



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 11963 2% NUROCAIN DENTAL WITH ADRENALINE 1:100,000 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 February 1992, other than condition No. 8 and condition No. 9.

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 February 1992, other than condition No. 11.

Except where the sponsor has been contracted by an overseas party to manufacturer the goods and that party will be responsible for placing the goods on the market in countries other than Australia, the sponsor must have and shall retain, while the goods remain listed, evidence necessary to substantiate and support the accuracy of the indications in relation to the listed goods, and upon the request of the Head, Office of Prescription Medicines Authorisation Branch, Therapeutic Goods Administration, shall produce such evidence to this officer.

The conditions applying to these goods when they are exported from Australia are given below:

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. 2% NUROCAIN DENTAL WITH ADRENALINE 1:100,000 2.2mL injection cartridge

Product Type	Single Medicine Product	Effective date	31/07/2003
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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

INDICATIONS AS AT 17 JULY 2003 : Lignocaine solutions are indicated for the production of local anaesthesia in routine dental procedures and oral surgery by means of infiltration and nerve block techniques. Lignocaine solutions with adrenaline are recommended for oral surgery requiring prolonged duration of anaesthesia and haemostasis.

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	Poison Schedule
2.2mL x 100	(S4) Prescription Only Medicine

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Components

1. Medicine Component

Dosage Form	Injection, solution
Route of Administration	Infiltration Subcutaneous Dental
Visual Identification	Clear, colourless solution

Active Ingredients

adrenaline (epinephrine) acid tartrate	18.2 microgram/mL
lidocaine (lignocaine) hydrochloride monohydrate	21.3 mg/mL

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