

# Vinorelbine Ebewe

vinorelbine tartrate 10mg/mL  
Concentrated Solution for Injection

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## Consumer Medicine Information

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### What is in this leaflet

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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.

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### What is Vinorelbine Ebewe used for

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

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

Vinorelbine Ebewe is thought to work by stopping cancer cells from growing and multiplying.

Vinorelbine Ebewe may be used in combination with other medicines to treat cancer.

If you have breast cancer, you have probably taken another medicine to treat it before. However, your doctor has now recommended you should be given Vinorelbine Ebewe.

**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 not enough information on its effects in children**

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### Before you are given Vinorelbine Ebewe

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*When you must not be given it*

**Do not have Vinorelbine Ebewe if you have an allergy to Vinorelbine Ebewe or any of the ingredients listed at the end of this leaflet. Symptoms**

of an allergic reaction to Vinorelbine Ebewe 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.

Do not have Vinorelbine Ebewe if you have, or have had, any of the following medical conditions:

- severe liver problems
- condition of the blood with a reduced number of white blood cells

**Tell your doctor if you have an infection or high temperature.** Your doctor may decide to delay your treatment until the infection has gone. A mild illness, such as a cold, is not usually a reason to delay treatment.

**Do not have Vinorelbine Ebewe 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 some kind of birth control while you are using vinorelbine and for at least 12 weeks after you stop treatment. A barrier method of birth control, such as a condom, should be used while you are being given vinorelbine and for the first week of this 12 week period. Your doctor will discuss this with you.

**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.

**If you are not sure whether you should be given Vinorelbine Ebewe, talk to your doctor or pharmacist.**

### ***Before you are given it***

**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:**

- liver problems
- lung problems, including asthma

- blood disorder with a reduced number of white blood cells
- heart disease caused by reduced blood flow in the blood vessels of the heart muscle, causing angina or heart attack.

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

**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:

- other medicines used to treat cancer, such as cisplatin, mitomycin
- Phenindione, a medicine used to treat blood clots or prevent them from forming.

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.

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## **How Vinorelbine Ebewe is given**

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### ***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 weight, height, white blood cell count, liver function and other chemotherapy medicines you are being given.

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.

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## **While you are being given Vinorelbine Ebewe**

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### *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.

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## Things you must not do

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### *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.**

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## Side effects

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**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:**

- feeling of tiredness

- feeling sick, upset stomach
- vomiting
- constipation
- diarrhoea
- unusual hair loss or thinning
- skin rash
- aching muscles, muscle tenderness or weakness, not caused by exercise
- joint pain; painful swollen joints
- jaw pain
- pain at the tumour site
- small bowel not working properly; severe pain in the stomach with bloating, gut cramps and vomiting
- sore mouth
- severe upper stomach pain

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 in 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, altered heart beat
- swelling of feet and ankles

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.

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:**

- 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
- lack of red blood cells: symptoms include tiredness, headaches, dizziness, being short of breath when exercising, looking pale.
- lack of white blood cells: symptoms include frequent infections, fever, severe chills, sore throat or mouth ulcers.
- low number of platelets in the blood: symptoms include bleeding or bruising more easily than normal, nosebleeds.
- burning feeling when passing urine
- liver disease with symptoms such as weakness, tiredness, loss of appetite, weight loss and stomach pain

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

You may not experience any of them

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## After using Vinorelbine Ebewe

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### *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.

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## Product description

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### *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:

- Vinorelbine Ebewe 10mg  
10mg vinorelbine tartrate
- Vinorelbine Ebewe 50mg  
50mg vinorelbine tartrate

Other ingredients

- water for injection

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

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## Manufacturer

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### ***Manufacturer***

Vinorelbine Ebewe is made by EBEWE Pharma GmbH Nfg KG A-4866, Unterach AUSTRIA

### ***Sponsor***

Vinorelbine Ebewe is distributed in Australia by:  
InterPharma  
Suite 3, 14 Sydney Rd  
Manly NSW 2095

Australian Registration Numbers

10mg in 1mL AUST R 126693  
50mg in 5mL AUST R 99724

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