Package leaflet: Information for the user

NAVELBINE 20mg soft capsule
NAVELBINE 30mg soft capsule
NAVELBINE 80mg soft capsule

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 further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. 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 of the 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 Navelbine soft capsule is and what it is used for
2. Before you take Navelbine soft capsule
3. How to take Navelbine soft capsule
4. Possible side effects
5 How to store Navelbine soft capsule
6. Contents of the pack and other information.

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

Navelbine contains the active substance Vinorelbine (as tartrate) and belongs to a family of medicines called the vinca-alkaloid family, used to treat cancer.
Navelbine 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 Navelbine soft capsule

Do not take Navelbine soft capsule

- If you are allergic to Vinorelbine, or 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 breast feeding.
- 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 Navelbine.
- 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

Warnings and precautions

Talk to your doctor or pharmacist before taking Navelbine soft capsule 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, cough).
- You plan to have a vaccination. Many vaccines (live attenuated vaccines) are not recommended during

treatment.
- You have a severe hepatic disease unrelated to your cancer.
- You are pregnant.

Before and during your treatment with Navelbine 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 under 18 years old.

Other medicines and and Navelbine soft capsule
Tell your doctor or pharmacist if you are taking, or have recently taken, 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 Navelbine with other medicines with known bone marrow toxicity (affecting your white and red blood cells and your platelet) could also worsen some side effects.

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

You should not breast-feed if you are taking Navelbine (see section 2 ‘Do not take Navelbine soft capsule’).

If you are a woman of child-bearing potential, you must use an effective contraception (birth control) during treatment and for 7 months after the end of treatment.

If you are a man being treated with Navelbine, you 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 because Navelbine may alter your fertility. You must use an effective contraception during treatment and for 4 months after end of treatment.

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

Navelbine soft capsule contains sorbitol, alcohol, sodium
This medicine Navelbine 20 mg contains 5.36 mg of sorbitol in each capsule.
This medicine Navelbine 30 mg contains 8.11 mg of sorbitol in each capsule.
This medicine Navelbine 80 mg contains 14.91 mg of sorbitol in each capsule.

This medicine Navelbine 20 mg contains 5 mg of alcohol (ethanol) in each capsule, which is equivalent to 0.07 mg/kg.

This medicine Navelbine 30 mg contains 7.5 mg of alcohol (ethanol) in each capsule, which is equivalent to 0.11 mg/kg.
This medicine Navelbine 80 mg contains 20 mg of alcohol (ethanol) in each capsule, which is equivalent to 0.29 mg/kg.

The amount in each capsule of this medicine (Navelbine 20mg, 30mg, 80mg) is equivalent to less than 1 ml beer or 1 ml wine.

The small amount of alcohol in this medicine (Navelbine 20mg, 30mg, 80mg) will not have any noticeable effects.

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. How to take Navelbine soft capsule

Before and during your treatment with Navelbine 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 Navelbine.

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 Navelbine 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.

Before opening the blisters containing Navelbine, 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 Navelbine soft capsule:

- Swallow Navelbine 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 Navelbine, contact your doctor; **do not repeat the dose.**

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

If you take more Navelbine soft capsule than you should:
If you may have taken more Navelbine than the prescribed dose, contact a doctor **immediately**.
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 Navelbine 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 taking Navelbine 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, Navelbine can have side effects although not everybody gets them.

Immediately contact your doctor while taking Navelbine, if you develop any of the following symptoms:

- 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,
- 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.

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 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 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.
- 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 due 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance; website: www.hpra.ie.

By reporting side effects, you can help provide more information on the safety of this medicine

5. How to store Navelbine soft capsule

Keep out of the sight and reach of children
Do not use Navelbine 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). Store in the original package.

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 to protect the environment.

6. Contents of the pack and other information

What Navelbine soft capsule contains

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

- The solution contains: ethanol anhydrous; purified water; glycerol; macrogol 400.
- The capsule shell contains: gelatin; glycerol 85%; anidrisorb 85/70 (contains sorbital (E420), sorbitan, mannitol (E421), superior polyols); colouring agents (E171 titanium dioxide and E172 red and/or yellow iron oxide depending on the strength); medium chain triglycerides; PHOSAL 53 MCT (contains phosphatidylcholine, glycerides).
- The edible printing ink contains: carminic acid (E120), sodium hydroxide, aluminium chloride hexahydrate, hypromellose, propylene glycol (E1520).

What Navelbine soft capsule looks like and contents of the pack

Navelbine 20 mg soft capsules are light brown coloured, printed with "N20"
Navelbine 30 mg soft capsules are pink coloured, printed with "N30"
Navelbine 80 mg soft capsules are pale yellow coloured, printed with "N80"

Soft capsules of 20, 30 and 80 mg are available as packs of 1 blister of 1 soft capsule.
Not all pack sizes may be marketed

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Other formats:
To listen to or request a copy of this leaflet in Braille, large print or audio call +44 (0)1733 375370.
Be ready to give the following information

Product Name	**Reference Number**
Navelbine 20 mg soft capsule:	PA 0329/011/001
Navelbine 30 mg soft capsule:	PA 0329/011/002
Navelbine 80 mg soft capsule:	PA 0329/011/004

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