



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	35208	CO-PHENYLCAINE FORTE spray aerosol
<b>ARTG entry for</b>	Medicine Registered	
<b>Sponsor</b>	ENT Technologies Pty Ltd	
<b>Postal Address</b>	Suite 304 / 12 Cato Street, Hawthorn East, VIC, 3123 Australia	
<b>ARTG Start Date</b>	24/02/1992	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 . CO-PHENYLCAINE FORTE spray aerosol**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	25/02/2022
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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**

1. Preparation of nasal mucosa for surgery. 2. Aid in the treatment of acute nose bleeds and removal of foreign bodies from the nose. 3. Topical anaesthesia prior to indirect or direct laryngoscopy 4. Topical anaesthesia and local vasoconstriction prior to endoscopy of upper airways.

**Warnings**

No Warnings included on Record

**Additional Product information**

**Container information**

Type	Material	Life Time	Temperature	Closure	Conditions
Aerosol - Pump Actuated	Not recorded	2 Years	Store below 30 degrees Celsius	Not recorded	Not recorded

**Pack Size/Poison information**

Pack Size	Poison Schedule
25 mL	(S2) Pharmacy Medicine
15 mL	(S2) Pharmacy Medicine
2.5 mL	(S2) Pharmacy Medicine
50mL	(S2) Pharmacy Medicine

**Components**

1 .

<b>Dosage Form</b>	Spray, nasal
<b>Route of Administration</b>	Nasal
<b>Visual Identification</b>	Clear colourless liquid.

**Active Ingredients**

<b>lidocaine (lignocaine) hydrochloride monohydrate</b>	<b>50 mg/mL</b>
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phenylephrine hydrochloride

5 mg/mL

**Other Ingredients (Excipients)**

benzalkonium chloride

citric acid

disodium edetate

monobasic sodium phosphate dihydrate

purified water

sodium hydroxide

sodium metabisulfite

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