

# VINORELBINE 10 LINK (Vinorelbine 10 mg/1mL Concentrated Injection) VINORELBINE 50 LINK (Vinorelbine 50 mg/5mL Concentrated Injection )

Vinorelbine (as tartrate)

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about VINORELBINE 10 LINK and VINORELBINE 50 LINK.

It does not contain all the available information.

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

All medicines have risks and benefits. Your doctor has weighed the risks of you being given VINORELBINE LINK 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 with the medicine.** You may need to read it again.

### What VINORELBINE LINK is used for

VINORELBINE LINK is used to treat advanced breast cancer and non-small cell lung cancers.

VINORELBINE LINK belongs to a class of medicines called antineoplastic or cytotoxic medicines. This medicine works by stopping cancer cells from growing and multiplying.

You may have been given another medicine to treat your lung or breast cancer. However, your doctor has now decided to treat you with VINORELBINE LINK instead.

VINORELBINE LINK may be used alone or in combination with other medicines to treat cancer

Ask your doctor if you have any questions about why VINORELBINE LINK has been prescribed for you.

Your doctor may have prescribed VINORELBINE LINK for another reason.

VINORELBINE LINK is not addictive.

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

VINORELBINE LINK is not recommended for use in children, as there is not enough information on its effects in children.

### Before you are given VINORELBINE LINK

*When you must not be given it*

**Do not use VINORELBINE LINK if you have an allergy to:**

- Vinorelbine, the active ingredient in VINORELBINE LINK
- Other vinca alkaloids such as vinblastine, vincristine or vindesine.
- any of the other ingredients of VINORELBINE LINK listed at the end of this leaflet

Symptoms of an allergic reaction to VINORELBINE LINK may include shortness of breath, wheezing or difficulty breathing or a tight feeling in your chest; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin; dizziness or light-headedness.

**Do not use VINORELBINE LINK 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.
- condition of the blood with a reduced number of platelets.

- severe infection due to your white blood cells numbers being low.

**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.

VINORELBINE LINK should not be administered if you are pregnant or intend to become pregnant. Like most medicines used to treat cancer, VINORELBINE LINK is not recommended for use during pregnancy. VINORELBINE LINK may affect your developing baby if you take it during pregnancy. If there is a need to consider VINORELBINE LINK during your pregnancy, your doctor will discuss with you the benefits and risks of using it.

**Do not breast-feed if you are being treated with this medicine.**

VINORELBINE LINK might pass into breast milk and there is a possibility that your baby may be affected.

**VINORELBINE LINK should not be administered after the expiry date printed on the pack.**

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

**VINORELBINE LINK, 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 doctor or pharmacist for disposal.

**If you are not sure whether you should start using VINORELBINE LINK, talk to your doctor or pharmacist.**

## *Before you are given it*

**Tell your doctor 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 angina
- liver problems
- lung problems, including asthma.
- blood disorders with a reduced number of white blood cells

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

**If you have not told your doctor about any of the above, tell them before you are given VINORELBINE LINK.**

## *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 LINK may interfere with each other. These include:

- some other medicines used to treat cancer, such as mitomycin and cisplatin

These medicines may be affected by VINORELBINE LINK, 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 will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking VINORELBINE LINK.

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## **How VINORELBINE LINK is given**

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### *How much is given*

**Your doctor will decide what dose you will receive. This depends on your condition and several other factors including your height, weight, white blood cell count, liver function, and whether or not other chemotherapy medicines are also being given.**

VINORELBINE LINK may be given alone or in combination with other medicines to treat cancer.

VINORELBINE LINK is usually given once a 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.

Several courses of VINORELBINE LINK therapy may be needed, depending on your response to treatment.

VINORELBINE LINK reduces the number of white blood cells in the body. Your doctor will check your blood cell numbers regularly.

Additional treatment may not be repeated until your blood cell numbers return to acceptable levels and any uncontrolled effects have been controlled.

**Ask your doctor if you want to know more about the dose of VINORELBINE LINK you will be receiving.**

### *How it is given*

VINORELBINE LINK is given as a slow injection or infusion ('drip') into your vein.

**It must only be given by a nurse or doctor.**

### *How long it is given*

VINORELBINE LINK is usually given once a 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 LINK.

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 VINORELBINE LINK 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 after being given VINORELBINE LINK, tell your doctor, nurse or pharmacist.**

Symptoms of a VINORELBINE LINK 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 LINK**

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### *Things you must do*

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

**If you are about to be started on any new medicine, remind your doctor, dentist and pharmacist that you are being given VINORELBINE LINK.**

**Tell any other doctors, dentists, and pharmacists who treat you that you are being given this medicine.**

**If you become pregnant while you are being treated with this medicine, tell your doctor immediately.**

**Keep all of 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 to detect any unwanted side effects.

**Keep follow up appointments with your doctor.** It is important to have your follow-up doses of VINORELBINE LINK at the appropriate times to get the best effects from your treatments.

This medicine 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:

**Take the following precautions to reduce your risk of infection or bleeding:**

- Avoid people who have infections.
- 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.
- 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 you must not do*

**Do not give VINORELBINE LINK to anyone else, even if they have the same condition as you.**

*Things to be careful of*

**Be careful driving or operating machinery until you know how VINORELBINE LINK affects you.**

This medicine may cause dizziness or light-headedness in some people. If you have any of these symptoms, does not drive, operate machinery, or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine. If you drink alcohol, dizziness or light-headedness, and tiredness may be worse.

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## Side effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given VINORELBINE LINK.**

Like other medicines used to treat cancer, VINORELBINE LINK may have unwanted side effects, some of which may be serious. You may need medical attention 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 (feeling sick) or vomiting
- diarrhoea
- constipation
- hair loss
- sore mouth, mouth ulcers
- mild redness, discomfort or discolouration of the vein near the injection site
- fatigue (tiredness).

The above list includes side effects which are usually mild or short-lived.

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

- tingling or numbness in the hands or feet
- increased feeling of sensitivity, especially in the skin
- weakness in the arms or legs
- pain in the jaw, bones, muscles, or at the tumour site
- tiredness, headaches, being short of breath when exercising, dizziness and looking pale.

The above list includes serious side effects, which may require medical attention.

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

- severe pain near the injection site
- any signs of infection such as fever, chills, sore throat or cough, low back or side pain, painful or difficult urination
- severe stomach pain, which may be accompanied by nausea and vomiting
- signs of an allergic reaction, such as shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin
- unusual bleeding or bruising (such as bloody or black stools, blood in urine)
- pain in the bladder or back
- breathlessness, which may be severe and worse on lying down
- chest pain
- swelling of the feet or legs due to fluid build-up.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

**Tell your doctor, nurse or pharmacist if you notice anything that is making you feel unwell.** Other side effects not listed above may occur in some people. Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

The benefits and side effects of VINORELBINE LINK may take some time to occur. Therefore even after you have finished treatment with VINORELBINE LINK, you should tell your doctor if you notice anything that is making you feel unwell.

**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 LINK

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### Storage

VINORELBINE LINK is usually stored in the hospital ward or clinic, or at the pharmacy. It is

stored at 2-8<sup>0</sup>C (in the refrigerator)  
Do not freeze it.

**Protect VINORELBINE LINK from light.**

### *Disposal*

If your doctor or pharmacist tells you to stop having VINORELBINE LINK, return any leftover vials to your pharmacist.

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## **Product description**

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### *What it looks like*

VINORELBINE LINK is a colourless to pale yellow, clear concentrated solution for injection in a glass vial.

It is available in single pack sizes of 10 mg/1mL or 50 mg/5mL and in multiple pack sizes of 10 vials of 10 mg/1 ml each and 50 mg/5ml each. Not all pack sizes may be marketed.

### *Ingredients*

VINORELBINE LINK contains 10 mg/mL of vinorelbine (13.85 mg/mL vinorelbine tartrate) as the active ingredient. It also contains water for injections.

#### Other ingredients

VINORELBINE LINK does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

### *Sponsor*

Link Medical Products Pty. Ltd.  
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[www.linkpharma.com.au](http://www.linkpharma.com.au)

- 10 mg/1mL Single-Use Vial, Carton of 1 vial (AUST R 144030).
- 50 mg/5mL Single-Use Vial, Carton of 1 vial (AUST R144046).
- 10 mg/1mL Single-Use Vial, Multiple pack of 10 vials (AUST R 144030).
- 50 mg/5mL Single-Use Vial, Multiple pack of 10 vials (AUST R 144046).

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