

VELABINE

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 taking VELABINE capsules?

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

2. What should I know before I take VELABINE capsules?

Do not use if you have ever had an allergic reaction to VELABINE capsules 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 take VELABINE capsules?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with VELABINE capsules 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 take VELABINE capsules?

Swallow your VELABINE capsules whole with a full glass of water, without chewing or sucking the capsule.

More instructions can be found in Section [4. How do I take VELABINE capsules?](#) in the full CMI.

5. What should I know while taking VELABINE capsules?

Things you should do	<ul style="list-style-type: none">• Keep all appointments with your doctor to check on your progress and monitor side effects.• If you become pregnant while taking VELABINE capsules, tell your doctor immediately.
Things you should not do	<ul style="list-style-type: none">• Women being treated with VELABINE capsules should not breast-feed while you are being treated with VELABINE capsules.• Women being treated with VELABINE capsules should not become pregnant during therapy or for 7 months after the treatment.• Men being treated with VELABINE capsules 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 or 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	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how VELABINE capsules affect you.
Drinking alcohol	<ul style="list-style-type: none">• Fatigue and dizziness are common side effects of VELABINE capsules. Drinking alcohol may make these symptoms worse.
Looking after your medicine	<ul style="list-style-type: none">• Store VELABINE capsules in the refrigerator (2 to 8°C). Do not freeze it.• Store capsules out of reach of children, in the packaging.

For more information, see Section [5. What should I know while taking VELABINE capsules?](#) 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.

VELABINE

Active ingredient: Vinorelbine tartrate

Consumer Medicine Information (CMI)

This leaflet provides important information about taking VELABINE capsules. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking VELABINE capsules.**

Where to find information in this leaflet:

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

1. Why am I taking VELABINE capsules?

VELABINE capsules contain the active ingredient vinorelbine tartrate. Vinorelbine belongs to a family of medicines called vinca alkaloids.

VELABINE capsules belong to a group of medicines called antineoplastic or cytotoxic medicines. You may also hear of these medicines being called chemotherapy.

VELABINE capsules are used to treat lung cancer and advanced breast cancer. VELABINE capsules may be used on its own or in combination with other medicines to treat cancer. VELABINE capsules work by stopping cancer cells from growing and multiplying causing the cells to die.

VELABINE capsules are 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 take VELABINE capsules?

Warnings

Do not take VELABINE capsules 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 VELABINE capsules 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.

- you are currently receiving radiation therapy to your liver.
- you are pregnant or plan to become pregnant
- you are breastfeeding

- 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.
- you plan to have a yellow fever vaccine or have just had one.
- 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

Do not take VELABINE capsules if you are pregnant or intend to become pregnant.

Like most medicines used to treat cancer, VELABINE capsules are not recommended for use in pregnancy.

VELABINE capsules may affect your developing baby if you take them during pregnancy.

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

Do not breastfeed while being treated with VELABINE capsules.

VELABINE capsules 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. VELABINE capsules 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 VELABINE capsules as they may increase the risk of life-threatening vaccine disease.
- if your ability to carry out activities of daily living is strongly reduced.

VELABINE capsules are 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, VELABINE capsules are not recommended for use in pregnancy. VELABINE capsules 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 VELABINE capsules. Women must use an effective contraception during treatment for 7 months after your last dose of VELABINE capsules.

Men being treated with VELABINE capsules 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 VELABINE capsules.

If there is a need to consider VELABINE capsules 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 VELABINE capsules.

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 VELABINE capsules 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;
- ritonavir, a medicine used to treat HIV and AIDS;
- rifampicin, a medicine used to treat tuberculosis or meningitis;
- phenytoin, a medicine used to treat epilepsy or fits.
- ciclosporin and tacrolimus, drugs which reduce the body's ability to fight illness/ disease (known as immunosuppressants).

These medicines may be affected by VELABINE capsules 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 VELABINE capsules.

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

4. How do I take VELABINE capsules?

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. Your dose may be more than 1 capsule.
- VELABINE capsules may be given alone or in combination with other drugs.
- Several courses of VELABINE therapy may be required depending on your response to treatment.
- VELABINE capsules reduce the number of white blood cells in the body. Your doctor will check these levels regularly. Further doses of VELABINE may be delayed until your blood cell numbers return to acceptable levels.

When to take VELABINE

- VELABINE is given as a capsule. Swallow your VELABINE capsules whole with a full glass of water, without chewing or sucking the capsule. The liquid inside VELABINE capsules 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 a normal saline solution.
- VELABINE capsules should be taken with food.

- If vomiting occurs within a few hours of taking VELABINE capsules, the dose 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 it is given

VELABINE capsules are 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 take VELABINE capsules

Tell your doctor as soon as possible if you realise that you have missed your dose of VELABINE capsules.

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 take too much VELABINE

If you think that you have used too much VELABINE, 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 taking VELABINE capsules?

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 VELABINE capsules.
- If you become pregnant while taking VELABINE capsules, tell your doctor immediately. VELABINE capsules 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 VELABINE capsules.

Remind any doctor, dentist or pharmacist you visit that you are having treatment with VELABINE capsules.

Things you should not do

- You should not breast-feed while you are being treated with VELABINE capsules. Breastfeeding must be discontinued before starting treatment with VELABINE capsules.
- Men being treated with VELABINE capsules are advised not to father a child during and up to 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 VELABINE capsules.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how VELABINE capsules affect 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 VELABINE capsules. Make sure you know how VELABINE capsules affect 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 VELABINE capsules at home, store VELABINE capsules in the refrigerator (2 to 8°C) in the original packaging. Do not freeze it.

Do not store VELABINE capsules 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 VELABINE capsules, or it has passed its expiry date, return any leftover capsules to your pharmacist. Do not dispose of VELABINE capsules 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
<p>Pain Related</p> <ul style="list-style-type: none"> aching muscles, muscle tenderness or weakness, not caused by exercise 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 reactions 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 trouble sleeping dizziness headache <p>Gastrointestinal upset</p> <ul style="list-style-type: none"> nausea vomiting diarrhoea constipation upset stomach loss of appetite indigestion weight loss/ weight gain <p>Respiratory related</p> <ul style="list-style-type: none"> coughing change in or loss of taste 	<p>Speak to your doctor if you have any of these less 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 a chest pain, breathlessness and fainting, which can be a symptom of a clot in a blood vessel in the lungs (pulmonary embolism) <p>Infection related</p> <ul style="list-style-type: none"> frequent infections or signs of infection such as fever, severe chills, sore throat, 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 <p>Head and neurology related</p> <ul style="list-style-type: none"> 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. <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) <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 <p>Throat related</p> <ul style="list-style-type: none"> difficulty swallowing <p>Urinary related</p> <ul style="list-style-type: none"> pain or burning feeling when passing urine or other urinary problems. <p>Heart related</p> <ul style="list-style-type: none"> chest pain palpitations, fast or irregular heart beat high or low blood pressure <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 <p>Liver related</p> <ul style="list-style-type: none"> liver disorders (abnormal liver test) 	<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>

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 VELABINE capsules contain

Active ingredient (main ingredient)	vinorelbine tartrate
Other ingredients (inactive ingredients)	ethanol medium-chain triglycerides purified water polysorbate 80 macrogol 400 The capsule shell contains: gelatin sorbitol titanium dioxide, iron oxide yellow (20 mg and 80 mg capsules only) iron oxide red (30 mg capsules only)

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

What VELABINE capsules look like

20 mg soft capsule: oval-shaped light brown soft capsule (AUST R 381471)

30 mg soft capsule: oblong-shaped pink soft capsule (AUST R 381470)

80 mg soft capsule: oblong-shaped pale yellow soft capsule (AUST R 381472)

Who distributes VELABINE capsules

Arrotex Pharmaceuticals Pty. Ltd
15-17 Chapel St,
Cremorne VIC 3121
www.arrotex.com.au

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