1.5.5.1 Patient Information Leaflet

SCHEDULING STATUS

S4

NAVELBINE® ORAL 20 mg, soft gelatine capsules

NAVELBINE® ORAL 30 mg soft gelatine capsules

Vinorelbine tartrate

Contains sugar:

Each capsule of NAVELBINE ORAL 20 mg soft capsule contains 2,00 mg glycerol, 37,98 mg glycerol (85 %), 0,80 mg mannitol and 5,36 mg sorbitol.

Each capsule of NAVELBINE ORAL 30 mg soft capsule contains 3,00 mg glycerol, 55,63 mg glycerol (85 %), 1,22 mg mannitol and 8,11 mg sorbitol.

Read all of this leaflet carefully before you start taking NAVELBINE ORAL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- NAVELBINE ORAL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What NAVELBINE ORAL is and what it is used for.
2. What you need to know before you take NAVELBINE ORAL.
3. How to take NAVELBINE ORAL.
4. Possible side effects.

5. How to store NAVELBINE ORAL.
6. Contents of the pack and other information.

1. What NAVELBINE ORAL is and what it is used for

What NAVELBINE ORAL is:

NAVELBINE ORAL contains vinorelbine which belongs to a family of medicines used to treat cancer called the vinca-alkaloid family.

What it is used for:

NAVELBINE ORAL is used alone or in combination for:

- The first line treatment of stage 3 or 4 non-small cell lung cancer.
- The treatment of advanced breast cancer stage 3 and 4 relapsing after or who have failed to respond to an anthracycline-containing therapy.

2. What you need to know before you take NAVELBINE ORAL

Do not take NAVELBINE ORAL:

- if you are hypersensitive (allergic) to vinorelbine or any of the other ingredients of NAVELBINE ORAL (listed in section 6);
- if you have a disease significantly affecting gastro-intestinal function;
- if you had previous surgical resection (removal part or all) of the stomach and small bowel;
- if you have a low white blood cell and/or platelet count;
- if you have an active infection preceding 2 weeks (Karnofsky score < 70);
- if you have severe liver insufficiency;
- if you have medicine-induced severe granulocytopenia (decrease in the number of granulocytes) or severe thrombocytopenia (low blood platelet count) as determined by your healthcare professional;

- if you are pregnant or breastfeeding (see Pregnancy and breastfeeding);
- if you plan to have a yellow fever vaccine or have just had one;
- if you require long-term oxygen therapy.

Warnings and precautions

Take special care with NAVELBINE ORAL:

- NAVELBINE ORAL should only be prescribed by an experienced cancer chemotherapeutic doctor.
- Before and during your treatment with NAVELBINE ORAL, 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.
- Tell your doctor or healthcare provider if you have mistakenly chewed on or sucked the capsule or if the capsule is damaged or cut to be given the proper care.
- If any contact occurs, immediate thorough washing with water or preferably with normal saline should be undertaken.
- If you vomit after a few hours of taking NAVELBINE ORAL, you may be given supportive treatment with medicines such as $5HT_3$ antagonists.

Talk to your doctor before you are given NAVELBINE ORAL if:

- you have a history of heart attack or severe chest pain;
- you have received radiotherapy where the treatment field included the liver;
- you have signs or symptoms of infection (such as fever, chills, cough);
- you plan to have a vaccination. Live attenuated vaccines (e.g. measles vaccine, mumps vaccine, rubella vaccine) are not recommended with NAVELBINE ORAL as they may increase the risk of life-threatening vaccine disease;

- your liver or kidney function is not normal;
- you are currently on inhibitors or inducers of CYP3A4 (e.g. ciclosporin, clotrimazole, progesterone, nevirapine);
- you are currently on phenytoin or itraconazole.

Children and adolescents

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

Other medicines and NAVELBINE ORAL

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor if you are taking any of the following medicines:

- Live attenuated vaccines (e.g. for yellow fever vaccine).
- Medicines used to thin your blood (anticoagulants).
- Anti-epileptic medicines (e.g. phenytoin).
- Antifungal medicines (e.g. itraconazole and ketoconazole).
- Anti-cancer medicines as mitomycin C or lapatinib.
- Medicines that impair your immune system such as ciclosporin and tacrolimus.

The combination of NAVELBINE ORAL with other medicines with known bone marrow toxicity (affecting your white and red blood cells and your platelets) could also worsen some side effects.

NAVELBINE ORAL with food, drink and alcohol

NAVELBINE ORAL must be swallowed whole with water, without chewing, sucking or dissolving the capsule.

- It is recommended to administer the capsule with some food.

- Do not take your medicine with alcohol.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

If you are a woman of child-bearing age, you must use effective contraception (birth control) during treatment and up to ~~3~~ 7 months after treatment is stopped.

If you are a man being treated with NAVELBINE ORAL, you are advised not to father a child during and up to ~~3~~ 4 months after the last capsule.

Men must use effective contraception during treatment and for 4 months after treatment.

There is also a risk that treatment with NAVELBINE ORAL will lead to male infertility and you may wish to seek advice about sperm storage before the treatment starts.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed but on studies done on the effect of NAVELBINE ORAL on the body, it appears that NAVELBINE ORAL does not affect the ability to drive and use machines.

It is not always possible to predict to what extent NAVELBINE ORAL may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which NAVELBINE ORAL affects them.

Caution is necessary when treated with NAVELBINE ORAL, considering some of its adverse effects (see section 4, Possible Side Effects).

NAVELBINE ORAL contains alcohol, sorbitol, mannitol and glycerol

NAVELBINE ORAL contains glycerol, mannitol and sorbitol which may have an effect on the control of

your blood sugar if you have diabetes mellitus.

If you have been told that you have an intolerance to some sugars, you should not take NAVELBINE ORAL.

3. How to take NAVELBINE ORAL

Do not share medicines prescribed for you with any other person.

Always take NAVELBINE ORAL exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

For oral use only.

- NAVELBINE ORAL should be swallowed whole with water without chewing or sucking the capsule.
- It is recommended to take the capsule with some food (see NAVELBINE ORAL with food, drink and alcohol).
- The usual dose is 60 mg/m² of body surface area.
- Your doctor will decide what is appropriate for your condition.

Before opening the blisters containing NAVELBINE ORAL soft capsules, make sure that there are no damaged capsules inside because the liquid inside is an irritant and may be harmful if it comes into contact with your skin, eyes or mucous membranes. 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.

Taking NAVELBINE ORAL:

- Swallow NAVELBINE ORAL 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 and tell your doctor immediately.
- If you vomit within a few hours after taking your NAVELBINE ORAL, contact your doctor immediately. Do not repeat the dose.

If you take an anti-nausea medicine

Vomiting can occur with NAVELBINE ORAL (see Possible Side Effects). If your doctor has prescribed an anti-nausea medicine, always take it exactly as the doctor has told you.

Take NAVELBINE ORAL during a light meal; this will help to reduce the feeling of nausea.

If you have the impression that the effect of NAVELBINE ORAL is too strong or too weak, talk to your doctor or pharmacist.

If you take more NAVELBINE ORAL than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Take this leaflet and any remaining tablets with you, so that your doctor knows what you have taken.

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 and have liver disorders.

If you forget to take NAVELBINE ORAL

Do not take a double dose to make up for a forgotten dose. Contact your doctor who will take the decision about rescheduling your dose.

If you stop taking NAVELBINE ORAL

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.

4. Possible side effects

NAVELBINE ORAL can have side effects.

Not all side effects reported for NAVELBINE ORAL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking NAVELBINE ORAL, please consult your healthcare provider for advice.

If any of the following happens, stop taking NAVELBINE ORAL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting;
- 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.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to NAVELBINE ORAL. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Cough, fever and chills which may be signs of a major infection or a general infection (septicaemia) that can be severe.
- Blood infections (sepsis) with symptoms such as high fever and deterioration in general health.
- Severe dizziness, light-headedness 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 ischemic heart disease or heart attack.
- A decrease in platelets which can increase the risk of bleeding or bruising, decrease in white blood cells, decrease in neutrophils; loss of some reflex reactions, occasional difference in the perception of touch; infections at different sites.
- Difficulties to coordinate muscle movements and weakness of lower extremities; liver disorders; high blood pressure.
- Fast or slow heartbeat and heart failure.
- Gastrointestinal bleeding.
- Severe constipation with abdominal pain when your bowels have not been open for several days.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- A decreased in red blood cells which can make the skin pale and cause weakness or breathlessness; hair loss usually mild form; weight loss, loss of appetite; nausea; vomiting; gastric disorders; diarrhoea; constipation, abdominal pain; tiredness (fatigue) and general feeling of being sick (malaise); fever.
- Shortness of breath and cough; headache; dizziness; a difference in your taste of flavours; inflammation or sores in the mouth or throat; inflammation of the gullet (oesophagus), difficulty when swallowing food or liquids; skin reactions; pain where your tumour is; feeling cold or chills; joint pain; jaw pain; muscle pain; difficulty sleeping; eyesight impairment, difficulty urinating, weight gain.

Less frequent side effects:

- Severe difficulties with your body movements (dizziness).

Side effects where the frequency is unknown:

- Low blood levels of sodium in your blood (which can cause symptoms of tiredness, confusion, muscle twitching and unconsciousness), abnormal liver function test results.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the “6.04 Adverse Drug Reactions Reporting Form”, found online under SAHPRA’s publications:

https://www.sahpra.org.za/Publications/Index/8

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

ORAL.

5. How to store NAVELBINE ORAL

- **Store all medicines out of reach of children.**
- Store between + 2 °C and + 8 °C (in refrigerator) in the closed original packaging.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What NAVELBINE ORAL contains

The active ingredient is:

Each NAVELBINE ORAL 20 mg soft gelatine capsule contains 27,70 mg vinorelbine tartrate equivalent to 20 mg vinorelbine base.

Each NAVELBINE ORAL 30 mg soft gelatine capsule contains 41,55 mg vinorelbine tartrate equivalent to 30 mg vinorelbine base.

The other ingredients are:

Fill solution:

Ethanol, anhydrous

Glycerol

Macrogol 400

Purified Water

Shell capsule:

Gelatin

Glycerol 85 %

Anidrisorb 85/70 (contains sorbitol (E420); sorbitan-1,4; mannitol (E421); superior polyols)

Titanium dioxide E171

Red iron oxide (depending on the strength)

Yellow iron oxide E172 (depending on the strength)

Medium chain triglycerides,

Phosal 53 MCT (contains phosphatidylcholine; glycerides)

Edible printing ink:

Carminic acid (E120)

Sodium hydroxide

Aluminium chloride hexahydrate

Hypromellose

Propylene glycol (E1520)

What NAVELBINE ORAL looks like and contents of the pack

What NAVELBINE ORAL looks like:

1 gelatine capsule is packed in a PVC/PVDC/aluminium blister. The capsule is packed in a carton.

Contents of the pack:

NAVELBINE ORAL 20 mg: Soft capsule, oval size 3, regular and smooth contour, free from cracks and leaks, opaque and shiny, uniform light brown colour, “N20” printed in red and visible, containing a viscous, clear, light yellow to orange-yellow solution, essentially free of visible particles.

NAVELBINE ORAL 30 mg: Soft capsule, oblong size 4, regular and smooth contour, free from cracks and leaks, opaque and shiny, uniform pink colour, “N30” printed in red and visible, containing a viscous, clear, light yellow to orange-yellow solution, essentially free of visible

particles.

Holder of the certificate of registration

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