



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 172315 PARACETAMOL AN paracetamol 1000mg/100mL injection solution vial

ARTG entry for Medicine Registered
Sponsor Medis Pharma Pty Ltd
Postal Address PO Box 6127, North Sydney, NSW, 2059
 Australia
ARTG Start Date 21/11/2011
Product category Medicine
Status Active
Approval area Drug Safety Evaluation Branch

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. PARACETAMOL AN paracetamol 1000mg/100mL injection solution vial

Product Type	Single Medicine Product	Effective date	19/11/2015
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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

Relief of mild to moderate pain and reduction of fever where an intravenous route of administration is considered clinically necessary.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Vial	Glass Type II Clear	24 Months	Store below 25 degrees Celsius	Not recorded	Do not Refrigerate Protect from Light Do not Freeze

Pack Size/Poison information

Pack Size	Poison Schedule
10 vials	(S4) Prescription Only Medicine
12 vials	(S4) Prescription Only Medicine
1 vial	(S4) Prescription Only Medicine

Components

1.

Dosage Form Injection, solution

Route of Administration Intravenous

Visual Identification clear liquid

Active Ingredients

Paracetamol 1 g

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