Australian Government

Department of Health
Therapeutic Goods Administration

# Public Summary

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| **Summary for ARTG Entry:** | 129579 GENEXOL paclitaxel 150mg/25mL solution for injection vial |
| **ARTG entry for** | Medicine Registered |
| **Sponsor** | Medis Pharma Pty Ltd |
| **Postal Address** | Locked Bag 2053, North Ryde, NSW, 1670<br>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 150mg/25mL solution for injection vial

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|---|---|---|---|
| **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 (NSCLC); 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 25mL 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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