Package leaflet: Information for the patient

Vinorelbine 20 mg soft capsules
Vinorelbine 30 mg soft capsules
Vinorelbine 80 mg soft capsules

Vinorelbine (as tartrate)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Vinorelbine is and what it is used for
2. What you need to know before you take Vinorelbine
3. How to take Vinorelbine
4. Possible side effects
5. How to store Vinorelbine
6. Contents of the pack and other information

1. What Vinorelbine is and what it is used for

This medicine contains the active substance vinorelbine (as tartrate), and belongs to a family of medicines used to treat cancer called the vinca-alkaloid family.

Vinorelbine is used to treat:

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

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

2. What you need to know before you take Vinorelbine

Do not take Vinorelbine:
- If you are allergic (hypersensitive) to vinorelbine, to any of the related family of cancer drugs called the vinca alkaloids, or any of the other ingredients of this medicine (listed in section 6).
- 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 have a low blood platelet cell count (thrombocytopenia).
- If you plan to have a yellow fever vaccination or have just had one.
- If you require long-term oxygen therapy.

If in doubt, ask your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before taking Vinorelbine 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
- You have symptoms of infection (such as fever, chills, joint pain, and cough).
- You take, or have recently taken, any other medicines including medicines obtained without a prescription.
- You plan to have a vaccination. Many vaccines (live attenuated vaccines) are not recommended during treatment.
- You have severe liver disease unrelated to your cancer. Vinorelbine soft capsules are not recommended in this group of patients.
- You are pregnant.

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.

Children and adolescents

This medicine is not recommended for use by children or adolescents under 18 years old.

Other medicines and Vinorelbine

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

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,
- anti-cancer medicines called mitomycin C or lapatinib,
- medicines that impair your immune system such as ciclosporin and tacrolimus
- anti-tuberculosis medicine called rifampicin.

The combination of Vinorelbine with other medicines with known bone marrow toxicity (affecting your white and red blood cells and your platelet) could also worsen some side effects.

Many vaccines (live attenuated vaccines) are not recommended during treatment, especially in patients who already have weakened immune systems. Please inform your doctor if you require any vaccinations.

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

Vinorelbine with food and drink

Vinorelbine must be swallowed whole with water without chewing or sucking the capsule.It is recommended to administer the capsule with some food.

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

Pregnancy, breast-feeding and fertility

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine because there are potential risks for the infant.

You should not breast-feed if you are taking Vinorelbine. Breast-feeding must be discontinued if treatment with Vinorelbine is necessary. Ask your doctor or pharmacist for advise before taking any medicine.

Women of child-bearing age must use effective contraception (birth control) during treatment and for 7 months after the end of treatment.

Men being treated with Vinorelbine are advised not to father a child during treatment and for 4 months after the last taken capsule. You should discuss sperm banking with your doctor before starting treatment with Vinorelbine as male fertility may be altered. You must use an effective contraception during treatment and for 4 months after the end of treatment.

Driving and using machines
No studies on the effects on the ability to drive and use machines have been performed. 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. However, as in all cases you should not drive if you feel unwell or if your doctor has advised you not to drive.

Vinorelbine contains sorbitol
This medicine contains 38.44mg sorbitol in each 20mg soft capsule, 59.85mg sorbitol in each 30mg soft capsule and 99.91mg sorbitol in each 80mg soft capsule.

Sorbitol is a source of fructose. If you doctor has told you that you have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you take or receive this medicine.

3. How to take Vinorelbine

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 recommeded for use by children under 18 years old.

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 surface area which your doctor will calculate from your weight and body height.

The usual weekly dose, taken in a single dose, is 60 mg/m^2 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/m^2 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.

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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 effetcs. 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**.**

Opening the 'peel-push' blister:

1. Cut the blister along the black dotted line with a pair of scissors.
2. Peel the soft plastic foil off.
3. Push the capsule through the aluminium foil.

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 an anti-sickness medicine
Vomiting can occur with Vinorelbine, (refer to 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.

If you take more Vinorelbine than you should
If you 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

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

If you stop taking Vinorelbine
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 medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Immediately contact your doctor while taking Vinorelbine, if you develop any of the following symptoms:
– signs of a major infection such as cough, fever and chills, or a general infection (septicemia) that can be severe
– severe constipation with abdominal pain when your bowels have not been open for several days,
– severe dizziness, light-headedness when you stand up, sign of severe reduced blood pressure,
– 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 ischaemic heart disease,
– difficulty in breathing, dizziness, decreased blood pressure, rash affecting your whole body, or swelling of the eyelids, face, lips or throat which may be an allergic reaction.
– a chest pain, breathlessness and fainting, which can be a symptom of a clot in a blood vessel in the lungs (pulmonary embolism)
– headaches, changed mental state which may lead to confusion and coma, convulsions, blurred vision and high blood pressure, which could be sign of a neurological disorder such as posterior reversible encephalopathy syndrome

Very common side effects (may affect more than 1 in 10 people)
- Infections at different sites;
- Gastric disorders;
- Diarrhoea;
- Constipation, abdominal pain;
- Nausea, vomiting;
- Inflammation in the mouth;
- A fall in red blood cells (anaemia) which can make the skin pale and cause weakness or breathlessness;
- A fall in platelets which can increase the risk of bleeding or bruising;
- A decrease in white blood cells which makes you more vulnerable to infection;
- Loss of some reflex reactions, occasionally difference in the perception of touch;
- Hair loss usually mild form;
- Tiredness;
- Fever;
- Malaise;
- Weight loss;
- Loss of appetite;

Common side effects (may affect up to 1 in 10 people)**:**
- Difficulties to coordinate muscle movements;
- Differences in your eyesight;
- Shortness of breath, cough;
- Difficulties when urinating, other genitourinary symptoms;

- Difficulty in sleeping;
- Headache;
- Dizziness;
- A difference in your taste of flavours;
- Inflammation of the gullet, difficulty when swallowing food or liquids;
- Skin reactions;
- Chills;
- Weight gain;
- Joint pain (arthralgia), jaw pain, muscle pain (myalgia); pain at different sites in your body and pain where your tumour is;
- High blood pressure;
- Liver disorders (abnormal liver test).

Uncommon side effects (may affect up to 1 in 100 people):
- Heart failure which can cause shortness of breath and ankle swelling,
- Irregular heartbeats,
- Lack of muscle control may be associated with abnormal gait, speech changes and abnormalities in eyes movement (ataxia).

Not known: frequency cannot be estimated from the available data
- Blood infections (sepsis) with symptoms such as high fever and deterioration in general health;
- Low blood levels of sodium in your blood. This low sodium level may be attributed in some cases to an overproduction of a hormone causing fluid retention resulting in weakness, muscle twitching, tiredness, confusion or unconsciousness (Syndrome of Inappropriate Antidiuretic Hormone secretion - SIADH);
- Gastrointestinal bleeding;
- Heart attack (myocardial infarction).

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Vinorelbine

Keep this medicine out of the sight and reach of children.

Store in a refrigerator (2°C-8°C).

Do not use this medicine after the expiry date which is stated on the blister and carton box after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Vinorelbine contains

- The active substance is vinorelbine (as tartrate) 20, 30 or 80 mg respectively.
- The other ingredients are:

Capsule content: macrogol 400, polysorbate 80 (E433), purified water

Capsule shell: gelatin , partially dehydrated sorbitol liquid (E420), titanium dioxide (E171), purified water,
Vinorelbine 20 mg and 80 mg soft capsules also contain iron oxide yellow (E172).
Vinorelbine 30 mg soft capsules also contain iron oxide red (E172)

What Vinorelbine looks like and contents of the pack

Vinorelbine 20 mg soft capsules are oval-shaped light brown coloured.
Vinorelbine 30 mg soft capsules are oblong-shaped pink coloured.
Vinorelbine 80 mg soft capsules are oblong-shaped pale yellow coloured.

Vinorelbine soft capsules are available as packs of 1 or 4 blisters of 1 soft capsule each.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Consilient Health Ltd.,
Floor 3, Block 3, Miesian Plaza,
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