



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

**Public Summary**

**Summary for ARTG Entry:** 143188 Suspended from ARTG - GenRx ACID & HEARTBURN RELIEF ranitidine 150mg (as hydrochloride) tablet blister pack

**ARTG entry for** Medicine Registered  
**Sponsor** Apotex Pty Ltd  
**Postal Address** PO Box 280, NORTH RYDE BC, NSW, 1670  
 Australia  
**ARTG Start Date** 14/08/2007  
**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 . GenRx ACID & HEARTBURN RELIEF ranitidine 150mg (as hydrochloride) tablet blister pack**

**Product Type** Single Medicine Product **Effective Date** 29/01/2009

**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 the relief of symptoms of gastro-oesophageal reflux.

**Warnings**

No Warnings included on Record

**Additional Product information**

**Container information**

Type	Material	Life Time	Temperature	Closure	Conditions
Blister Pack	Not recorded	3 Years	Store below 25 degrees Celsius	Not recorded	Not recorded

**Pack Size/Poison information**

Pack Size	Poison Schedule
28 tablets	(S2) Pharmacy Medicine
14 tablets	Not scheduled. Not considered by committee

**Components**

**1 . Medicine Component**

**Dosage Form** Tablet, film coated  
**Route of Administration** Oral  
**Visual Identification** White to off-white, round, biconvex, film-coated tablet. Scored on one side and engraved "RAN" over "150" on the other side.

**Active Ingredients**

ranitidine hydrochloride	167.9 mg
Equivalent: ranitidine	150 mg

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**Other Ingredients (Excipients)**

Carnauba Wax  
colloidal anhydrous silica  
hypromellose  
magnesium stearate  
microcrystalline cellulose  
polydextrose  
titanium dioxide  
vanillin

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Public Summary