

Consumer Medicine Information

VINORELBINE TE ARAI 20mg soft capsule

VINORELBINE TE ARAI 30mg soft capsule

VINORELBINE TE ARAI 80mg soft capsule

Vinorelbine as tartrate

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Vinorelbine soft capsule is and what it is used for
2. Before you take Vinorelbine soft capsule
3. How to take Vinorelbine soft capsule
4. Possible side effects
5. Storing Vinorelbine soft capsule
6. Further information

1. What Vinorelbine soft capsule is and what it is used for

Vinorelbine belongs to a family of medicines used to treat cancer called the vinca-alkaloid family.

Vinorelbine is used to treat:

- o Non-small cell lung cancer
- o Advanced breast cancer that has not responded to other medicines.

It is **not** recommended for use by children under 18 years old.

2. Before you take Vinorelbine soft capsule

Do not take Vinorelbine soft capsule

If you are allergic (hypersensitive) to the active ingredient, vinorelbine, or any of the related family of cancer drugs called the vinca alkaloids.

- If you are allergic to any of the other ingredients in Vinorelbine capsules (refer to section 6 of this leaflet).
- If you are pregnant or think that you might be pregnant.
- If you are breast feeding.
- If you have a severe liver disease.
- If you have had an operation on your stomach or small bowel, or if you have gut disorder which affects how you absorb food. These may affect how your body absorbs Vinorelbine.
- If you have a low white blood cell count (neutrophils, leucocytes) or a severe infection current or recent within two weeks.
- If you require long-term oxygen therapy

If in doubt, ask your doctor or pharmacist.

Please inform your doctor if:

- You have a history of heart attack or severe chest pain.
- Your ability to carry out activities of daily living is strongly reduced.

- You have problems with your liver or you have received radiotherapy where the treatment field included the liver.
- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- You have symptoms of infection (such as fever, chills, joint pain, cough).
- You take, or have recently taken, any other medicines including medicines obtained without a prescription.
- You plan to have a vaccination or have just had one

Before and during your treatment with Vinorelbine blood cell counts are performed to check that it is safe for you to receive treatment. If the results of this analysis are not satisfactory, your treatment may be delayed and further checks made until these values return to normal.

Taking other medicines

Please inform your doctor or pharmacist if you are taking, or have recently taken, any other medicines, including medicines obtained without a prescription.

If you are given Vinorelbine as well as medicines that affect your bone marrow it may make some of the side effects worse.

Your doctor should take special attention if you are taking the following medicines:

- medicines used to thin your blood (anticoagulants),
- an anti-epileptic medicine called phenytoin,
- antifungal medicines such as itraconazole and ketoconazole,
- an anti-cancer medicine called mitomycin C,
- medicines that impair your immune system such as ciclosporin and tacrolimus

Taking Vinorelbine soft capsule with food and drink

The soft capsule of Vinorelbine should be swallowed whole with water without chewing or sucking the capsule.

It is preferable to take Vinorelbine with a light meal.

Vinorelbine should not be taken with a hot drink as it will dissolve the capsule too quickly.

Male fertility

Men being treated with Vinorelbine are advised not to father a child during and up to 3 months after the last capsule. You should discuss sperm banking with your doctor before starting treatment with Vinorelbine.

Women of child bearing age

Women of child-bearing age must use effective contraception (birth control) during treatment and up to 3 months after treatment.

Pregnancy

Do not take Vinorelbine if you are pregnant or think that you might be pregnant. If you have to start treatment with Vinorelbine and you are pregnant, or if pregnancy occurs during your treatment with Vinorelbine, do not stop taking Vinorelbine. Immediately ask your doctor about the potential risks for the unborn child.

Breast-feeding

Do not take Vinorelbine if you are breast feeding.

Breast feeding must be discontinued if treatment with Vinorelbine is necessary.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

It is unlikely that Vinorelbine will affect your ability to drive or operate machinery.

However, some of the possible side effects of Vinorelbine could affect your ability to drive or perform skilled tasks: see section 4; Possible side effects below for details. Therefore, it is recommended that you should not drive if you feel unwell or if your doctor has advised you not to drive.

Important information about some of the ingredients

This medicine contains sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Vinorelbine soft capsule

Vinorelbine should be given under the supervision of a qualified doctor who is experienced in the use of cancer treatments.

Vinorelbine must be taken by mouth.

Vinorelbine is used in patients over 18 years old.

It is not recommended for use by children under 18 years old.

Always take Vinorelbine exactly as your doctor has told you.
You should check with your doctor or pharmacist if you are not sure

Dosage

Before and during your treatment with Vinorelbine your doctor will check your blood cell count to determine when you receive your treatment and which dose is suitable for you. Your doctor will tell you the number and strength of capsules which you should take. This will depend on your body weight and body height.

Your doctor will calculate your body surface area in square meters (m²). The usual weekly dose, taken in a single dose, is 60 mg/m² of body surface area for the first 3 doses. After the third dose, your doctor will decide if the dose will be increased to 80mg/m² of body surface area. In any case, your doctor may adjust the dose of Vinorelbine.

If you are receiving the capsules with another medicine to treat your cancer/condition, your doctor will decide on an appropriate dose for you.

The total dose should never exceed 160 mg per week.
You should never take Vinorelbine more than once a week

Frequency of administration

Normally Vinorelbine treatment is scheduled once a week. The frequency will be determined by your doctor.

Duration of treatment

The duration of your treatment is decided by your doctor.

If you take an anti-sickness medicine

Vomiting can occur with Vinorelbine: see section 4. Possible side effects. If your doctor has prescribed an anti-sickness medication, always take it exactly as the doctor has told you.

Take Vinorelbine during a light meal; this will help to reduce the feeling of sickness.

Method of administration

Before opening the blisters containing Vinorelbine, make sure that there are no damaged capsules because the liquid inside is an irritant and may be harmful if it comes into contact with your skin, eyes or mucosa. If it happens, wash the affected area **immediately** and thoroughly with water.

Do not swallow any damaged capsules; return them to your doctor or pharmacist.

Taking Vinorelbine soft capsule:

- Swallow Vinorelbine whole with water, preferably with a light meal. It should not be taken with a hot drink as it will dissolve the capsule too quickly.
- **Do not** chew or suck the capsules.
- If you chew or suck a capsule by mistake, rinse your mouth thoroughly with water and tell your doctor **immediately**.
- If you vomit within a few hours after taking your Vinorelbine, contact your doctor; **do not repeat the dose**.

If you take more Vinorelbine soft capsule than you should:

If you may have taken more Vinorelbine than the prescribed dose, contact a doctor **immediately**.

Your dose of Vinorelbine is carefully monitored and checked by your doctor and pharmacist.

However, although you will have received the correct amount of chemotherapy your body may sometimes react giving severe symptoms.

Some of these symptoms may develop as signs of an infection (such as fever, chills, cough, joint pain).

You may also become severely constipated. You must immediately contact your doctor if any of these severe symptoms occur.

If you forget to take Vinorelbine soft capsule:

Do not take a double dose to make up a forgotten dose. Contact your doctor who will take the decision about rescheduling your dose.

If you stop using Vinorelbine soft capsule

Your doctor will decide when you should stop your treatment. However, if you want to stop your treatment earlier, you should discuss other options with your doctor.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Vinorelbine can have side effects **although not everybody gets them**.

While taking Vinorelbine, if you develop any of the following symptoms you should **contact your doctor immediately**:

- signs of a major infection such as cough, fever and chills
- severe constipation with abdominal pain when your bowels have not been open for several days,
- severe dizziness, light-headedness when you stand up
- severe chest pain which is not normal for you
- signs of allergy such as itching, shortness of breath

<p style="text-align: center;">Very common side effects (can occur in more than 1 in 10 patients treated)</p>	<p style="text-align: center;">What should you do?</p>
<ul style="list-style-type: none"> · Feeling sick (nausea) · Vomiting 	<p>Immediately contact your doctor if this becomes uncontrollable. These side effects may be controlled with standard therapy.</p> <p>Do not repeat the dose if you vomit within a few hours after taking your Vinorelbine.</p>
<ul style="list-style-type: none"> · A fall in some white blood cells which makes you more vulnerable to infection. This can commonly cause bacterial, viral or fungal infections in your body (respiratory, urinary, gastro-intestinal systems and possibly others) 	<p>Immediately contact your doctor, especially if your temperature reaches 38°C or higher.</p>
<ul style="list-style-type: none"> · A fall in red blood cells (anaemia) which can make the skin pale and cause weakness or breathlessness · A fall in blood platelets (thrombocytopenia) which can increase the risk of bleeding or bruising · Loss of some reflex reactions, occasionally difference in the perception of touch 	<p>Immediately contact your doctor for treatment, should these symptoms become severe.</p>
<ul style="list-style-type: none"> · Inflammation or sores in the mouth or throat (stomatitis) · Diarrhoea · Constipation. If you have abdominal pain or if you do not have a bowel movement for several days · Gastric disorders 	<p>Immediately contact your doctor.</p>
<ul style="list-style-type: none"> · Hair loss (alopecia), · Tiredness (fatigue) · Malaise · Fever · Weight loss · Loss of appetite (anorexia) 	<p>Ask your doctor for advice if the symptoms persist. These are possible symptoms when receiving chemotherapy.</p>

<p style="text-align: center;">Common side effects (can occur in less than 1 in 10 patients treated)</p>	<p style="text-align: center;">What should you do?</p>
<ul style="list-style-type: none"> · Difficulty in sleeping · Headache · Dizziness · A difference in your taste of the flavours · Inflammation of the throat and gullet (oesophagitis) · Difficulty when swallowing food or liquids · Skin reactions · Joint pain (arthralgia) · Jaw pain · Muscle pain (myalgia) · Pain at different sites in your body and pain where your tumour is · Chills · Weight gain 	<p>Ask your doctor for advice if the symptoms persist.</p>

<ul style="list-style-type: none"> · Neuromotor disorders · Differences in your eyesight · High blood pressure with symptoms such as a headache · Low blood pressure with symptoms such as dizziness or feeling faint · Shortness of breath · Cough · Abnormal liver test · Pain, burning and difficulty in passing urine 	<p>Immediately contact your doctor for treatment, should any of these symptoms become severe.</p>
---	--

Uncommon side effects (can occur in more than 1 in 100 patients treated)	What should you do?
<p>Effects on your nervous system:</p> <ul style="list-style-type: none"> · Balance disorders (ataxia) <p>Effects on your gastrointestinal system:</p> <p>Severe constipation with abdominal pain when your bowels have not been open for several days (paralytic ileus)</p>	<p>Immediately contact your doctor</p>

The list below specifies side effects also reported with Vinorelbine soft capsule, with frequency not known:	
Side effects with frequency not known	What should you do?
<p>Effects on your blood:</p> <ul style="list-style-type: none"> · Low blood sodium (severe hyponatraemia) which can cause symptoms of tiredness, confusion, muscle twitching and coma. Generalised infection (sepsis) due to severe fall of white blood cells <p>Effects on your gastrointestinal system:</p> <ul style="list-style-type: none"> · Gastrointestinal bleeding <p>Effects on your heart and blood vessels:</p> <ul style="list-style-type: none"> · Heart attack (myocardial infarction in patients with cardiac medical history or cardiac risk factors) <p>Effects on your breathing:</p> <ul style="list-style-type: none"> · Severe difficulties in breathing 	<p>Immediately contact your doctor</p>

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

5. Storing Vinorelbine

Keep out of the reach and sight of children

Do not use Vinorelbine after the expiry date which is stated on the blister and box (after Exp). The expiry date refers to the last day of that month.

Store in a refrigerator (2°C - 8°C). Do not freeze. Protect from light.

Medicines should not be disposed of via wastewater or household waste. For safety reasons any unused capsules must be returned to your doctor or pharmacist for destruction. These measures will help to protect the environment.

6. Further Information

What Vinorelbine soft capsule contains

The active substance is: Vinorelbine (as tartrate) 20, 30 or 80 mg.

The other ingredients are:

- The fill contains: purified water; polysorbate 80; macrogol 400.
- The capsule shell contains: gelatin; sorbitol; triglycerides, medium chain; purified water and colouring agents (E171-titanium dioxide and E172 red and/or yellow iron oxide depending on the strength).

What Vinorelbine soft capsule looks like and contents of the pack

Vinorelbine 20mg soft capsules are light brown coloured,

Vinorelbine 30mg soft capsules are pink coloured.

Vinorelbine 80mg soft capsules are pale yellow coloured.

Soft capsules of 20, 30 and 80 mg are available as packs of 1 blister of 1 soft capsule.

Supplied in New Zealand by

Te Arai BioFarma Ltd

PO Box 46205

Herne Bay

Auckland, 1147

0800 832 724

This leaflet was last approved 18 March 2021.