Public Summary

Summary for ARTG Entry:	129580 GENEXOL paclitaxel 300mg/50mL solution for injection vial
ARTG entry for	Medicine Registered
Sponsor	Medis Pharma Pty Ltd
Postal Address	Locked Bag 2053, North Ryde, NSW, 1670 Australia
ARTG Start Date	18/08/2008
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 . GENEXOL paclitaxel 300mg/50mL solution for injection vial

Product Type	Single Medicine Product	**Effective Date**	25/02/2011

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

Genexol is indicated for: Primary treatment of ovarian cancer in combination with a platinum agent; Treatment of metastatic carcinoma of the ovary and of the breast after failure of standard therapy; Adjuvant treatment of node positive breast cancer administered sequentially to doxorubicin and cyclophosphamide; Treatment of metastatic cancer of the breast, in combination with trastuzumab (Herceptin), in patients who have tumours that over-express HER-2 and who have not received previous chemotherapy for their metatastic disease; Treatment of non-small cell lung cancer; In combination with gemcitabine (Gemzar), is indicated for the treatment of patients with unresectable, locally recurrent or metastatic breast cancer who have relapsed following adjuvant/ neoadjuvant chemotherapy. Prior chemotherapy should have included an anthracycline unless clinically contraindicated.

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	2 Years	Store below 25 degrees Celsius	Not recorded	Protect from Light

Pack Size/Poison information

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

Components

1 . Medicine Component

Dosage Form	Injection, solution
Route of Administration	Intravenous
Visual Identification	Clear colourless to yellow viscous solution.

Active Ingredients

paclitaxel	**6 mg/mL**

Other Ingredients (Excipients)

ethanol absolute

PEG-35 castor oil

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