

Nab-PACLITAXEL JUNO

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Nab-PACLITAXEL JUNO?

Nab-PACLITAXEL JUNO contains the active ingredient paclitaxel. Nab-PACLITAXEL JUNO is used to treat breast cancer, lungs cancer and pancreatic cancer.

For more information, see Section [1. Why am I using Nab-PACLITAXEL JUNO?](#) in the full CMI.

2. What should I know before I use Nab-PACLITAXEL JUNO?

Do not use if you have ever had allergic to paclitaxel or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or (for males, if your partner plans to become pregnant) are breastfeeding.

For more information, see Section [2. What should I know before I use Nab-PACLITAXEL JUNO?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Nab-PACLITAXEL JUNO and affect how it works. See in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is Nab-PACLITAXEL JUNO given?

- Your doctor will decide what dose of Nab-PACLITAXEL JUNO you will receive. This depends on your condition and other factors.

More instructions can be found in Section [4. How is Nab-PACLITAXEL JUNO given?](#) in the full CMI.

5. What should I know while using Nab-PACLITAXEL JUNO?

| | |
|----------------------------------|--|
| Things you should do | <ul style="list-style-type: none">Call your doctor straight away if you become pregnant while you are being treated with this medicineTell any other doctors, dentists, and pharmacists who are treating you that you are being given this medicine, especially if you are about to be started on any new medicineIf you are going to have surgery, tell the surgeon or anaesthetist that you are being treated with this medicine. It may affect other medicines used during surgery.Keep all your doctor's appointments so your progress can be checked.You have an increased chance of getting an infection or bleeding. Precautions should be taken to reduce your risk of infection or bleeding; see Section 5. What should I know while using Nab-PACLITAXEL JUNO? in the full CMI.Your body breaks down Nab-PACLITAXEL JUNO and uses it to fight cancer. The breakdown products may be excreted in body fluids and waste, including blood, urine, faeces, vomitus and semen. Precautions to protect other people should be taken while you are receiving chemotherapy and for one week after the treatment period; see Section 5. What should I know while using Nab-PACLITAXEL JUNO? in the full CMI. |
| Driving or using machines | <ul style="list-style-type: none">Some people may feel tired or dizzy after being given Nab-PACLITAXEL JUNO. If this happens to you, do not drive or use any tools or machines. |

For more information, see Section [5. What should I know while using Nab-PACLITAXEL JUNO?](#) in the full CMI.

6. Are there any side effects?

Like all medicines, Nab-PACLITAXEL JUNO can cause side effects. Your doctor will discuss potential side effects with you and will explain the risks and benefits of your treatment. Some side effects can be serious and you may require medical attention.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Nab-PACLITAXEL JUNO

Powder for injection (suspension)

Active ingredient(s): *Paclitaxel (pak-li-TAX-el)*

Consumer Medicine Information

This leaflet provides important information about using Nab-PACLITAXEL JUNO. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Nab-PACLITAXEL JUNO.**

Where to find information in this leaflet:

- [1. Why am I using Nab-PACLITAXEL JUNO?](#)
- [2. What should I know before I use Nab-PACLITAXEL JUNO?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is Nab-PACLITAXEL JUNO given?](#)
- [5. What should I know while using Nab-PACLITAXEL JUNO?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Nab-PACLITAXEL JUNO?

Nab-PACLITAXEL JUNO belongs to a group of medicines called antineoplastic or cytotoxic medicines. You may also hear of these being called chemotherapy medicines.

It works by killing cancer cells and stopping them from multiplying.

Nab-PACLITAXEL JUNO contains the active ingredient paclitaxel.

This medicine is used to treat:

- Breast cancer
- Lung Cancer
- Pancreatic Cancer

The safety and effectiveness of paclitaxel in children (under 18 years) has not been established.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

2. What should I know before I use Nab-PACLITAXEL JUNO?

Warnings

Do not use Nab-PACLITAXEL JUNO if:

- you are allergic to paclitaxel or human albumin, or any of the ingredients listed at the end of this leaflet.
Always check the ingredients to make sure you can use this medicine.
Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.
- you have a very low white blood cell (WBC) count.
- you are pregnant or plan to become pregnant. Like most cytotoxic medicines Nab-PACLITAXEL JUNO is not recommended for use during pregnancy. If there is any need to consider this medicine during your pregnancy, your doctor will discuss with you the benefits and risks of using it.
- Males: tell your doctor if your partner plans to become pregnant while you are being treated with this medicine or shortly after you have stopped treatment with it. Nab-PACLITAXEL JUNO may cause birth defects if either the male or female is being treated with it at the time of conception. It is recommended that you use some kind of birth control while you are being treated with Nab-PACLITAXEL JUNO and for at least 6 months after you received the last dose of Nab-PACLITAXEL JUNO . Your doctor will discuss this with you.
- are breastfeeding.
The active ingredient in Nab-PACLITAXEL JUNO passes into breast milk and there is a possibility that your baby may be affected.

Check with your doctor if you :

- You have an infection or high temperature. Your doctor may decide to delay your treatment until the infection is gone. A mild illness, such as a cold, is not usually a reason to delay treatment.
- liver disease You must not be given this medicine if you have severe liver damage.
- kidney disease
- heart problems
- any blood disorder with a reduced number of blood cells, or platelets
- any disease of the nerves
- lowered immunity due to diseases such as HIV/AIDS
- lowered immunity due to treatment with medicines such as cyclosporine, or other medicines used to treat cancer (including radiation therapy)

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Like most cytotoxic medicines paclitaxel is not recommended for use during pregnancy. If there is any need to consider this medicine during your pregnancy, your doctor will discuss with you the benefits and risks of using it.

Males: tell your doctor if your partner plans to become pregnant while you are being treated with this medicine or shortly after you have stopped treatment with it.

Paclitaxel may cause birth defects if either the male or female is being treated with it at the time of conception. It is recommended that you use some kind of birth control while you are being treated with paclitaxel and for at least 12 weeks after you stop using it. Your doctor will discuss this with you.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

The active ingredient in Nab-PACLITAXEL JUNO passes into breast milk and there is a possibility that your baby may be affected.

Do not breast-feed if you are taking this medicine.

If you are not sure whether you should be given this medicine, talk to your doctor.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and paclitaxel may interfere with each other. Some medicines may be affected by paclitaxel or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Tell your doctor if you are taking any of the following:

- medicines for treating infections (i.e. antibiotics such erythromycin, rifampicin, etc.; ask your doctor, nurse or pharmacist if you are unsure whether the medicine you are taking is an antibiotic), and including medicines for treating fungal infections (e.g. ketoconazole)
- medicines used to help you stabilize your mood also sometimes referred to as anti-depressants (e.g. fluoxetine)
- medicines used to treat seizures (epilepsy) (e.g. carbamazepine, phenytoin)
- medicines used to help you lower blood lipid levels (e.g. gemfibrozil)
- medicine used for heartburn or stomach ulcers (e.g. cimetidine)
- medicines used to treat HIV and AIDS (e.g. ritonavir, saquinavir, indinavir, nelfinavir, efavirenz, nevirapine)
- a medicine called clopidogrel used to prevent blood clots.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

4. How is Nab-PACLITAXEL JUNO given?

How and how much will be given

- Nab-PACLITAXEL JUNO is usually given as an infusion (drip) into a vein over 30 minutes.
- Your doctor will decide what dose of Nab-PACLITAXEL JUNO you will receive. This depends on your condition and other factors, such as your weight, kidney function and other chemotherapy medicines you are being given.

- Nab-PACLITAXEL JUNO should be given alone or in combination with other drugs.
- Several courses of Nab-PACLITAXEL JUNO therapy may be needed depending on your response to treatment.
- Additional treatment may not be repeated until your blood cell numbers return to acceptable levels and any uncontrolled effects have been controlled.
- Ask your doctor if you want to know more about the dose of Nab-PACLITAXEL JUNO you receive.

How long will it be given for

Breast Cancer:

Nab-PACLITAXEL JUNO is usually given once every three weeks (i.e. on day 1 of a 21-day cycle). Each infusion is called one 'cycle' of chemotherapy. Your doctor will decide how many of these cycles you will need.

Lung Cancer:

Nab-PACLITAXEL JUNO is given every week (i.e. on days 1, 8 and 15 of each 21-day cycle). Another medicine called carboplatin is also given on day 1 only of each 21-day cycle.

Your doctor will decide how many of these cycles you will need.

Pancreatic Cancer:

Nab-PACLITAXEL JUNO is given every week (i.e. on days 1, 8 and 15 of each 28-day cycle). Every 28 days is called one 'cycle' of chemotherapy.

Another medicine called gemcitabine is also given on days 1, 8 and 15 after Nab-PACLITAXEL JUNO has been given.

Your doctor will decide how many of these cycles you will need.

If you miss a dose

It is very important for you to keep all appointments to receive Nab-PACLITAXEL JUNO. If you miss an appointment, ask your doctor when to schedule your next dose.

If you use too much Nab-PACLITAXEL JUNO

As Nab-PACLITAXEL JUNO is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience severe side effects after being given this medicine, tell your doctor or nurse immediately or phone the

Poisons Information Centre (**by calling 13 11 26**), or go to the Emergency Department at your nearest hospital. **You should do this even if there are no signs of discomfort or poisoning.**

Symptoms of paclitaxel overdose include the side effects listed below under Section [6. Are there any side effects?](#) but are usually of a more severe nature.

5. What should I know while using Nab-PACLITAXEL JUNO?

Things you should do

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being treated with Nab-PACLITAXEL JUNO.
- Tell any other doctors, dentists, and pharmacists who are treating you that you are being given this medicine.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are being treated with this medicine. It may affect other medicines used during surgery.
- If you become pregnant while you are being treated with this medicine, tell your doctor immediately.
- Keep all your doctor's appointments so your progress can be checked. Your doctor may want to check your blood pressure and do some blood and other tests from time to time to check on your progress and detect any unwanted side effects.
- Keep follow-up appointments with your doctor. It is important to have your follow-up cycles of Nab-PACLITAXEL JUNO at the appropriate times to get the best effects from your treatments.

Infections or bleeding

This medicine can lower the number of white blood cells and platelets in your blood. This means that you have an increased chance of getting an infection or bleeding.

The following precautions should be taken to reduce your risk of infection or bleeding:

- Avoid people who have infections. Check with your doctor immediately if you think you may be getting an infection, or if you get a fever, chills, cough, hoarse throat, lower back or side pain or find it painful or difficult to urinate.
- Be careful when using a toothbrush, toothpick or dental floss. Your doctor, dentist, nurse or pharmacist may recommend other ways to clean

your teeth and gums. Check with your doctor before having any dental work.

- Be careful not to cut yourself when you are using sharp objects such as a razor or nail cutters.
- Avoid contact sports or other situations where you may bruise or get injured.

Body fluids and waste

Your body breaks down paclitaxel and uses it to fight cancer. The breakdown products may be excreted in body fluids and waste, including blood, urine, faeces, vomitus and semen.

In general, precautions to protect other people should be taken while you are receiving chemotherapy and for one week after the treatment period by:

- Flushing the toilet twice to dispose of any body fluids and waste.
- Wearing gloves to clean any spill of body fluid or waste. Use paper towels or old rags, a strong solution of non-bleaching detergent and large amounts of water to mop up the spill. Discard the towels or rags into a separate waste bag and dispose of fluids in the toilet.
- Wash linen or clothing that is heavily contaminated by body fluids or waste separately from other items. Use a strong solution of nonbleaching detergent and large amounts of water.
- Place soiled disposable nappies and other pads in a plastic bag, seal and dispose into the garbage.
- For sexual intercourse, use a barrier method such as a condom.

Driving or using machines

Be careful driving or operating machinery until you know how Nab-PACLITAXEL JUNO affects you.

Some people may feel tired or dizzy after being given Nab-PACLITAXEL JUNO. If this happens to you, do not drive or use any tools or machines.

If you are given other medication as part of your treatment, you should ask your doctor for advice on driving and using machines.

Looking after your medicine

Nab-PACLITAXEL JUNO will be stored in the pharmacy or on the ward. The injection is kept in a cool, dry place, protected from light, where the temperature stays below 25°C.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

The benefits and side effects of Nab-PACLITAXEL JUNO may take some time to occur. Therefore, even after you have finished receiving your treatment, you should tell your doctor immediately if you notice any of the side effects listed in this section.

Serious side effects

| Serious side effects | What to do |
|---|--|
| <ul style="list-style-type: none"> • pain, swelling, irritation and redness at the injection site • flushing • light-headedness, dizziness or fainting (due to low blood pressure) • numbness or tingling in the fingers and/or toes • changes in vision • abdominal pain • shortness of breath, coughing, wheezing or difficulty breathing • swelling of the face, lips, tongue, or other parts of the body • rash, itching or hives on the skin • extreme weakness or tiredness • seizures (fits) • fast, slow or irregular heart beat • chest pain • yellowing of the skin or eyes • unusual bleeding or bruising (including blood in your stools or urine) • fever, sore throat or other signs of infection | <p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> |

Other side effects

| Other side effects | What to do |
|--------------------|------------|
|--------------------|------------|

| | | |
|--|--|---|
| <p>Very common</p> <ul style="list-style-type: none"> • Abnormal decrease in the number of types of white blood cells (neutrophils, lymphocytes or leukocytes) in the blood • Deficiency of red blood cells • Reduction in the number of platelets in the blood • Anorexia • Effect on peripheral nerves (pain, numbness, tingling or loss of feeling) • Nausea, diarrhoea, constipation, throat pain, loss of appetite • Vomiting • Loss of hair • Rash • Pain in a joint or joints • Pain in the muscles • Weakness and tiredness, fever <p>Common</p> <ul style="list-style-type: none"> • Infection, including in the urinary tract, follicles, upper airways, thrush and sinuses • Fever with decrease in the number of a type of white blood cell (neutrophils) in the blood, flushing, severe infection in your blood which may be caused by reduced white blood cells • Dehydration • Decreased appetite • Low levels of potassium in the blood • Sleep problems • Depression, anxiety • Diminished muscular coordination or difficulty in reading, increased or | <p>Speak to your doctor if you have any of these side effects and they worry you.</p> | <ul style="list-style-type: none"> decreased tears, loss of eyelashes • Blurred vision • Taste disturbance • Headache, dizziness • Dry mouth, difficulty in swallowing • Muscle weakness • Changes in heart rate or rhythm • •Decreased or increased blood pressure • Blood clot in the lungs • Swelling of mucosal and soft tissues • Flushing • Difficulty in breathing • Coughing up blood • Nose bleeds, stuffy nose • Chest or throat pain • Cough • Indigestion, abdominal discomfort or pain • Itching, dry skin, nail disorder • Pain in back or limb, bone pain, muscle cramps • Weight loss • Reduction in all blood cell counts <p>Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.</p> <p>Other side effects not listed here may occur in some people.</p> <p>Reporting side effects</p> <p>After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.</p> <p>Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.</p> |
|--|--|---|

7. Product details

This medicine is only available with a doctor's prescription.

What Nab-PACLITAXEL JUNO contains

| | |
|---|--|
| Active ingredient (main ingredient) | Paclitaxel |
| Other ingredients (inactive ingredients) | Human albumin solution (containing sodium octanoate and N-acetyl-DL-tryptophan) |

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Do not take this medicine if you are allergic to any of these ingredients.

What Nab-PACLITAXEL JUNO looks like

Nab-PACLITAXEL JUNO is a white to yellow solid powder cake in a clear glass vial.

When it is reconstituted it will be a milky liquid.

(AUST R 328527)

Sponsor

Cipla Australia Pty Ltd.,
Level 1/132-136 Albert road,
South Melbourne Vic 3205
drugsafety@cipla.com
Phone: 1800-569-074

Who distributes Nab-PACLITAXEL JUNO

Juno Pharmaceuticals Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121

This leaflet was prepared in December 2024.