Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 227306 IRINOTECAN ACT irinotecan hydrochloride trihydrate 100 mg/5 mL 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 100 mg/5 mL concentrated injection vial

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

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 use as a component of first line therapy for patients with metastatic carcinoma of the colon or rectum and in 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	Do not Freeze Protect from Light

Pack Size/Poison information

Pack Size

1 vial

Poison Schedule

(S4) Prescription Only Medicine

Components

1. IRINOTECAN ACT irinotecan hydrochloride 100 mg/5 mL concentrated injection vial

Dosage Form	Injection, concentrated
Route of Administration	Intravenous
Visual Identification	clear to pale yellow solution in a brown type I glass vial stoppered by a bromobutylic rubber stopper and sealed with an aluminium crimp and an orange polypropylene disk.

Active Ingredients

irinotecan hydrochloride trihydrate	**100 mg**

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