

VINORELBINE EBEWE®

Vinorelbine tartrate Concentrated Solution for Injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Vinorelbine Ebewe.

It does not contain all the available information.

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

All medicines have risks and benefits. Your doctor has weighed the risks of you being given Vinorelbine Ebewe Injection against the benefits they expect it will have for you.

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

Keep this leaflet in a safe place.

You may need to read it again.

What is Vinorelbine Ebewe used for

Vinorelbine Ebewe is used to treat lung cancer and advanced breast cancer.

Vinorelbine Ebewe may be used on its own or in combination with other medicines to treat cancer.

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

Vinorelbine Ebewe contains the medicine, vinorelbine which belongs to a family of medicines called vinca alkaloids. Vinorelbine Ebewe works by stopping cancer cells from growing and multiplying causing the cells to die.

Your doctor may have prescribed Vinorelbine Ebewe for another reason. Ask your doctor if you have any questions about why Vinorelbine Ebewe has been prescribed for you.

Vinorelbine Ebewe is not addictive.

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

Vinorelbine Ebewe is not recommended for use in children, as there is no information on its effects in children.

Before you are given Vinorelbine Ebewe

When you must not be given it

Do not take Vinorelbine Ebewe if you have an allergic to:

- the active substance, vinorelbine
- other vinca alkaloids (vinblastine, vincristine, vindesine, vinflunine)
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction 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 light headedness.

Do not take this medicine 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.

Do not take this medicine 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.

Do not take this medicine if you have recently had a yellow fever vaccination or plan to have one.

Do not take this medicine if you are pregnant or plan to become pregnant.

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

Males: Tell your doctor or pharmacist if your partner intends to become pregnant while you are being given vinorelbine or shortly after you have stopped treatment with vinorelbine.

Vinorelbine may cause birth defects if either the male or female is using it at the time of conception. It is recommended that you use an effective method of contraception while you are using vinorelbine and for at least 3 months after you stop treatment.

Men being treated with this medicine 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 this medicine.

Do not breastfeed while being treated with Vinorelbine Ebewe.

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

Breastfeeding must be discontinued before starting treatment with Vinorelbine Ebewe.

Do not take this medicine after the expiry date printed on the pack or 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 be given Vinorelbine Ebewe, talk to your doctor or pharmacist.

Before you are given it

Vinorelbine Ebewe is a potent cytotoxic medicine 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 to the stomach area.

This medicine must not be given 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 (e.g. measles vaccine, mumps vaccine, rubella vaccine) are not recommended while having this medicine.

If you have not told your doctor about any of the above, tell them before you are given Vinorelbine Ebewe.

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 Vinorelbine Ebewe may interfere with each other. These include:

- phenindione, warfarin, heparin - medicines used to prevent blood clots (anticoagulants)
- phenytoin - medicine used to treat epilepsy
- ciclosporin, tacrolimus - medicines which lower your immunity
- itraconazole, 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 - medicine used to treat AIDS
- rifampicin - medicine used to treat tuberculosis.

These medicines may be affected by Vinorelbine Ebewe, or may affect how well it works. You may need 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 avoid while being given Vinorelbine Ebewe.

How Vinorelbine Ebewe is given

How much is given

Your doctor will decide what dose of Vinorelbine Ebewe you will receive. This depends on your medical condition and other factors, such as your body surface area, white

blood cell count, liver function and other chemotherapy medicines you are being given.

Your doctor may adjust your dose during treatment.

Vinorelbine Ebewe may be given alone or in combination with other drugs.

Several courses of Vinorelbine Ebewe therapy may be needed depending on your response to treatment.

Vinorelbine Ebewe reduces the number of white blood cells in the body. Your doctor will check these levels regularly. Further doses of Vinorelbine Ebewe may be delayed until your blood cell numbers return to acceptable levels.

Ask your doctor if you want to know more about the dose of Vinorelbine Ebewe you receive.

How it is given

Vinorelbine Ebewe is given as a slow injection into your veins, usually with an infusion (drip). Vinorelbine Ebewe must only be given by a doctor or nurse.

How long it is given

Vinorelbine Ebewe is usually given every week, but 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 Vinorelbine Ebewe.

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 are given too much (overdose)

As Vinorelbine Ebewe is most likely to be given to you in hospital under the supervision of your doctor, it is very unlikely that you will receive an overdose. **However, if you experience severe side effects tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.**

Symptoms of a Vinorelbine Ebewe overdose include the side effects listed below in the 'Side Effects' section, but are usually of a more severe nature.

While you are being given Vinorelbine Ebewe

Things you must do

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

Be sure to keep all your doctor's appointments so your progress can be checked.

Your doctor may want to 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 doses of Vinorelbine Ebewe 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 being given Vinorelbine Ebewe.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are being given Vinorelbine Ebewe.

If you become pregnant while you are being given Vinorelbine Ebewe tell your doctor immediately.

Vinorelbine Ebewe 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:

- 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.

Your body breaks down vinorelbine 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 non-bleaching detergent and large amounts of water to mop up the spill
- 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.

Things you must not do

Things to be careful of

Be careful driving or operating machinery until you know how Vinorelbine Ebewe affects you.

As with many other medicines, Vinorelbine Ebewe may cause fatigue in some people. Make sure you know how you react to Vinorelbine Ebewe before you drive a car, operate machinery, or do anything else that could be dangerous if

you are feeling tired. If this occurs, do not drive. If you drink alcohol, tiredness may be worse.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are being given Vinorelbine Ebewe.

Like other medicines that treat cancer, Vinorelbine Ebewe may have unwanted side effects, some of which may be serious. You may need medical treatment if you get some of the 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
- fever.

These are the more common side effects of Vinorelbine Ebewe.

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 and 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
- blood infection (sepsis) with symptoms such as high fever and deterioration in general health

- lack of muscle control, which may be associated with abnormal gait, and speech changes.

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
- 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 myocardial infarction (sometimes with fatal outcome)
- palpitations, fast or irregular heart beat
- rash, itching or hives on the skin
- swelling of 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 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 Vinorelbine Ebewe treatment.

The benefits and side effects of Vinorelbine Ebewe may take some time to occur.

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

You may not experience any of them.

Vinorelbine Ebewe does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Vial stopper is not made with natural rubber latex.

Supplier

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road
Macquarie Park, NSW 2113
Australia
Tel: 1800 726 369

Australian Register Numbers

10 mg in 1 mL injection: AUST R 126693 (vial)

50 mg in 5 mL injection: AUST R 99724 (vial)

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After using Vinorelbine Ebewe

Storage

Vinorelbine Ebewe will be stored in the pharmacy or on the ward. The injection is kept in a refrigerator, where the temperature stays between 2 and 8°C, is protected from light and is not frozen. After use, any unused portion of the injection will be discarded.

Disposal

If your doctor or pharmacist tells you to stop having Vinorelbine Ebewe, return any leftover vials to your pharmacist. Do not dispose of Vinorelbine Ebewe via wastewater or household waste. This will help to protect the environment.

Product description

What it looks like

Vinorelbine Ebewe is a clear, colourless to pale yellow solution. It comes in a clear glass vial with a rubber stopper and a cap. Each vial is packed in a carton.

Ingredients

Active ingredients:

- 1 mL of Vinorelbine Ebewe contains 13.85 mg of vinorelbine tartrate (equivalent to 10 mg of vinorelbine)

Other ingredients:

- nitrogen
- water for injection.