Package leaflet: Information for the user

[Product Name] 20 mg Soft Capsules
[Product Name] 30 mg Soft Capsules
[Product Name] 80 mg Soft Capsules
Vinorelbine 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [Product Name] is and what it is used for

[Product Name] contains the active substance vinorelbine and belongs to a family of medicines called the vinca alkaloid, family used to treat cancer.
[Product Name] is used to treat some types of lung cancer and some types of breast cancer in patients over 18 years old.

2. What you need to know before you take [Product Name]

Do not take [Product Name]:
- if you are allergic to vinorelbine, or to any of the related family of cancer medicines called the vinca alkaloids, or any other ingredients of this medicine (listed in section 6)
- if you are breast feeding
- if you have had an operation on your stomach or small bowel, or if you have intestinal disorders
- if you have a low white blood cell and/or platelet count, or a severe infection current or recent (within 2 weeks)
- if you plan to have a yellow fever vaccine or have just had one
- if you require long-term oxygen therapy

Warning and precautions
Talk to your doctor or pharmacist before taking [Product Name] 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 received radiotherapy where the treatment field included the liver
- you have symptoms of infection (such as fever, chills, cough)
- you plan to have a vaccination. Live attenuated vaccines (e.g. measles vaccine, mumps vaccine, rubella vaccine...) are not recommended with vinorelbine as they may increase the risk of life-threatening vaccine disease.
- you have a severe hepatic disease unrelated to your cancer
- you are pregnant.

Before and during treatment with [Product Name], 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
It is not recommended for use by children under 18 years old.

Other medicines and [Product Name]
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines

Your doctor should take special care if you are taking the following medicines:
- medicines used to thin your blood (anticoagulants)
- anti-epileptic medicines (e.g. phenytoin)
- antifungal medicines (e.g. itraconazole)
- anti-cancer medicines such as mitomycin C or lapatinib
- medicines that impair your immune system such as ciclosporin and tacrolimus

The combination of [Product Name] with other medicines with known bone marrow toxicity (affecting your white and red blood cells and your platelets) could also worsen some side effects.

Pregnancy, breast feeding and fertility
Before starting treatment, you must tell your doctor if you are pregnant, if you think you are pregnant or if you intend to become pregnant because there are potential risks for the infant. You should not breast-feed if you are taking [Product Name].

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

Men being treated with [Product Name] are advised not to father a child during and for at least 4 months after taking the last capsule, and to seek advice on conservation of sperm prior to treatment because [Product Name] may alter male fertility.

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

[Product Name] contains sorbitol

Each soft capsule containing 20 mg vinorelbine contains 10.54 mg sorbitol.
Each soft capsule containing 30 mg vinorelbine contains 15.96 mg sorbitol.
Each soft capsule containing 80 mg vinorelbine contains 29.35 mg sorbitol.

[Product Name] contains ethanol

This medicine contains 5 mg of alcohol (ethanol) in each 20 mg soft capsule which is equivalent to 2.85 %. The amount in 20 mg dose of this medicine is equivalent to less than 1 ml beer or 1 ml wine.

This medicine contains 7.5 mg of alcohol (ethanol) in each 30 mg soft capsule which is equivalent to 2.85%. The amount in 30 mg dose of this medicine is equivalent to less than 1 ml beer or 1 ml wine.

This medicine contains 20 mg of alcohol (ethanol) in each 80 mg soft capsule which is equivalent to 2.85%. The amount in 80 mg dose of this medicine is equivalent to less than 1 ml beer or 1 ml wine.

The small amount of alcohol in this medicine will not have any noticeable effects.

3. How to take [Product Name]

Before and during treatment with [Product Name] your doctor will check your blood cell count. Your doctor will tell you the number and strength of capsules you should take, how often you should take the capsules and for how long you should be treated; depending on your body surface area, the results of your blood tests and your general condition.

The total dose should never exceed 160 mg per week.
You should never take [Product Name] more than once per 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.

Before opening the blisters containing [Product Name], 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**.**

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 [Product Name]:
- Swallow the [Product Name] capsule whole with water, preferably with a light meal. It should not be taken with a hot drink as this 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 and tell your doctor immediately.
- If you vomit within a few hours after taking your [Product Name], contact your doctor immediately. **Do not repeat the dose.**

If you take an anti-sickness medicine
Vomiting can occur with [Product Name] (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 [Product Name] during a light meal; this will help to reduce the feeling of sickness.

If you take more [Product Name] than you should
If you have taken more [Product Name] than you should, contact a doctor immediately.
Severe symptoms related to your blood components may appear and you may develop signs of infection (such as fever, chills, cough). You could also become severely constipated.

If you forget to take [Product Name]
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 [Product Name]

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 [Product Name], if you develop any of the following symptoms:
- Signs of an infection such as cough, fever and chills,
- Severe constipation with abdominal pain when your bowels have not been open for several days,
- Severe dizziness, lightheadedness when you stand up, sign of a 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 myocardial infarction (sometimes with fatal outcome).
- Difficulty in breathing, dizziness, decreased blood pressure, rash affecting your whole body, or swelling of the eyelids, face lips or throat which may be signs of 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 (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 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 cell 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 (may affect up to 1 in 10 people)
- Difficulties to coordinate muscle movements;
- Differences in your eyesight;
- Shortness of breath, cough;
- Difficulties to urinate, 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, jaw pain, muscle pain;
- Pain at different sites in your body and pain where your tumour is;
- High blood pressure;
- Liver disorders (abnormal liver test).

Uncommon (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 genral health;
- Heart attack (myocardial infarction);
- Gastrointestinal bleeding;
- Low sodium level in your blood resulting in weakness, muscle twitching, tiredness, confusion and unconsciousness. This low sodium level may be attributed in some cases to an overproduction of a hormone causing fluid retention (Syndrome of Inappropriate Antidiuretic Hormone secretion – SIADH).

Reporting of side effects:
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V.
By reporting side effects, you can help provide more information on the safety of this medicine

5. How to store [Product Name] soft capsule

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

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

Store in a refrigerator (2°C - 8°C) in the original package to protect from light.

Do not throw away any medicines 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 protect the environment.

6. Contents of the pack and other information

What [Product Name] contains
The active substance is Vinorelbine (as tartrate) 20 mg, 30 mg or 80 mg

The other ingredients are:

Capsule filling:
anhydrous ethanol
purified water
glycerol
macrogol 400

Capsule cover:
gelatin
glycerol
partially dehydrated sorbitol liquid
titanium dioxide (E171)
purified water
[Product Name] 20 mg and 80 mg Soft Capsules- iron oxide yellow (E172)
[Product Name] 30 mg Soft Capsules-iron red oxide (E172)

Other ingredients:
printing ink (Non volatile component-shellac glaze, black iron oxide (E172), propylene glycol) medium chain triglycerides

What [Product Name] looks like and contents of the pack
20 mg soft capsule: An oval-shaped light brown soft capsule with a size of 9.0mm x 7.0mm with black “20” printed on the surface
30 mg soft capsule: An oblong-shaped pink soft with a size of 15.0mm x 6.0mm capsule with black “30” printed on the surface
80 mg soft capsules: An oblong-shaped pale yellow soft capsule with a size of 20.0mm x 8.0mm. with black “80” printed on the surface.

[Product Name] 20 mg Soft Capsules: Pack of 1 blister with 1 soft capsule.
Pack of 4 blisters with 1 soft capsule each
[Product Name] 30mg Soft Capsules: Pack of 1 blister with 1 soft capsule.
Pack of 4 blisters with 1 soft capsule each
[Product Name] 80 mg Soft Capsules: Pack of 1 blister with 1 soft capsule.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicinal product is authorized in the Member States of the EEA under the following names:

{Name of the Member State} {Name of the medicinal product}
{Name of the Member State} {Name of the medicinal product}
[To be completed nationally]

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[To be completed nationally]