pharmacist Only Medicine
7	(S3) Pharmacist Only Medicine
2	(S3) Pharmacist Only Medicine

#### Components

1.

**Dosage Form** Tablet, enteric coated  
**Route of Administration** Oral  
**Visual Identification** Yellow to ochre, elongated coated tablet

#### Active Ingredients

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pantoprazole

20 mg

**Other Ingredients (Excipients)**

colloidal anhydrous silica

croscarmellose sodium

iron oxide yellow

lactose monohydrate

macrogol 3350

magnesium stearate

methacrylic acid copolymer

microcrystalline cellulose

polysorbate 80

polyvinyl alcohol

purified talc

purified water

quinoline yellow aluminium lake

sodium lauryl sulfate

titanium dioxide

triethyl citrate

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