



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 146598 EPIRUBICIN AN epirubicin hydrochloride 100 mg/50 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 1/05/2009
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. EPIRUBICIN AN epirubicin hydrochloride 100 mg/50 mL concentrated injection vial

Product Type	Single Medicine Product	Effective date	1/05/2017
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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

Epirubicin hydrochloride has produced responses in a wide spectrum of neoplastic diseases, and is indicated for the treatment of breast cancer, gastric cancer, ovarian cancer, small-cell lung cancer, lymphoma (non-Hodgkin's lymphoma), advanced/ metastatic soft tissue sarcoma and superficial bladder cancer (Tis, Ta). In bladder cancer, epirubicin hydrochloride is also indicated in the prophylaxis of recurrence after transurethral resection of stage T1 papillary cancers and stage Ta multifocal papillary cancers (grade 2 and 3).

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 Clear	3 Years	Store at 2 to 8 degrees Celsius	Not recorded	Refrigerate Protect from Light Do not Freeze

Pack Size/Poison information

Pack Size	Poison Schedule
1 x 50 mL vial	(S4) Prescription Only Medicine

Components

1. EPIRUBICIN AN epirubicin hydrochloride 100 mg/50 mL concentrated injection vial

Dosage Form Injection, concentrated

Route of Administration Intravenous

Visual Identification Red, clear solution

Active Ingredients

epirubicin hydrochloride 100 mg

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