

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 used to treat cancer called the vinca-alkaloid family.

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 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 Navebine.

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

Men being treated with Navelbine 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 Navelbine as male fertility may be altered.

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, ethanol

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.

This medicinal product contains small amounts of ethanol (alcohol), less than 100mg per dose, you will not be affected by this small quantity.

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/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 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:

- 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, 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

Very common side effects (may affect more than 1 in 10 people)

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; Loss of some reflex reactions, occasionally difference in the perception of touch; Hair loss usually mild form; Tiredness, 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, Difficulties to urinate; Difficulty in sleeping; Headache; Dizziness; A difference in your taste of flavours, inflammation of the gullet, difficulty when swallowing food or liquids; Skin reactions; Weight gain; Joint pain (arthralgia), jaw pain, muscle pain (myalgia); pain at different sites in your body and pain where your tumour is.

Uncommon side effects (may affect up to 1 in 100 people):

Heart failure which can cause shortness of breath and ankle swelling, Irregular heartbeats;

Not known: frequency cannot be estimated from the available data

Low blood levels of sodium in your blood (which can cause symptoms of tiredness, confusion, muscle twitching and unconsciousness); 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail medsafety@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: anhydrous ethanol; water purified; glycerol; macrogol 400
- The capsule shell contains: gelatin; glycerol; ANIDRISORB 85/70 (D-sorbitol and 1,4-sorbitan); medium chain triglycerides and PHOSAL 53 MCT (phosphatidylcholine; glycerides; anhydrous ethanol) and colouring agents (E171 titanium dioxide and E172 red and/or yellow iron oxide depending on the strength).
- The edible printing ink contains: carminic acid (E120), sodium hydroxide, aluminium chloride hexahydrate, hypromellose, propylene glycol, isopropyl alcohol, purified water.

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

Marketing Authorisation Holder

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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 1287/1/1
Navelbine 30 mg soft capsule:	PA 1287/1/2
Navelbine 80 mg soft capsule:	PA 1287/1/4

This is a service provided by the Royal National Institute of the Blind

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