



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	21532	NDK ACIDULATED FLUORIDE GEL bottle
ARTG entry for	Medicine Registered	
Sponsor	Professional Dentist Supplies Pty Ltd	
Postal Address	3/8 Nicole Close, BAYSWATER NORTH, VIC, 3153 Australia	
ARTG Start Date	8/10/1991	
Product Category	Medicine	
Status	Active	
Approval Area	Non-Prescription Medicines	

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 . NDK AIDULATED FLUORIDE GEL bottle

Product Type	Single Medicine Product	Effective Date	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

No Specific Indications included on Record

Warnings

No Warnings included on Record

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
250mL	(S2) Pharmacy Medicine
30mL	(S2) Pharmacy Medicine
500mL	(S2) Pharmacy Medicine

Components

1 . Medicine Component

Dosage Form	Gel
Route of Administration	Dental
Visual Identification	Pink gel

Active Ingredients

Public Summary



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hydrofluoric acid	9 mg/mL
phosphoric acid	10 mg/mL
sodium fluoride	20 mg/mL

Other Ingredients (Excipients)

amaranth
ethanol
Flavour
hyetellose
potable water

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Public Summary