

# NAVELBINE SOFT CAPSULE

Vinorelbine Tartrate (20mg, 30mg)

## What is in this leaflet

1. What *Navelbine Soft Capsule* is used for
2. How *Navelbine Soft Capsule* works
3. Before you use *Navelbine Soft Capsule*
4. How to use *Navelbine Soft Capsule*
5. While you are using it
6. Side effects
7. Storage and Disposal of *Navelbine Soft Capsule*
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

## What *Navelbine Soft Capsule* is used for

*Navelbine* is used to treat non-small cell lung cancer and advanced breast cancer.

## How *Navelbine Soft Capsule* works

*Navelbine* belongs to a family of medicines called the vinca alkaloid. *Navelbine* is an antimitotic agent, causing cell death by blocking cell division.

## Before you use *Navelbine Soft Capsule*

### -When you must not use it:

- If you are allergic (hypersensitive) to vinorelbine (active ingredient), or any of the related group of cancer drugs called the vinca-alkaloids
- If you are allergic to any other ingredients of *Navelbine* (refer to section 'Ingredients' in this leaflet)
- If you have had an operation on your stomach or small bowel, or if you have intestinal disorders, or if you present disorder affecting absorption
- If you have a low white blood cell count (leukocytes and/or neutrophils) or a severe infection

currently or recently (within 2 weeks)

- If you have a low platelet count
- If you require long-term oxygen therapy
- If you are breast feeding
- If you plan to have a yellow fever vaccine or have just had one

### -Before you start to use it:

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 received radiotherapy treatment involving the liver
- You have symptoms of infection (such as fever, chills, cough)
- you are taking or have recently taken another medicine including one obtained without a prescription
- you are going to be vaccinated, (for the yellow fever vaccine, Never take **NAVELBINE** soft capsule)
- you are being treated with phenytoin, fosphenytoin, itraconazole, ketoconazole or posaconazole as combination of these substances with *Navelbine* is not recommended (see **Taking Other medicines**).
- you are suffering from a severe liver disease,
- you are pregnant.

Before and during treatment with *Navelbine*, blood cell counts are performed to check that it is safe for you to receive treatment (check of white blood cell and platelet count). If the results of this analysis are not satisfactory, your treatment may be delayed and further checks made until these values return to normal. This medicine should not be used in people with fructose intolerance (hereditary metabolic disease).

### -Taking other medicines:

This medicine must not be taken with a yellow fever vaccine. Taking this medicine with live attenuated vaccine (e.g. measles vaccine, mumps vaccine, rubella vaccine...), phenytoin, fosphenytoin (anti-seizure medicines), itraconazole, ketoconazole or posaconazole (anti-fungal medicines). Mitomycin C or Iapatinib (anticancer medicines) is not recommended. Please tell your doctor or pharmacist if you are taking, or have recently taken any other medicines, including medicines obtained without prescription.

## How to use *Navelbine Soft Capsule*

*Navelbine* should be prescribed by a qualified doctor who is experienced in the use of cancer treatments. *Navelbine* must be taken by mouth. It is not recommended for use by children.

### -How much to use

Before and during 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 per week.

**The total dose should never exceed 160 mg per week.**

**You should never take *Navelbine* more than once per week.**

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.

**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.

-When to use it

Normally, Navelbine treatment is scheduled once a week. The frequency will be determined by your doctor.

• How long to use it

The duration of your treatment is decided by your doctor.

**If you are taking a medicine for nausea**

Vomiting can occur with Navelbine. If your doctor has prescribed an anti-sickness medication, always take it exactly as the doctor has told you. Take Navelbine with a light meal as this will help you to reduce nausea.

• If you forget to use it

Do not take a double dose to make up a forgotten dose. Contact your doctor who will reschedule your dose.

• If you use too much (overdose)

If you have taken more Navelbine than the prescribed dose, 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 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.

**While you are using it**

- Things you must do

**Navelbine Soft Capsule with food and drink**

The soft capsule of Navelbine should be swallowed whole with water

without chewing and sucking the capsule. It is preferable to take Navelbine with a light meal. If you have chewed or sucked a capsule by mistake, rinse your mouth thoroughly with water and contact your doctor immediately. If you vomit within a few hours after taking Navelbine, inform your doctor immediately: do not repeat the same dose.

- Things you must not do

Pregnancy, breast-feeding and fertility

Fertility:

Men being treated with Navelbine are advised not to father a child during and up to 3 months after treatment, and to seek advice on conservation of sperm prior to treatment because Navelbine may alter male fertility irreversibly.

Women of child-bearing potential

Women of child-bearing potential 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 or intend to become pregnant. If you have to start treatment with Navelbine and are pregnant or if pregnancy occurs during your treatment with Navelbine, you must immediately contact your doctor for advice on the potential risk for harmful effects on the child.

Breast-feeding

Do not take Navelbine if you are breast-feeding. Breast feeding must be discontinued if a treatment with Navelbine is necessary.

- Things to be careful of

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.

Important information about some of the ingredients of Navelbine soft capsule

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.

**Side effects**

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

**While taking Navelbine, if you develop any of the following symptoms you should contact your doctor immediately:**

- 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 or faintness when standing up which may be a sign of a large fall in your blood pressure.
- severe chest pain which may be due to incorrect functioning of the heart because of reduced blood flow (ischaemic heart disease).signs of allergy such as itching, shortness of breath, dizziness, reduced blood pressure, skin rash over your whole body or swelling of the eyelids, lips or throat.

Below is a list of side effects that have occurred in some people following treatment with Navelbine. This list is classified according to the frequency of side effects occurred.

**Very common side effects**(can occur in more than 1 in 10 people treated)

- Nausea; Vomiting; Diarrhoea; Constipation; Gastric disturbances; Fall in red cells (anaemia) which may cause pallor, fatigue or breathlessness; Inflammation or aphthous ulcers in the mouth or throat (stomatitis); Reduced platelet

count (thrombocytopenia) which may increase the risk of bleeding or haematomas; Loss of some reflexes, occasionally with reduction in touch sensation; Hair loss (alopecia), generally mild and during prolonged treatment; Fatigue; Malaise; Weight loss; Loss of appetite (anorexia).

**Common side effects**(can occur between 1 to 10 per 100 people treated)

- Neuromotor disturbances: Changes in vision; Respiratory difficulties (dyspnoea); Pain, burning and difficulty passing urine; Sleep disturbances; Headache; Dizziness; Altered taste for food and drinks; Inflammation of the throat and oesophagus (oesophagitis); Difficulty swallowing foods or liquids; Skin reactions; Weight gain; Joint pain; Jaw pain; Muscle pain; Pain at different sites in the body and at the site of the tumour.

**Uncommon side effects**(can occur in 1 to 10 per 1 000 people treated)

- Heart failure which may cause respiratory difficulties or swelling of the ankles; Irregular heart rate (cardiac arrhythmias).

**Other adverse effects of not known incidence have been reported:**

- Low level of sodium (severe hyponatraemia) in the blood which may cause symptoms of fatigue, confusion or muscle contractions; Gastro-intestinal bleeding; Heart attack (myocardial infarction in patients with a past medical history or cardiac risk factors).

Navelbine is also marketed as a concentrate for solution for infusion, administered intravenously into a vein.

The list below shows the adverse effects only reported for the Navelbine concentrate for solution for infusion which have not been seen with your treatment (oral) although which cannot be excluded.

**Uncommon adverse effects (may occur in 1 to 10 per 1,000 patients)**

- Breathing difficulties (bronchospasm); Sensation of cold hands and feet (cold extremities); Hot flushes;

**Rare adverse effects (may occur in 1 to 10 per 10,000 patients)**

- Breathing difficulties (occasionally fatal interstitial lung disease); Severe abdominal and back pain (pancreatitis).

**If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.**

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [npra.moh.gov.my](http://npra.moh.gov.my) (*Report an Adverse Event*).

**Storage and Disposal of Navelbine Soft Capsule**

- **Storage**

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

Store between + 2°C and + 8°C (in refrigerator).

Keep the immediate packaging tightly closed.

Do not use Navelbine Soft Capsule if you notice that the capsule is crushed or is leaking.

- **Disposal**

For safety reasons, any unused or damaged capsule should be returned to your doctor or pharmacist to be destroyed in accordance with applicable procedure for cytotoxic substances.

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.

**Product Description**

- **What it looks like**

Navelbine 20 mg soft capsule: oval, uniform light brown colour, N20 printed in red and visible, containing

a viscous, clear, light yellow to orange- yellow solution,

Navelbine 30 mg soft capsule: oblong, uniform pink colour, N30 printed in red and visible, containing a viscous, clear, light yellow to orange- yellow solution,

**Ingredients**

-Active ingredient

Vinorelbine 20 or 30 mg.

As Vinorelbine Ditartrate 27.70mg, or 41.55mg

For one soft capsule

-Inactive ingredients:

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).

The edible printing ink contains: cochineal extract (E120), hypromellose, propylene glycol.

**MAL Numbers :**

Navelbine 20mg Soft Capsule

(MAL20071635AZ)

Navelbine 30mg Soft Capsule

(MAL20071636AZ)

**Manufacturer**

Pierre Fabre Medicament Production  
Etablissement Aquitaine Pharm  
International Avenue Du Bearn  
64320 Idron France

**Product Registration Holder**

Orient EuroPharma (M) Sdn Bhd.  
E-08 Garden Shoppe, One City,  
Jalan USJ 25/1C, 47650 Subang Jaya,  
Selangor, Malaysia

**Date of revision**

01/03/2018 based on France PIL July 2016

**Serial Number:**

NPRA (R1/1) 29032018/027