

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 332380 Montavit Cathejell Lignocaine 2% sterile lubricant gel

ARTG entry for Medicine Registered

Sponsor Endotherapeutics Pty Ltd

Postal Address PO Box 673, EPPING, NSW, 1710

Australia

ARTG Start Date 24/03/2020
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 . Montavit Cathejell Lignocaine 2% sterile lubricant gel

Product Type Single Medicine Product Effective Date 24/03/2020

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 anaesthesia of mucous membranes and as a lubricant for:,- The male and female urethra during cystoscopy, catheterization, exploration by sound and other endourethral operations.,- Nasal and pharyngeal cavities in endoscopic procedures such as gastroscopy and bronchoscopy.,- Tracheal intubation.,- Cystoscopy and symptomatic treatment of painful cystitis and urethritis.

Warnings

No Warnings included on Record

Additional Product information

Container information

Туре	Material	Life Time	Temperature	Closure	Conditions
Ampoule	PP	2 Years	Store below 25 degrees Celsius	Neither child resistant closure nor restricted flow insert	Protect from Light

Pack Size/Poison information

Pack Size Poison Schedule
12.5g (S2) Pharmacy Medicine

Components

1.

Dosage FormGelRoute of AdministrationTopical

Visual Identification Montavit Cathejell Lignocaine 2% is presented as a colourless and clear, water-soluble gel. 12.5g of gel is supplied in a

prefilled sterile accordion syringe (collapsible syringe) and sealed with an applicator cone with a break-off tip.

Active Ingredients

lidocaine (lignocaine) hydrochloride monohydrate

2.133 % w/w

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Other Ingredients (Excipients)

glycerol hydrochloric acid hyetellose sodium hydroxide water for injections

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