

DBL™ Vinorelbine Injection Concentrate

Vinorelbine (vi-NOR-el-been)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL™ Vinorelbine Injection Concentrate (vinorelbine). 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 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.

You may need to read it again.

What DBL™ Vinorelbine Injection Concentrate is used for

This medicine is used to treat:

- advanced breast cancer
- non-small cell lung cancer.

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

It works by stopping cancer cells from growing and multiplying. It may be used alone or in combination with other medicines to treat cancer.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

It is available only with a doctor's prescription.

There is not enough information to recommend the use of this medicine for children.

Before you are given DBL™ Vinorelbine Injection Concentrate

When you must not be given it

You must not be given DBL™ Vinorelbine Injection Concentrate if you have an allergy to:

- any medicine containing vinorelbine
- any other similar medicines, such as vinblastine, vincristine or vindesine.

Some of the symptoms of an allergic reaction may include 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.

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.

Females: tell your doctor or pharmacist if you are pregnant or intend to become pregnant.

Like most cytotoxic medicines vinorelbine is not recommended for use during pregnancy. If there is any need to consider vinorelbine during your pregnancy, your doctor or pharmacist will discuss with you 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 breast-feed if you are being treated with this medicine.

Vinorelbine passes into breast milk and there is a possibility that your baby may be affected.

You must not be given this medicine if you have any of the following medical conditions:

- very low numbers of neutrophils (a type of white blood cell)
- severe infection due to your neutrophil numbers being low
- severe liver problems.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have any of the following medical conditions:

- heart problems, including angina
- liver problems
- lung problems, including asthma.

Tell your doctor if you are receiving radiotherapy that involves the abdominal or stomach area.

If you have not told your doctor about any of the above, tell him/her before you are given vinorelbine.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and vinorelbine may interfere with each other. These include:

- some other medicines used to treat cancer, such as mitomycin and cisplatin
- phenindione, a medicine used to treat blood clots or prevent them from forming
- some medicines used to treat viral or fungal infections
- rifampicin, a medicine used to treat bacterial infections, including tuberculosis
- medicines used to treat epilepsy (seizures), such as phenytoin and carbamazepine
- St John's wort (*Hypericum perforatum*), a herbal remedy.

These medicines may be affected by vinorelbine or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

How DBL™ Vinorelbine Injection Concentrate is given

How much is given

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

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

Vinorelbine 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 therapy may be needed, depending on your response to treatment.

Vinorelbine 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 you will be receiving.

How it is given

DBL™ Vinorelbine Injection Concentrate is given as a slow injection or infusion ('drip') into a vein. It must only be given by a nurse or doctor.

If you receive too much (overdose)

As DBL™ Vinorelbine Injection Concentrate is given to you 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.

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

Ask your doctor or pharmacist if you have any concerns.

In case of overdose, immediately contact the Poisons Information Centre for advice (telephone 13 11 26 in Australia, or call 0800 764 766 in New Zealand).

While you are being given DBL™ Vinorelbine Injection Concentrate

Things you must do

Tell your doctor 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 and pharmacist that you are being given vinorelbine.

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 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:

- 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.

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.
- 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 to be careful of

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

This medicine may cause dizziness or light-headedness in some people. If you have any of these symptoms, do 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.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are being treated with vinorelbine.

Like other medicines used to treat cancer, vinorelbine may have unwanted side effects, some of which may be serious. You may need medical attention if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

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 may take some time to occur. Therefore even after you have finished treatment with vinorelbine, you should tell your doctor if you notice anything that is making you feel unwell.

After using DBL™ Vinorelbine Injection Concentrate

Storage

DBL™ Vinorelbine Injection Concentrate will be stored in the pharmacy or on the ward. The injection is kept in the refrigerator where the temperature stays between 2 and 8°C, and is protected from light and freezing.

Product description

What it looks like

DBL™ Vinorelbine Injection Concentrate is a pale yellow, clear fluid for injection in an amber glass vial. It is available in single pack sizes of 10 mg/1mL and 50 mg/5mL.

Ingredients

DBL™ Vinorelbine Injection Concentrate contains 10 mg/mL of vinorelbine (13.85 mg/mL vinorelbine tartrate) as the active ingredient.

It also contains:

- Water for Injections.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

Australian Sponsor:

Hospira Australia Pty Ltd
ABN 58 097 064 330
Level 3
500 Collins Street
Melbourne VIC 3000
Australia

New Zealand Sponsor:

Hospira NZ Limited
58 Richard Pearse Drive
Airport Oaks, Mangere 2022
Auckland
New Zealand

AUST R Number(s):

- 10 mg/1mL AUST R 97647
- 50 mg/5mL AUST R 97648

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