

Paclitaxel Injection

Paclitaxel 6 mg/ml

Concentrate for Solution for Infusion

1. What Paclitaxel Injection Is Used For

Paclitaxel is an anti-cancer medication belonging to the group of medicines known as taxanes. It works by inhibiting the growth of cancer cells.

It is used for the following indications:

- **Ovarian Cancer**
 - First-line and subsequent therapy for advanced ovarian carcinoma.
- **Breast Cancer**
 - Treatment of advanced breast cancer after failure of other treatments.
 - As adjuvant therapy following initial treatment for node-positive breast cancer.
- **Non-Small Cell Lung Cancer (NSCLC)**
 - Treatment of advanced NSCLC in combination with cisplatin.
- **AIDS-Related Kaposi's Sarcoma**
 - Treatment of advanced Kaposi's sarcoma in

patients who have failed prior therapy.

2. Before Paclitaxel Injection Is Administered to You

Paclitaxel Injection Should Not Be Used If:

- You are allergic to paclitaxel or any of the other ingredients, especially macrogolglycerol ricinoleate.
- You have a low baseline neutrophil count (a type of white blood cell).
- You are pregnant or breastfeeding.

Special Care Should Be Taken with Paclitaxel Injection:

- **Blood Disorders:** Paclitaxel can suppress bone marrow function, leading to low blood cell counts.
- **Nerve Damage:** May cause peripheral neuropathy (numbness or tingling in hands and feet).
- **Heart Problems:** Inform your doctor if you have a history of heart disease.
- **Liver Impairment:** Dose adjustments may be necessary for patients with liver problems.
- **Infections:** Use with caution if you have ongoing infections.

Pregnancy and Breastfeeding

Pregnancy

Paclitaxel can harm an unborn baby and should not be used during pregnancy. Effective contraception must be used during treatment.

Breastfeeding

Do not breastfeed while receiving paclitaxel, as it may pass into breast milk.

3. How Paclitaxel Injection Is Administered to You

Method and Routes of Administration

- Administered under the supervision of a qualified physician experienced in chemotherapy.
- Given as an intravenous infusion (drip into a vein).

Dosage

- **Ovarian and Breast Cancer:**
 - **Standard Dose:** 175 mg/m² over 3 hours every 3 weeks.
- **Non-Small Cell Lung Cancer:**
 - **Standard Dose:** 175 mg/m² over 3 hours, followed by cisplatin, every 3 weeks.
- **AIDS-Related Kaposi's Sarcoma:**
 - **Standard Dose:** 100 mg/m² over 3 hours every 2 weeks.

Pre-Medication

- Before administration, you will receive medications (such as corticosteroids and antihistamines) to minimize the risk of allergic reactions.

Preparation and Administration

- The solution is prepared and diluted by healthcare professionals before use.
- Administered through an in-line filter with a microporous membrane not greater than 0.22 microns.

4. Possible Side Effects

Like all medicines, paclitaxel can cause side effects. Not everyone experiences them.

Common Side Effects:

- **Blood and Lymphatic System Disorders:**
 - Neutropenia (low white blood cells)
 - Anemia (low red blood cells)
 - Thrombocytopenia (low platelets)
- **Nervous System Disorders:**
 - Peripheral neuropathy (numbness or tingling)
- **Gastrointestinal Disorders:**
 - Nausea and vomiting

- Diarrhea
- Mouth sores (mucositis)
- **Skin and Subcutaneous Tissue Disorders:**
 - Hair loss (alopecia)
- **Musculoskeletal Disorders:**
 - Joint and muscle pain (arthralgia, myalgia)
- **General Disorders:**
 - Reactions at the injection site (pain, redness, swelling)

Serious Side Effects (Seek Medical Attention):

- Severe allergic reactions (difficulty breathing, swelling of the face or throat)
- Chest pain or irregular heartbeat
- Severe infections (fever, chills)
- Unusual bruising or bleeding

Note: Inform your doctor if you experience any side effects.

- **Shelf Life:** 3 years.
- **After Dilution:** Use immediately. If not used immediately, storage conditions are the responsibility of the healthcare provider.

6. Further Information

Composition

Each milliliter of concentrate contains:

- **Paclitaxel:** 6 mg

Other Ingredients:

- Macrogolglycerol ricinoleate
- Anhydrous ethanol

Presentation

- Supplied in single-use vials containing:
 - **5 ml vial:** 30 mg paclitaxel
 - **16.7 ml vial:** 100 mg paclitaxel
 - **50 ml vial:** 300 mg paclitaxel

5. Storing Paclitaxel Injection

- **Storage Temperature:** Store at room temperature between 15°C and 25°C (59°F to 77°F).
- **Protection:** Keep the vial in the outer carton to protect from light.

Manufacturer:



Imported & marketed by:



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