

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.

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

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

Navelbine 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 under 18 years old.

2. Before you take Navelbine soft capsule

Do not take Navelbine 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 Navelbine 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 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

If in doubt, ask your doctor or pharmacist.

Take special care with Navelbine soft capsule

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 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.

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 Navelbine 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

Many vaccines (live attenuated vaccines) are not recommended during treatment. Please inform your doctor if you require any vaccinations.

Taking Navelbine soft capsule with food and drink

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

It is preferable to take Navelbine with a light meal.

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

Male fertility

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.

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

Breast-feeding

Do not take Navelbine if you are breast feeding.

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

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

Driving and using machines

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

However, some of the possible side effects of Navelbine 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.

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

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

Navelbine must be taken by mouth.

Navelbine is used in patients over 18 years old.

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

Always take Navelbine 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 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 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 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

Frequency of administration

Normally Navelbine 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 Navelbine: 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 Navelbine during a light meal; this will help to reduce the feeling of sickness.

Method of administration

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 more Navelbine soft capsule than you should:

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

Your dose of Navelbine 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 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 using 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:

- Cough, fever and chills which may be signs of a major infection 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, 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, 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 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 tumor 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 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).

Reporting of side effects:

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Yellow Card Scheme; website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. Storing Navelbine

Keep out of the reach and sight 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). Do not freeze. Store in the original package in order to 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 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 %; sorbitol/sorbitan (anidrisorb 85/70); triglycerides, medium chain and PHOSAL 53 MCT (phosphatidylcholine; glycerides; ethanol anhydrous) and colouring agents (E171-titanium dioxide and E172 red and/or yellow iron oxide depending on the strength).
- The edible printing ink contains: cochineal extract (E120), hypromellose, propylene glycol.

What Navelbine soft capsule looks like and contents of the pack

Navelbine 20mg soft capsules are light brown coloured, printed with “N20”.

Navelbine 30mg soft capsules are pink coloured, printed with “N30”.

Navelbine 80mg 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.

Marketing Authorisation Holder

Pierre Fabre Limited
250 Longwater Avenue
Green Park
Reading RG2 6GP
United Kingdom

Manufacturer

Pierre Fabre Médicament Production
Avenue du Béarn
64320 Idron
France

For any information on this product please contact Pierre Fabre Ltd; Phone: 0800 085 5292

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK only). Please be ready to give the following information:

Product Name	Reference Number
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Navelbine 20mg soft capsule: PL 00603/0029

Navelbine 30mg soft capsule: PL 00603/0030

Navelbine 80mg soft capsule: PL 00603/0032

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