



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	29561	BETADINE ANTISEPTIC OINTMENT povidone-iodine 100mg/g tube
ARTG entry for	Medicine Registered	
Sponsor	Sanofi-Aventis Healthcare Pty Ltd T/A Sanofi Consumer Healthcare	
Postal Address	PO Box 403, VIRGINIA, QLD, 4014 Australia	
ARTG Start Date	25/10/1991	
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 . BETADINE ANTISEPTIC OINTMENT povidone-iodine 100mg/g tube

Product Type	Single Medicine Product	Effective Date	26/05/2020
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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 the treatment of common skin infections. E.g. infections of the skin around the nails, cold sores and prevention of infections in minor burns, cuts and abrasions. Betadine Antiseptic Ointment is a bactericidal antiseptic.

Warnings

No Warnings included on Record

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Tube	Not recorded	2 Years	Store below 25 degrees Celsius	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
25g	Not scheduled. Not considered by committee
65g	Not scheduled. Not considered by committee

Components

1 .

Dosage Form	Ointment
Route of Administration	Topical
Visual Identification	A brown viscous ointment

Active Ingredients

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povidone-iodine	100 mg/g
Equivalent: iodine	10 mg/g

Other Ingredients (Excipients)

macrogol 1000
macrogol 1500
macrogol 3350
macrogol 400
purified water
sodium bicarbonate

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