



Patient information leaflet

(For All Products not subject to Medical Prescription)

PACLITERO 30 (Paclitaxel Injection USP 30mg/5mL) (6mg/mL)

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine.

Keep this leaflet. You may need to read it again.

If you have any further questions, please ask your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

If any of the side effects get serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

In this leaflet:

1. What Paclitaxel Injection, USP is and what it is used for
2. What you need to know before you use Paclitaxel Injection, USP
3. How to use Paclitaxel Injection, USP
4. Possible side effects
5. How to store Paclitaxel Injection, USP
6. Further information

1. WHAT PACLITAXEL INJECTION, USP IS AND WHAT IT IS USED FOR

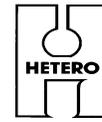
Paclitaxel injection, USP is a prescription medicine used to treat some forms of:

- ovarian cancer
- breast cancer
- lung cancer
- Kaposi's sarcoma

It is not known if Paclitaxel Injection, USP is safe or effective in children.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE PACLITAXEL INJECTION, USP

Paclitaxel Injection, USP can cause serious side effects including death.



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Serious allergic reactions (anaphylaxis) can happen in people who receive paclitaxel injection, USP. Anaphylaxis is a serious medical emergency that can lead to death and must be treated right away.

Tell your healthcare provider right away if you have any of these signs of an allergic reaction:

- trouble breathing
- sudden swelling of your face, lips, tongue, throat, or trouble swallowing
- hives (raised bumps) or rash

Your healthcare provider will give you medicines to lessen your chance of having an allergic reaction.

3. HOW TO USE PACLITAXEL INJECTION, USP

- Paclitaxel injection, USP is injected into a vein (intravenous [IV] infusion) by your healthcare provider.

Your healthcare provider will do certain tests while you receive paclitaxel injection, USP.

4. POSSIBLE SIDE EFFECTS

Tell your healthcare provider right away if you have:

- severe stomach pain
- severe diarrhea

The most common side effects of paclitaxel include:

- low red blood cell count (anemia) feeling weak or tired
- hair loss
- numbness, tingling, or burning in your hands or feet (neuropathy)
- joint and muscle pain
- nausea and vomiting
- hypersensitivity reaction - trouble breathing; sudden swelling of your face, lips, tongue, throat, or trouble swallowing; hives (raised bumps) or rash
- diarrhea
- mouth or lip sores (mucositis)
- infections - if you have a fever (temperature above 100.4°F) or other sign of infection, tell your healthcare provider right away
- swelling of your hands, face, or feet

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- bleeding events
- irritation at the injection site
- low blood pressure (hypotension)

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of paclitaxel injection, USP. For more information, ask your healthcare provider or pharmacist.

5. HOW TO STORE PACLITAXEL INJECTION, USP

Keep this medicine out of the sight and reach of children.

Store below 30°C and protect from moisture

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Paclitaxel Injection, USP contains

The active substance is Paclitaxel. Each mL contains 6 mg Paclitaxel USP, 527 mg of polyoxyl 35 castor oil (cremophor ELP) USP-NF, 49.7% (v/v) Dehydrated Alcohol USP and 2 mg Anhydrous Citric acid USP.

The other ingredients are Cremophor ELP USP/NF, Anhydrous Citric acid USP and Dehydrated alcohol USP (Ethanol)

What Paclitaxel Injection, USP looks like and contents of the pack

Paclitaxel Injection, USP is a Clear colorless to slightly yellow viscous solution free from visible particles.

Paclitaxel Injection, USP available in glass vials of:

Glass Vials: 10's count (5 ml glass vial, 20 mm rubber stopper with 20 mm flip of seal)

PACLITERO 30

(Paclitaxel Injection USP 30mg/5mL) (6mg/mL)



Hetero

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Name: Hetero Labs Limited

Business Address: 7-2-A2, Hetero Corporate,
Industrial Estates,
Sanath Nagar,
Hyderabad-500 018
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Country: INDIA

Manufacturer:

(Company) Name : Hetero Labs Limited (Unit-VI)

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MODULE 1:

ADMINISTRATIVE INFORMATION AND PRODUCT INFORMATION

1.4.4 MOCK-UPS AND SPECIMENS