What is in this leaflet

This leaflet answers some common questions about NAVALBINE Capsules. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking NAVALBINE Capsules against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What NAVALBINE Capsules is used for

NAVALBINE Capsules are used for the treatment of:

- non-small cell lung cancer (NSCLC)
- advanced breast cancer that has not responded to other medicines

NAVALBINE Capsules may be used on their own or in combination with other medicines to treat cancer.

NAVALBINE Capsules contain the active ingredient vinorelbine which belongs to a family of medicines called vinca alkaloids.

It belongs to a group of medicines called antineoplastic or cytotoxic medicines. You may also hear of these medicines being called chemotherapy.

It works by stopping cancer cells from growing and multiplying causing the cells to die.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

This medicine is not expected to affect your ability to drive a car or operate machinery.

NAVALBINE Capsules are not recommended for use in children as there is no information on its effects in children.

Before you are given NAVALBINE Capsules

When you must not be given it

You must not be given Do not take NAVALBINE Capsules if you have an allergy to:

- vinorelbine or to the other vinca alkaloids, (vinblastine, vincristine, vindesine, vinflunine)
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

NAVALBINE Capsules must not be administered if you have, or have had, any of the following medical conditions:

- severe liver problems
- a reduced number of white blood cells (known as neutropenia) which you may notice as frequent infections such as fever, severe chills, sore throat or mouth ulcers
- a reduced number of platelets (blood cells which help the blood to clot) which you may notice as bleeding or bruising more easily than normal
- surgery on your stomach or small bowel
- stomach or intestinal disorders that affect how you absorb food
- any condition requiring long-term oxygen therapy

NAVALBINE Capsules must not be administered if you have recently had a yellow fever vaccination or plan to have one.

You must not be given this medicine if you are pregnant or think you may be pregnant.

Like most medicines used to treat cancer, it may affect your developing baby if you take it during pregnancy.

If you are a fertile man or woman, you should use an effective method of contraception during your treatment with NAVALBINE Capsules and for three months after your last dose.

If pregnancy occurs during your treatment, you must immediately contact your doctor for advice.
Men being treated with NAVELBINE Capsules are advised not to father a child during and up to a minimum of 3 months after treatment. Prior to treatment, men are advised to seek advice on conserving sperm due to the chance of irreversible fertility resulting from treatment with NAVELBINE Capsules.

You must not breast-feed if you are being given this medicine.

The active ingredient in NAVELBINE Capsules passes into breast milk and there is a possibility that your baby may be affected.

This medicine must not be given after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, it may not work as well.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you are given it

NAVELBINE Capsules are a potent cytotoxic drug that results in a decrease in blood cells. Your blood count will be carefully monitored before and during your treatment.

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- heart problems (including chest pain and heart attack)
- liver problems, or if you are currently receiving or have received radiation therapy to your liver
- a low white blood cell count which you may notice as signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers
- lung problems, including asthma
- stomach problems (including surgery on your stomach)
- the rare hereditary problem of fructose intolerance (due to the presence of sorbitol)
- your ability to carry out activities of daily living is strongly reduced

If you have not told your doctor about any of the above, tell him/her before you start taking NAVELBINE Capsules.

Taking other medicines

Before you are given NAVELBINE Capsules, tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and NAVELBINE Capsules may interfere with each other. These include:

- medicines used to prevent blood clots (anticoagulants) e.g. phenindione, warfarin heparin
- phenytoin, a medicine used to treat epilepsy
- cyclosporin, tacrolimus, medicines which lower your body's ability to fight illness/disease (known as immunosuppressants)
- itraconazole and ketoconazole, medicines used to treat fungal infections
- mitomycin, lapatinib, medicines used to treat cancer
- medicines with known bone marrow toxicity (causing a reduced number of red or white blood cells or platelets)
- other medicines used to treat cancer such as cisplatin
- ritonavir, a medicine used to treat HIV and AIDS
- rifampicin, an antibiotic used to treat bacterial infections

These medicines may be affected by NAVELBINE Capsules or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Tell your doctor if you plan to have a vaccination.

Having a live attenuated vaccine (eg: measles, mumps, rubella vaccine) is not recommended while taking NAVELBINE Capsules as they may increase the risk of life-threatening vaccine disease.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while being given this medicine.

How NAVELBINE Capsules will be given

Follow all directions given to you by your doctor or pharmacist carefully while you are being given NAVELBINE Capsules.

They may differ from the information contained in this leaflet.

How much will be given

Your doctor will decide what dose you will receive. This depends on your body surface area, your condition and factors such as your liver function and whether you are receiving any other chemotherapy medicines.

Your doctor may adjust your dose during treatment.

NAVELBINE Capsules may be given alone or in combination with other drugs.

Several courses of NAVELBINE Capsules therapy may be needed depending on your response to treatment.

NAVELBINE Capsules reduces the number of white blood cells in the body. Your doctor will check these levels regularly. Further doses of may be delayed until your blood cell numbers return to acceptable levels.

How you will be given

NAVELBINE Capsules will be given under the supervision of a health care
Swallow your NAVELBINE Capsules whole with a full glass of water, without chewing or sucking the capsule.

The liquid inside the capsules is an irritant and may cause damage if it comes in contact with your skin, mucosa or eyes. Damaged capsules should not be swallowed.

If contact with the contents of the capsule does occur, wash the affected area thoroughly with water or a normal saline solution.

NAVELBINE Capsules should be taken with food.

If vomiting occurs within a few hours of taking NAVELBINE Capsules, the dose of NAVELBINE Capsules should not be repeated. Your doctor may prescribe a medication to help with vomiting if it is a problem.

The doctor or nurse will usually have the capsules ready for you, however, if you need to open the child resistant packaging:

- cut the blister along the black dotted line
- peel off the soft plastic foil
- push the capsule through the aluminium foil

How long you will be given it

NAVELBINE Capsules are usually given every week, but it may be given less often if you are also having other medicines to treat cancer.

Your doctor will decide how many doses you will need.

If you miss a dose

Tell your doctor as soon as possible if you realise that you have missed an appointment for receiving your dose of NAVELBINE Capsules.

If you have problems remembering when your next dose is due, use a diary or calendar or ask a friend to remind you.

Please also refer to the NAVELBINE patient booklet.

Overdose

As NAVELBINE Capsules are given to you under the supervision of a healthcare professional, it is very unlikely that you will receive too much.

However, if you experience any side effects while, or after being given NAVELBINE Capsules, tell your doctor, nurse or pharmacist.

While you are being given NAVELBINE Capsules

Things you must do

Keep all appointments with your doctor.

Your doctor may want to do some blood and other tests from time to time to check on your progress and monitor any unwanted side effects.

It is important to have your follow-up doses of NAVELBINE Capsules at the appropriate times to get the best effects from your treatments.

Tell any other doctors, dentists and pharmacists who are treating you that you are having treatment with NAVELBINE Capsules.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are having treatment with NAVELBINE Capsules.

If you become pregnant while taking NAVELBINE Capsules, tell your doctor immediately.

NAVELBINE Capsules can lower the number of white blood cells and platelets in your blood. This means that you have an increased chance of getting an infection or bleeding. Take the following precautions to reduce your risk of infection or bleeding:

- check with your doctor immediately if you think you may be getting an infection, or if you get a fever, chills, cough, hoarse throat, lower back or side pain or find it painful or difficult to urinate
- avoid people who have infections
- be careful when using a toothbrush, toothpick or dental floss. Your doctor, dentist, nurse or pharmacist may recommend other ways to clean your teeth and gums
- check with your doctor before having any dental work
- be careful not to cut yourself when you are using sharp objects such as a razor or nail cutters
- avoid contact sports or other situations where you may bruise or get injured

Things to be careful of

Be careful driving or operating machinery until you know how NAVELBINE Capsules affects you.

If you experience symptoms that affect your ability to concentrate and react, do not drive a car or operate machinery. Fatigue and dizziness are common side effects of NAVELBINE Capsules. Make sure you know how NAVELBINE Capsules affects you before you drive a car, operate machinery or do anything else that could be dangerous if you are feeling tired.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given NAVELBINE Capsules.

Like other medicines that treat cancer, NAVELBINE Capsules can have unwanted side effects. Sometimes they are serious and you may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience all of them.

Ask your doctor or nurse to answer any questions you may have.
Tell your doctor or nurse if you notice any of the following and they worry you:

- nausea
- vomiting
- diarrhoea
- loss of appetite
- unusual tiredness, weakness, sleepiness, drowsiness or lack of energy
- unusual hair loss or thinning
- weight loss or weight gain
- constipation
- upset stomach
- aching muscles, muscle tenderness or weakness, not caused by exercise
- skin reactions
- headache
- dizziness
- change in or loss of taste
- pain, including pain at the tumour site
- jaw pain
- painful swollen joints
- trouble sleeping
- coughing

The above list includes the more common side effects of your medicine.

Tell your doctor or nurse as soon as possible if you notice any of the following:

- frequent infections such as fever, severe chills, sore throat or mouth ulcers (symptoms of a lack of white blood cells)
- tiredness, headaches, being short of breath when exercising, dizziness and looking pale (symptoms of a decreased number of red blood cells)
- bleeding or bruising more easily than normal or nosebleeds (symptoms of a low blood platelet count)
- stomach pain with bloating, gut cramps and vomiting which may be symptoms of the small bowel not working properly
- viral, bacterial or fungal infections
- sore mouth
- mouth ulcers and cold sores
- high blood pressure
- low blood pressure
- difficulty swallowing
- pain when passing urine
- changes in your vision

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor or nurse immediately or go to Accident and Emergency at your nearest hospital:

- difficulty breathing, short of breath
- chest pain
- palpitations, fast or irregular heart beat
- rash, itching or hives on the skin
- swelling of the feet and ankles, face, lips, tongue or other parts of the body

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or nurse if you notice anything that is making you feel unwell. Other side effects not listed above may also occur in some people.

Tell your doctor or nurse if you notice anything that is making you feel unwell even after you have finished your treatment with NAELBINE Capsules.

The benefits and side effects of NAELBINE Capsules may take some time to occur.

After treatment with NAELBINE Capsules

Storage
NAELBINE Capsules will normally be stored in the hospital pharmacy.

If you are storing NAELBINE Capsules at home, it should be stored:

- in the refrigerator (2 to 8°C)
- protected from light

Do not freeze it.

Do not leave NAELBINE Capsules in the car.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal
If your doctor tells you to stop taking this medicine or the expiry date has passed, return any leftover vials to your pharmacist. Do not dispose of NAELBINE Capsules via wastewater or household waste. This will help to protect the environment.

Product description

What it looks like
NAELBINE Capsules are available in two strengths, 20 mg and 30 mg.

The capsules come in blister packs containing 1 soft capsule.

NAELBINE 20 mg soft capsules are light brown and printed N20.

NAELBINE 30 mg soft capsules are pink and printed N30.

Ingredients

Active ingredient:

- vinorelbine tartrate

Other ingredients:

- ethanol
NAVELBINE Capsules

- water-purified
- glycerol
- macrogol 400
- gelatin
- sorbitol
- sorbitan
- medium-chain triglycerides
- phosphatidyl choline
- glycerides
- hypromellose
- propylene glycol
- edible printing ink E20
- titanium dioxide
- iron oxide yellow
- iron oxide red

NAVELBINE Capsules do not contain lactose, sucrose, gluten, tartrazine or any other azodyes.

**Supplier**

NAVELBINE Capsules are supplied in New Zealand by:

New Zealand Medical & Scientific Ltd
P O Box 132400
Sylvia Park
AUCKLAND 1644

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