

Navelbine IV

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 Navelbine IV?

Navelbine IV contains the active ingredient vinorelbine tartrate. Navelbine IV is used to treat lung cancer and advanced breast cancer. For more information, see Section [1. Why am I using Navelbine IV?](#) in the full CMI.

2. What should I know before I use Navelbine IV?

Do not use if you have ever had an allergic reaction to 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 are breastfeeding.

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

3. What if I am taking other medicines?

Some medicines may interfere with Navelbine IV and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Navelbine IV?

Navelbine IV is given as a slow infusion (drip) into your veins. Navelbine IV must only be given by a doctor or nurse.

More instructions can be found in Section [4. How do I use Navelbine IV?](#) in the full CMI.

5. What should I know while using Navelbine IV?

| | |
|------------------------------------|--|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Navelbine IV.• Keep all appointments with your doctor to check on your progress and monitor side effects.• If you become pregnant while taking Navelbine IV, tell your doctor immediately. |
| Things you should not do | <ul style="list-style-type: none">• You should not breast-feed while you are being treated with Navelbine IV.• Do not use if you have or have had an infection or high temperature in the last 2 weeks• Do not use if you are currently receiving radiation therapy.• Do not use if you have recently had a yellow fever vaccination or plan to have one.• Do not use if you have severe liver problems or if you have a reduced number of platelets or red blood cells. |
| Driving or using machines | <ul style="list-style-type: none">• Be careful driving or operating machinery until you know how Navelbine IV affects you. |
| Drinking alcohol | <ul style="list-style-type: none">• Fatigue is a common side effect of Navelbine IV. Drinking alcohol may make the tiredness worse. |
| Looking after your medicine | <ul style="list-style-type: none">• If you are storing Navelbine IV at home:• Store Navelbine IV in the refrigerator (2 to 8°C). Do not freeze it.• Keep away from light and where children cannot reach |

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

6. Are there any side effects?

Common side effects include nausea, vomiting, diarrhoea, unusual tiredness, weakness, sleepiness, drowsiness or lack of energy, unusual hair loss, constipation, aching muscles, chest pain, jaw pain, painful swollen joints, injection site reactions, shortness of breath and high or low blood pressure.

Serious side effects include difficulty breathing, pain in bladder or back, blood in urine, chest pain, fast or irregular heartbeat, rash, itching or hives on the skin, swelling of the feet and ankles, face, lips, tongue or other parts of the body.

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.

Navelbine IV

Active ingredient(s): vinorelbine tartrate

Consumer Medicine Information (CMI)

This leaflet provides important information about using Navelbine IV. **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 Navelbine IV.**

Where to find information in this leaflet:

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

1. Why am I using Navelbine IV?

Navelbine IV contains the active ingredient vinorelbine tartrate. Vinorelbine belongs to a family of medicines called vinca alkaloids.

Navelbine IV belongs to a group of medicines called antineoplastic or cytotoxic medicines. You may also hear of these medicines being called chemotherapy.

Navelbine IV contains the medicine, vinorelbine which belongs to a family of medicines called vinca alkaloids.

Navelbine IV is used to treat lung cancer and advanced breast cancer.

Navelbine IV may be used on its own or in combination with other medicines to treat cancer. Navelbine IV works by stopping cancer cells from growing and multiplying causing the cells to die.

Navelbine IV is not recommended for use in children and adolescents as there is no information on its effects.

2. What should I know before I use Navelbine IV?

Warnings

Do not use Navelbine IV if:

- you are allergic to vinorelbine; or to the other vinca alkaloids, (vinblastine, vincristine, vindesine, vinflunine); or to any of the ingredients listed at the end of this leaflet. Symptoms of an allergic reaction to Navelbine IV may include:
 - o shortness of breath
 - o wheezing, difficulty breathing or a tight feeling in your chest
 - o swelling of the face, lips, tongue or other parts of the body
 - o rash, itching, hives or flushed, red skin
 - o dizziness or lightheadedness

- you have or have had an infection or high temperature in the last 2 weeks. Your doctor may decide to delay your treatment until the infection has gone.
- you have recently had a yellow fever vaccination or plan to have one.
- you are currently receiving radiation therapy to your liver.
- you have, or had any of the following medical conditions:
 - o severe liver problems
- a reduced number of white blood cells (known as neutropenia) which you may notice as frequent infections such as fever, severe chills, sore throat or mouth ulcers
- a reduced number of platelets (blood cells which help the blood to clot) which you may notice as bleeding or bruising more easily than normal.

Navelbine IV should not be administered if you are pregnant or intend to become pregnant.

Like most medicines used to treat cancer, Navelbine IV is not recommended for use in pregnancy. Navelbine IV may affect your developing baby if you take it during pregnancy. If there is a need to consider Navelbine IV during your pregnancy, your doctor will discuss with you the benefits and risks of using it.

Do not breastfeed while being treated with Navelbine IV.

Navelbine IV may pass into breast milk and therefore there is a possibility that the breast-fed baby may be affected.

Check with your doctor if you:

- have allergies to:
 - o any other medicines
 - o any other substances, such as foods, preservatives or dyes
- if you have, or have had, any of the following medical conditions:
 - o heart problems (including chest pain and heart attack)
 - o liver problems
 - o a low white blood cell count which you may notice as signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers
 - o lung problems, including asthma take any medicines for any other condition or treatments for cancer, including radiation therapy. Navelbine IV must not be administered if you are currently receiving radiation therapy to your liver.
- if you have recently had or plan to have a vaccination. Live attenuated vaccines (eg. measles vaccine, mumps

vaccine, rubella vaccine) are not recommended while having Navelbine IV.

Navelbine IV is a potent cytotoxic drug that results in a decrease in blood cells. Your blood count will be carefully monitored before and during your treatment

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 medicines used to treat cancer, Navelbine IV is not recommended for use during pregnancy. Navelbine IV may affect your developing baby if you take it during pregnancy.

If you are a fertile man or woman, you should use an effective method of contraception during your treatment with Navelbine IV. Women must use an effective contraception during treatment and for 7 months after your last dose of Navelbine IV.

Men being treated with Navelbine IV are advised to use effective contraception and not to father a child during and for a minimum of 4 months after treatment. Prior to treatment, men are advised to seek advice on conserving sperm due to the chance of irreversible fertility resulting from treatment with Navelbine IV.

If there is a need to consider Navelbine IV during your pregnancy, your doctor will discuss with you the benefits and risks of using it.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Do not breastfeed while being treated with Navelbine IV.

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 may interfere with Navelbine IV and affect how it works. These include:

- medicines used to prevent blood clots (anticoagulants) eg. phenindione, warfarin heparin
- phenytoin, a medicine used to treat epilepsy
- cyclosporin, tacrolimus, medicines which lower your immunity
- itraconazole and ketoconazole, medicines used to treat fungal infections
- mitomycin, lapatinib, medicines used to treat cancer
- medicines with known bone marrow toxicity (causing a reduced number of red or white blood cells or platelets)
- other medicines used to treat cancer such as cisplatin
- ritonavir, a medicine used to treat AIDS
- rifampicin, a medicine used to treat tuberculosis.

These medicines may be affected by Navelbine IV or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or to avoid while having Navelbine IV.

If you have not told your doctor about any of the above, do so before you begin treatment with Navelbine IV.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Navelbine IV.

4. How do I take Navelbine IV?

How much to take

- Your doctor will decide what dose you will receive. This depends on your body surface area, your condition and factors such as your liver function and whether you are receiving any other chemotherapy medicines. Your doctor may adjust your dose during treatment.
- Navelbine IV may be given alone or in combination with other drugs.
- Several courses of Navelbine IV therapy may be needed depending on your response to treatment.
- Navelbine IV reduces the number of white blood cells in the body. Your doctor will check these levels regularly. Further doses of Navelbine IV may be delayed until your blood cell numbers return to acceptable levels.

How to use

- Navelbine IV is given as a slow infusion (drip) into your veins.
- Navelbine IV must only be given by a doctor or nurse.

How long it is given

Navelbine IV is usually given every week, but it may be given less often if you are also having other medicines to treat cancer. Your doctor will decide how many doses you will need.

If you forget to use Navelbine IV

Tell your doctor as soon as possible if you realise that you have missed an appointment for receiving your dose of Navelbine IV.

If you have problems remembering when your next dose is due, use a diary or calendar or ask a friend to remind you.

If you use too much Navelbine IV

As Navelbine IV is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience any side effects while or after being given Navelbine IV, tell your doctor, nurse, or pharmacist.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Navelbine IV?

Things you should do

- Tell your doctor or nurse immediately if you feel any pain or discomfort during the infusion.
- Keep all appointments with your doctor. Your doctor may want to do some blood and other tests from time to time to check on your progress and monitor any unwanted side effects.
- Keep follow up appointments with your doctor. It is important to have your follow-up doses of Navelbine IV at the appropriate times to get the best effects from your treatments.
- If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are having treatment with Navelbine IV.
- If you become pregnant while taking Navelbine IV, tell your doctor immediately. Navelbine IV 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.
- Take the following precautions to reduce your risk of infection or bleeding:
 - o 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;
 - o Avoid people who have infections.
 - o 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.
 - o Be careful not to cut yourself when you are using sharp objects such as a razor or nail cutters.
 - o Avoid contact sports or other situations where you may bruise or get injured.

Call your doctor straight away if you:

- are feeling unwell after taking Navelbine IV.

Remind any doctor, dentist or pharmacist you visit that you are having treatment with Navelbine IV.

Things you should not do

- You should not breast-feed while you are being treated with Navelbine IV. Breastfeeding must be discontinued before starting treatment with Navelbine IV.

- Men being treated with Navelbine IV are advised not to father a child during and up to a minimum of 3 months after treatment. Prior to treatment, men are advised to seek advice on conserving sperm due to the chance of irreversible fertility resulting from treatment with Navelbine IV.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Navelbine IV affects you.

If you experience symptoms that affect your ability to concentrate and react, do not drive a car or operate machinery. Fatigue is a common side effect of Navelbine IV. Make sure you know how Navelbine IV affects you before you drive a car, operate machinery or do anything else that could be dangerous if you are feeling tired.

Drinking alcohol

Tell your doctor if you drink alcohol.

Drinking alcohol may make the tiredness worse.

Looking after your medicine

Navelbine IV is usually stored in the hospital, or at the pharmacy. However, if you are storing at home:

- Store Navelbine IV in the refrigerator (2 to 8°C). Do not freeze it.
- Protect Navelbine IV from light

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If your doctor stops your treatment with Navelbine IV, or it has passed its expiry date, return any leftover vials to your pharmacist. Do not dispose of Navelbine IV via wastewater or household waste. This will help to protect the environment.

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.

Less serious side effects

| Less serious side effects | What to do |
|---|---|
| Pain Related <ul style="list-style-type: none">• aching muscles, muscle tenderness or weakness, not caused by exercise | Speak to your doctor if you have any of these less |

| Less serious side effects | What to do |
|---|--|
| <ul style="list-style-type: none"> • pain, including pain at the tumour site • jaw pain • painful swollen joints <p>Problems with skin and hair</p> <ul style="list-style-type: none"> • skin rash • unusual hair loss or thinning <p>Head and neurology related</p> <ul style="list-style-type: none"> • unusual tiredness, weakness, sleepiness, drowsiness or lack of energy <p>Gastrointestinal upset</p> <ul style="list-style-type: none"> • nausea • vomiting • diarrhoea • constipation • upset stomach <p>Infection related</p> <ul style="list-style-type: none"> • fever | <p>serious side effects and they worry you.</p> |

Serious side effects

| Serious side effects | What to do |
|--|--|
| <p>Breathing problems:</p> <ul style="list-style-type: none"> • difficulty breathing, short of breath • breathlessness, which may be very severe and usually worse on lying down • a chest pain, breathlessness and fainting, which can be a symptom of a clot in a blood vessel in the lungs (pulmonary embolism) <p>Head and neurology related</p> <ul style="list-style-type: none"> • tiredness, headaches, being short of breath when exercising, dizziness and looking pale (symptoms of a decreased number of red blood cells) • numbness + tingling of fingers and toes • lack of muscle control, which may be associated with abnormal gait, and speech changes • weakness of legs or feet • headaches, changed mental state which may lead to confusion and coma, convulsions, blurred vision and high blood pressure, which could be sign of a neurological | <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> |

| Serious side effects | What to do |
|--|------------|
| <p>disorder such as posterior reversible encephalopathy syndrome</p> <p>Infection related</p> <ul style="list-style-type: none"> • frequent infections such as fever, severe chills, sore throat or mouth ulcers (symptoms of a lack of white blood cells) • sore mouth <p>Bleeding related</p> <ul style="list-style-type: none"> • bleeding or bruising more easily than normal or nosebleeds (symptoms of a low blood platelet count) • blood infection (sepsis) with symptoms such as a high fever and deterioration in general health <p>Eye problems</p> <ul style="list-style-type: none"> • changes in your vision <p>Gastrointestinal problems</p> <ul style="list-style-type: none"> • stomach pain with bloating, gut cramps and vomiting which may be symptoms of the small bowel not working properly • severe upper stomach pain <p>Skin related</p> <ul style="list-style-type: none"> • irritation, pain, swelling or colouring of the skin around the needle or along the vein during the infusion <p>Liver disease related</p> <ul style="list-style-type: none"> • weakness, tiredness, loss of appetite, weight loss or stomach pain that may be symptoms of liver disease. <p>Urinary related</p> <ul style="list-style-type: none"> • pain or burning feeling when passing urine • pain in bladder or back, blood in urine <p>Heart related</p> <ul style="list-style-type: none"> • chest pain • palpitations, fast or irregular heart beat • severe chest pain which is not normal for you, the symptoms may be due to disturbance in the heart function following insufficient blood flow, so called ischemic heart disease such as for example angina pectoris and | |

| Serious side effects | What to do |
|--|------------|
| <p>myocardial infarction (sometimes with fatal outcome)</p> <p>Allergy related</p> <ul style="list-style-type: none"> rash, itching or hives on the skin swelling of the feet and ankles, face, lips, tongue or other parts of the body. | |

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

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.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Navelbine IV contains

| | |
|---|----------------------|
| Active ingredient (main ingredient) | vinorelbine tartrate |
| Other ingredients (inactive ingredients) | water for injection |
| Potential allergens | No |

Navelbine IV does not contain lactose, sucrose, gluten, tartrazine or any other azodyes.

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

What Navelbine IV looks like

Navelbine IV is a clear, colourless to pale yellow solution. It comes in a clear glass vial with a rubber stopper and royal blue cap. Each vial is packed in a carton.

10mg/1mL: AUST R 62246

50mg/5mL: AUST R 62248

Who distributes Navelbine IV

Pierre Fabre Australia Pty Limited

Level 7, 32 Walker St

North Sydney NSW 2060

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