



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 227307 IRINOTECAN ACT irinotecan hydrochloride trihydrate 500mg/25mL concentrated injection vial

ARTG entry for Medicine Registered
Sponsor Medis Pharma Pty Ltd
Postal Address PO Box 6127, North Sydney, NSW, 2059
 Australia
ARTG Start Date 22/12/2014
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. IRINOTECAN ACT irinotecan hydrochloride trihydrate 500mg/25mL concentrated injection vial

Product Type	Single Medicine Product	Effective date	22/12/2014
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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

Indicated as a component of first line therapy for patients with metastatic carcinoma of the colon or rectum. Also indicated for patients with metastatic carcinoma of the colon or rectum whose disease has recurred or progressed following initial therapy

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 I Coloured	3 Years	Store below 30 degrees Celsius	Not recorded	Protect from Light Do not Freeze

Pack Size/Poison information

Pack Size	One	Poison Schedule	(S4) Prescription Only Medicine
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Components

1. IRINOTECAN ACT irinotecan hydrochloride 500mg/25mL concentrated injection vial

Dosage Form Injection, concentrated

Route of Administration Intravenous Infusion

Visual Identification Irinotecan is supplied in brown type 1 glass vial, containing a clear to pale yellow solution, stoppered by a bromobutylic rubber stopper and sealed with a aluminium crimp and a propylene disc.

Active Ingredients

irinotecan hydrochloride trihydrate 500 mg

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