Navelbine Oral

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 Oral?

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

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

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 Oral? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Navelbine Oral 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 Oral?

Navelbine Oral is given as a capsule. Swallow your Navelbine Oral capsule whole with a full glass of water, without chewing or sucking the capsule. More instructions can be found in Section 4. How do I use Navelbine Oral? in the full CMI.

5. What should I know while using Navelbine Oral?

Things you should do	• Keep all appointments with your doctor to check on your progress and monitor side effects. • If you become pregnant while taking Navelbine Oral, tell your doctor immediately.
Things you should not do	• You should not breast-feed while you are being treated with Navelbine Oral. • Men being treated with Navelbine Oral are advised not to father a child during and up to a minimum of 4 months after treatment. • 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, if you have a reduced number of platelets of red blood cells, if you have stomach or intestinal disorders or if you have any condition requiring long-term oxygen therapy
Driving or using machines	• Be careful driving or operating machinery until you know how Navelbine Oral affects you.
Drinking alcohol	• Fatigue and Dizziness are common side effects of Navelbine Oral. Drinking alcohol may make these symptoms worse.
Looking after your medicine	• Store Navelbine Oral 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 Oral? in the full CMI.

6. Are there any side effects?

Common side effects include nausea, vomiting, diarrhoea, loss of appetite, unusual tiredness, weakness, sleepiness, drowsiness or lack of energy, unusual hair loss, constipation, aching muscles, skin reactions, fever, jaw pain, painful swollen joints, weight loss, weight gain and high or low blood pressure.
Serious side effects include difficulty breathing, 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 Oral

Active ingredient(s): *vinorelbine tartrate*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using Navelbine Oral?

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

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

Navelbine Oral is used treat lung cancer and advanced breast cancer.

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

Navelbine Oral is not recommended for use in children and adolescents aged less than 18 years as there is no information on its effects in these age groups.

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

Warnings

Do not use Navelbine Oral 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 Oral 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
- if you have or have had (within the last two weeks), a severe infection. Your doctor may decide to delay your treatment until the infection has gone.
- if you plan to have a yellow fever vaccine or have just had one.
- if you are currently receiving radiation therapy to your liver.
- if you have or have had any of the following medical conditions:
    - severe liver problems
    - a low white blood cell and/or platelet count which you may notice as signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers
    - surgery on your stomach or small bowel
    - stomach or intestinal disorders
    - any condition requiring long-term oxygen therapy
- Always check the ingredients to make sure you can use this medicine.

Do not take Navelbine Oral if you are pregnant or intend to become pregnant.

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

Do not breastfeed while being treated with Navelbine Oral.

Navelbine Oral 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 or have had a severe infection in the last 2 weeks. Your doctor may decide to delay your treatment until the infection has gone.
- have allergies to:
    - any other medicines
    - any other substances, such as foods, preservatives or dyes
- if you have, or have had, any of the following medical conditions:
    - heart problems (including chest pain and heart attack)
    - liver problems
    - a low white blood cell and/or platelet count which you may notice as signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers
    - stomach problems (including surgery on your stomach)
    - lung problems, including asthma

- the rare hereditary problem of fructose intolerance (due to the presence of sorbitol).

- take any medicines for any other condition or treatments for cancer, including radiation therapy.
- Navelbine Oral must not be taken if you are currently receiving radiation therapy to your liver.
- if you plan to have a vaccination. Having a live attenuated vaccine (eg: measles, mumps, rubella vaccine) is not recommended while taking Navelbine Oral as they may increase the risk of life-threatening vaccine disease.
- if your ability to carry out activities of daily living is strongly reduced.

Navelbine Oral 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 Oral is not recommended for use in pregnancy. Navelbine Oral 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 Oral. Women must use an effective contraception during treatment and for 7 months after your last dose of Navelbine Oral.

Men being treated with Navelbine Oral are advised to use an effective contraception during treatment and not to father a child during and for a minimum of 4 months after treatment. Prior to treatment, advice should be sought for conserving sperm due to the chance of irreversible infertility as a consequence of treatment with Navelbine Oral.

If there is a need to consider Navelbine Oral 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. You must stop breast-feeding before starting treatment with Navelbine Oral.

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 Oral and affect how it works. These include:

- mitomycin and lapatinib, medicines used to treat cancer;
- warfarin, phenindione and other medicines used to prevent blood clots;
- other medicines used to treat cancer such as cisplatin;
- ketoconazole and itraconazole, medicines used to treat fungal infections;
- retonavir, a medicine used to treat HIV and AIDS;
- rifampicin, a medicine used to treat tuberculosis or meningitis;
- cyclosporin and tacrolimus, drugs which reduce the body's ability to fight illness/disease (known as immunosuppressants).
- phenytoin, a medicine used to treat epilepsy or fits.

These medicines may be affected by Navelbine Oral 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 Oral.

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

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 Oral.

4. How do I use Navelbine Oral?

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 Oral may be given alone or in combination with other drugs.
- Several courses of Navelbine Oral 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 Oral may be delayed until your blood cell numbers return to acceptable levels.

How to take Navelbine Oral

- Navelbine Oral is given as a capsule.
- Swallow your Navelbine Oral capsule whole with a full glass of water, without chewing or sucking the capsule. The liquid inside Navelbine Oral is an irritant and may cause damage if it comes in contact with your skin, mucosa or eyes.
- Damaged capsules should not be swallowed.
- If contact with the contents of the capsule does occur, wash the affected area thoroughly with water or physiological solution and contact your doctor immediately.
- Navelbine Oral should be taken with food.

- If vomiting occurs within a few hours of taking Navelbine Oral, the dose of Navelbine Oral should not be repeated. Your doctor may prescribe a medication to help with vomiting if it is a problem.
- To open the child resistant packaging:
    - Cut the blister along the black dotted line;
    - Peel off the soft plastic foil;
    - Push the capsule through the aluminium foil.

How long is it given

- Navelbine Oral 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 Oral

Tell your doctor as soon as possible if you realise that you have missed your dose of Navelbine Oral.

If you have problems remembering when your next dose is due, use a diary or calendar or ask a friend to remind you. Please also refer to your Navelbine Oral 'Patient Booklet'.

If you use too much Navelbine Oral

If you think that you have used too much Navelbine Oral, you may need urgent medical attention.

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 Oral?

Things you should do

- 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.
- If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are having treatment with Navelbine Oral.
- If you become pregnant while taking Navelbine Oral, tell your doctor immediately. Navelbine Oral 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.

Call your doctor straight away if you:

- are feeling unwell after taking Navelbine Oral.

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

Things you should not do

- You should not breast-feed while you are being treated with Navelbine Oral. Breastfeeding must be discontinued before starting treatment with Navelbine Oral.
- Men being treated with Navelbine Oral are advised not to father a child during and up to a minimum of 3 months after treatment. Prior to treatment, advice should be sought for conserving sperm due to the chance of irreversible infertility as a consequence of treatment with Navelbine Oral.

Driving or using machines

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

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

Drinking alcohol

Tell your doctor if you drink alcohol.

Drinking alcohol may make the tiredness and dizziness worse.

Looking after your medicine

- If you are storing Navelbine Oral at home:
- Store Navelbine Oral in the refrigerator (2 to 8°C) in the original packaging. Do not freeze it.
- Protect Navelbine Oral from light.

Do not store Navelbine Oral or any other medicine in the bathroom or near a sink. Do not leave it on a windowsill or in the car

Heat and dampness will destroy the medicine.

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

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If your doctor stops your treatment with Navelbine Oral, or it has passed its expiry date, return any leftover capsules to your pharmacist. Do not dispose of Navelbine Oral 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 • aching muscles, muscle tenderness or weakness, not caused by exercise • pain, including pain at the tumour site • jaw pain • painful swollen joints **Problems with skin and hair** • skin reactions • unusual hair loss or thinning **Head and neurology related** • unusual tiredness, weakness, sleepiness, drowsiness or lack of energy • trouble sleeping • dizziness • headache **Gastrointestinal upset** • nausea • vomiting • diarrhoea • constipation • upset stomach • loss of appetite • indigestion • weight loss • weight gain **Respiratory related** • coughing • change in or loss of taste	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Breathing Problems • difficulty breathing, short of breath • a chest pain, breathlessness and fainting, which can be a symptom of a clot in a blood vessel in the lungs (pulmonary embolism) **Infection related** • frequent infections or signs of infection such as fever, severe chills, sore throat or mouth ulcers (symptoms of a lack of white blood cells) • sore mouth • mouth ulcers and cold sores • viral, bacterial or fungal infections • blood infections (sepsis) symptoms such as high fever and deterioration in general health **Head and neurology related** • tiredness, headaches, dizziness and looking pale (symptoms of a decreased number of red blood cells) • lack of muscle control may be associated with abnormal gait, speech changes and abnormalities in eyes movement • 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 disorder such as posterior reversible encephalopathy syndrome **Bleeding related** • bleeding or bruising more easily than normal or nosebleeds (symptoms of a low blood platelet count) **Eye problems** • changes in your vision **Throat related** • difficulty swallowing **Urinary related** • pain or burning feeling when passing urine or other urinary problems. **Heart related** • chest pain	**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.**

Serious side effects	What to do
• palpitations, fast or irregular heart beat • high blood pressure • low blood pressure **Allergy related** • rash, itching or hives on the skin • swelling of the feet and ankles, face, lips, tongue or other parts of the body **Liver related** • liver disorders (abnormal liver test)	

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 Oral contains

Active ingredient (main ingredient)	vinorelbine tartrate
Other ingredients (inactive ingredients)	• ethanol • purified water • glycerol • macrogol 400 • gelatin • anidrisorb 85/70 • phosal 53 MCT • medium-chain triglycerides • edible ink red • titanium dioxide • iron oxide yellow • iron oxide red
Potential allergens	No

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

What Navelbine Oral looks like

Navelbine Oral soft capsules are available in four strengths: 20 mg, 30 mg, 40 mg* and 80 mg*.

Navelbine Oral 20 mg soft capsules are light brown and printed N20.

Navelbine Oral 30 mg soft capsules are pink and printed N30.

Navelbine Oral 40 mg soft capsules are brown and printed N40.

Navelbine Oral 80 mg soft capsules are pale yellow and printed N80.

Navelbine Oral comes in blister packs of 1 tablet.

*These pack sizes are not available in Australia.

Australian Registration Number:

20 mg: AUST R 99498

30 mg: AUST R 99558

40 mg: AUST R 99561

80 mg: AUST R 99564

Who distributes Navelbine Oral

Pierre Fabre Australia Pty Limited

Level 7, 32 Walker St

North Sydney NSW 2060

This leaflet was prepared in May 2025