

NAVELBINE® Injection 10 mg/mL, 40 mg/4 mL, 50 mg/5 mL

vinorelbine tartrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Navelbine® IV.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you being given Navelbine® IV against the benefits this medicine is expected to have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What Navelbine® IV is used for

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 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 works by stopping cancer cells from growing and multiplying causing the cells to die.

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

Your doctor may have prescribed Navelbine® IV for another purpose.

Ask your doctor if you have any questions about why Navelbine® IV has been prescribed for you.

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

Before you are given Navelbine® IV

When you must not be given it

Navelbine® IV should not be administered if you have an allergy to: the active substance, 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:

- shortness of breath
- wheezing, difficulty breathing or a tight feeling in your chest
- swelling of the face, lips, tongue or other parts of the body
- rash, itching, hives or flushed, red skin.
- dizziness or lightheadedness.

Navelbine® IV should not be administered if 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.

Navelbine® IV should not be administered if you have, or have had, any of the following medical conditions:

- 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 have recently had a yellow fever vaccination or plan to have one.

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 during 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 breastmilk and therefore there is a possibility that the breast-fed baby may be affected.

Navelbine® IV should not be administered after the expiry date printed on the pack. The expiry date refers to the last day of that month.

If you have this medicine after the expiry date has passed, it may not work as well.

Navelbine® IV should not be administered if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start having Navelbine® IV, talk to your doctor.

Before you are given it

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.

Tell your doctor or pharmacist if you have allergies to:

- any other medicines;
- any other substances, such as foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:

- heart problems (including chest pain and heart attack);
- liver problems;
- 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;
- lung problems, including asthma;

Tell your doctor if you are having or have had any other medicines or treatments for cancer, including radiation therapy.

Navelbine® IV must not be administered if you are currently

receiving radiation therapy to your liver.

Tell your doctor 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.

Tell your doctor if you are pregnant or intend to become pregnant.

Navelbine® IV is not recommended for use in pregnancy.

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

Tell your doctor if you are breast-feeding or plan to breast-feed.

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

Taking other medicines

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

Some medicines and Navelbine® IV may interfere with each other. 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.

How Navelbine® IV is given

How much is given

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® Oral 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 it is given

Navelbine® IV is given as a slow injection into your veins, usually with an infusion (drip). 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 miss a dose

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.

Overdose

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.

While you are being given Navelbine® IV

Things you must do

Tell your doctor or nurse immediately if you feel any pain or discomfort during the injection.

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.

Tell any other doctors, dentists and pharmacists who are treating you that you are having treatment with Navelbine® IV.

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:

- 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;
- Avoid people who have infections;
- 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.

Things to be careful of

Be careful driving or operating machinery 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 may make the tiredness worse.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are having Navelbine® IV.

Like other medicines that treat cancer, Navelbine® IV can cause side effects, some of which may be serious. You may need medical treatment if you get some of these side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you:

- nausea;
- vomiting;
- diarrhoea;
- unusual tiredness, weakness, sleepiness, drowsiness or lack of energy;
- unusual hair loss or thinning;
- constipation;
- upset stomach;
- aching muscles, muscle tenderness or weakness, not caused by exercise;
- skin rash;

- pain, including pain at the tumour site;
- jaw pain;
- painful swollen joints;

These are the more common side effects of Navelbine® IV.

Tell your doctor or nurse as soon as possible if you notice any of the following:

- frequent infections such as fever, severe chills, sore throat or mouth ulcers (symptoms of a lack of white blood cells);
- irritation, pain, swelling or colouring of the skin around the needle or along the vein during the infusion;
- numbness + tingling of fingers and toes;
- weakness of legs or feet;
- tiredness, headaches, being short of breath when exercising, dizziness and looking pale (symptoms of a decreased number of red blood cells);
- bleeding or bruising more easily than normal or nosebleeds (symptoms of a low blood platelet count);
- stomach pain with bloating, gut cramps and vomiting which may be symptoms of the small bowel not working properly;
- severe upper stomach pain;
- sore mouth;
- pain or burning feeling when passing urine;
- changes in your vision;
- weakness, tiredness, loss of appetite, weight loss or stomach pain that may be symptoms of liver disease.

These may be serious side effects. You may need medical attention.

If any of the following happen, tell your doctor or nurse immediately, or go to Accident and Emergency at your nearest hospital:

- difficulty breathing, short of breath;
- breathlessness, which may be very severe and usually worse on lying down;

- pain in bladder or back, blood in urine;
- chest pain;
- palpitations, fast or irregular heart beat;
- rash, itching or hives on the skin;
- swelling of the feet and ankles, face, lips, tongue or other parts of the body.

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Other side effects not listed above may occur in some patients. Tell your doctor, nurse or pharmacist if you notice anything else that is making you feel unwell.

Tell your doctor if you notice any of the side effects listed in this section, even after you have finished your Navelbine® IV treatment.

The benefits and side effects of Navelbine® IV may take some time to occur.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After treatment with Navelbine® IV

Storage

If you are storing Navelbine® IV at home:

Store Navelbine® IV in the refrigerator (2 to 8°C). Do not freeze it.

Protect Navelbine® IV from light.

Do not leave Navelbine® IV in the car.

Keep it where children cannot reach it.

Disposal

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.

Product description

What it 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.

Ingredients

Active ingredient:

- vinorelbine tartrate

Other ingredients:

- water for injection

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

Sponsor:

Navelbine® IV is supplied by:

Pierre Fabre Australia Pty Limited
Suite 601,
504 Pacific Highway
St Leonards NSW 2065

Australian Registration Number:

10mg/1mL: 62246

50mg/5mL: 62248

This leaflet was prepared in July, 2014.