



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

**Public Summary**

**Summary for ARTG Entry:** 11954 0.5% MARCAIN DENTAL with ADRENALINE 1:200,000 2.2mL injection cartridge

**ARTG entry for** Medicine Registered  
**Sponsor** Dentsply Sirona Pty Ltd  
**Postal Address** 11-21 Gilby Road, Mt Waverley, VIC, 3149  
 Australia  
**ARTG Start Date** 31/07/1991  
**Product category** Medicine  
**Status** Active  
**Approval area** Drug Safety Evaluation Branch

**Conditions**

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Conditions Applying to Therapeutic Goods Accepted for Registration or Listing as Goods Currently Supplied at the Commencement of the Therapeutic Goods Act 1989"

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. 0.5% MARCAIN DENTAL with ADRENALINE 1:200,000 2.2mL injection cartridge**

<b>Product Type</b>	Single Medicine Product	<b>Effective date</b>	3/07/2002
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**Permitted Indications**

No Permitted Indications included on Record

**Indication Requirements**

No Indication Requirements included on Record

**Standard Indications**

This product accepted for registration/listing as 'currently supplied' at the time of commencement of the Act. Indications held in ARTG paper records. (Old code)

**Specific Indications**

0.5% MARCAIN Dental with Adrenaline 1:200,000 is indicated for the production of local anaesthesia in routine dental procedures and oral surgery by means of infiltration and nerve block techniques.

**Warnings**

See Product Information and Consumer Medicine Information for this product

**Additional Product information**

**Container information**

Type	Material	Life Time	Temperature	Closure	Conditions
Cartridge	Glass Type I Clear	18 Months	Store below 25 degrees Celsius	Not recorded	Not recorded

**Pack Size/Poison information**

**Pack Size**  
2.2mL x 50

**Poison Schedule**  
(S4) Prescription Only Medicine

**Components**

**1. Medicine Component**

<b>Dosage Form</b>	Injection, solution
<b>Route of Administration</b>	Dental
<b>Visual Identification</b>	Clear, colourless solution

**Active Ingredients**

adrenaline (epinephrine) acid tartrate	9.1 microgram/mL
bupivacaine hydrochloride monohydrate	5 mg/mL

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