Applicant : Eurolab (Pty) Ltd
Proprietary name : Navilin 20 mg & 30 mg
Dosage form and strength : Soft capsules 20 mg & 30 mg
Submission date : 08 July 2020
Approval date : 08 June 2021

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

NAVILIN 20 mg & 30 mg Soft capsules

Vinorelbine

Read all of this leaflet carefully before you start taking NAVILIN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **NAVILIN** 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 **NAVILIN** is and what it is used for
2. What you need to know before you take **NAVILIN**
3. How to take **NAVILIN**
4. Possible side effects
5. How to store **NAVILIN**
6. Contents of the pack and other information

1 What NAVILIN is and what it is used for

What NAVILIN is

NAVILIN contains the active substance ‘vinorelbine’. This medicine belongs to a family of medicines used to treat cancer called the vinca-alkaloid family.

What NAVILIN is used for

NAVILIN is used to treat:

- Non-small cell lung cancer
- Advanced breast cancer that has not responded to other medicines.

2 What you need to know before you take NAVILIN

Do not take NAVILIN:

- if you are allergic (hypersensitive) the active ingredient, vinorelbine, or any of the related family of cancer medicines called the vinca alkaloids.
- If you are allergic to any of the other ingredients in **NAVILIN** (listed in section 6 of this leaflet).
- if you are pregnant, think you may be pregnant or are planning to become pregnant.
- if you are breast feeding.
- If you have 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 **NAVILIN**.
- If your unable to carry out daily activities unassisted.
- if you have a low white blood cell count (neutrophils, granulocytes) 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.
- Safety and effectiveness in children have not been established.

Warnings and Precautions

If you chew or suck on the capsule by error, rinse your mouth with water or preferably a normal saline solution, as the liquid is an irritant.
If the capsule is cut or damaged, it can damage your skin, eyes or mucous membrane. If any contact occurs, immediately and thoroughly wash with water or preferably with normal saline solution. You should not swallow the damaged capsule and should be returned to the pharmacy or doctor in order to properly be destroyed.

In case you vomit within a few hours after taking the medicine, do not take **NAVILIN** again. **NAVILIN** can easily cause nausea and vomiting. Taking anti-nausea medicine before taking **NAVILIN** and also taking **NAVILIN** with food is recommended, as this helps to reduce the incidence of nausea and vomiting.

If you take morphine or an opioid analgesic: laxatives and careful monitoring of bowel mobility are recommended. Prescription of laxatives may be appropriate if you have a prior history of constipation.

Special care should be taken with **NAVILIN** if:

- you have a history of heart attack or severe chest pain.
- you have problems with your liver, or you have received radiotherapy where the treatment field includes the liver.
- you have symptoms of infection (such as fever, chills, joint pain, cough).
- you plan to have a vaccination or have just had one.

Before and during your treatment with **NAVILIN** 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

NAVILIN is not recommended for use in children and adolescents under 18 years.

Other medicines and NAVILIN

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

In particular, tell your doctor or nurse if you are taking any of 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, especially for yellow fever. Please inform your doctor if you require any vaccinations.

Taking NAVILIN with food and drink

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

It is preferable to take **NAVILIN** with a light meal.

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

Pregnancy, breastfeeding and fertility

Pregnancy

For women taking **NAVILIN**

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

For men taking **NAVILIN**

Men being treated with **NAVILIN** 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 **NAVILIN**.

Breast-feeding

Do not take **NAVILIN** if you are breast feeding.

Breast feeding must be discontinued if treatment with **NAVILIN** is necessary.

Contraception

For women taking **NAVILIN**

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

Driving and using machines

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

However, some of the possible side effects of **NAVILIN** 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.

NAVILIN contains sorbitol and polysorbate

NAVILIN 20 mg contains 38,44 mg sorbitol per capsule, which is equivalent to 0,10 mg/ weight (38,44 mg/ 383,79 mg).

NAVILIN 30 mg contains 59,85 mg sorbitol per capsule, which is equivalent to 0,10 mg/ weight (59,85 mg/ 585,94 mg).

Sorbitol is a source of fructose. If your doctor has told you that you have an intolerance to some sugar or if you have been diagnosed with a hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you take or receive this medicine.

NAVILIN 20 mg contains 8 mg of polysorbate 80 per capsule, which is equivalent to 0,02 mg/ weight (8 mg/ 383,79 mg).

NAVILIN 30 mg contains 12 mg polysorbate 80 per capsule, which is equivalent to 0,02 mg/ weight (12 mg/ 585,94 mg).

Polysorbate in this medicine may alter the effects of other medicines. Talk to your doctor or pharmacist if you are taking other medicines.

3 How to take NAVILIN

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

Always take **NAVILIN** exactly as your doctor has told you. Check with your doctor if you are unsure.

NAVILIN should be taken by mouth only.

NAVILIN capsules should be swallowed whole with water, without chewing or sucking the capsule, with food.

Before and during your treatment with **NAVILIN** 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 (m^2). The usual weekly dose, taken in a single dose, is 60 mg/m^2 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/m^2 of body surface area. In any case, your doctor may adjust the dose of **NAVILIN**.
If you are receiving **NAVILIN** 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 NAVILIN more than once a week.

Your doctor will tell you how long your treatment with **NAVILIN** will last. Do not stop treatment early, because if you have the impression that the effect of **NAVILIN** is too strong or too weak, tell your doctor or pharmacist.

If you take more NAVILIN than you should

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

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

If you forget to take NAVILIN

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

4 Possible side effects

NAVILIN can have side effects.

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

Your doctor should take special care when prescribing **NAVILIN**, if you suffer from any history of a heart condition.

You should not take **NAVILIN**, if you are currently being treated with radiotherapy, if the treatment field includes your liver.

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

- fever, mouth ulcers, sore throat, painful swallowing, flu-like symptoms, shivering, sweating, diarrhoea, abdominal pain, pain when urinating, coughing or shortness of breath, that can all be signs of neutropenic infection/ febrile neutropenia or neutropenic sepsis, due to low white blood cell count.
- Severe low sodium concentration in the blood. Symptoms include confusion, seizures and coma.
- Chest pain spreading to the arms, neck, jaw, back or stomach, feeling sweaty and breathless, feeling sick or vomiting (which may be symptoms of a heart attack/myocardial infarction), especially if you have a history or heart risk factors.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Infections of all types, without low count of white blood cells.
- General infections of all types, due to low white blood cell count (neutropenia).
- Tiredness, shortness of breath or dizziness, coughing, fever, chills, rash, swelling, diarrhoea, pain or discomfort while urinating. All these symptoms can be signs of bone marrow depression, resulting mainly in neutropenia or leukopenia.
- Tiredness, pale, shortness of breath, light-headedness, dizziness or a fast heartbeat (lack of red blood cells - anaemia).
- if you have a low blood platelet cell count (thrombocytopenia). Symptoms include unexpected bruising, small purple or red spots under the skin, bleeding from the nose or gums, heavier menstrual period in women, black or bloody stool, red- or pink-coloured urine, bloody vomit and severe headaches.

- Persistent problems falling and staying asleep (insomnia).
- Change in taste, a wide array of pain syndromes, including nerve pain (numbness, tingling pain), mucosal sensitivity, change in hearing and sight or loss of tendon reflexes (neurosensory disorder).
- Slurred speech, difficulty swallowing some foods, a weak grip, muscle cramps and twitches, weight loss, all signs of neuromotor disorders.
- Headaches,
- Dizziness,
- Taste disorders,
- Visual disorders,
- High or low blood pressure,
- Shortness of breath (dyspnoea), coughing,
- Diarrhoea, vomiting, nausea, loss of appetite, painful swelling, and sores in mouth (stomatitis), abdominal pain, constipation, any other gastrointestinal disorders, difficulty swallowing (dysphagia).
- Damage or inflammation of the tube running from your throat to your stomach. This causes painful and difficulty in swallowing and chest pain when eating.
- Yellowed skin and eyes, stomach pain and swelling, nausea, vomiting, tiredness, dark-coloured urine. All can be signs of liver complications,
- Hair loss, usually mild in nature,
- Skin reactions,
- Joint pain, jaw pain, muscle pain,
- Discomfort when urinating,
- Other disorders of the urinary tract or genital/ reproductive system,
- Tiredness, general discomfort,
- Fever,

- Pain, including pain at the tumour site,
- Chills,
- Weight loss or weight gain.

Less frequent side effects:

- Impaired coordination (ataxia),
- Obstruction of the intestine due to paralysis of the intestinal muscle.

Frequency is not known:

- Gastro-intestinal bleeding.

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

Reporting of side effect

If you get side effects, talk to your doctor. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction 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 **NAVILIN.**

5 How to store NAVILIN

- Store all medicines out of reach of children.
- Store at 2 - 8 °C. Keep in the outer carton until required for use.
- Do not use after the expiry date stated on the label / carton.
- Do not use **NAVILIN** if you notice any visible signs of deterioration.
- Return all unused medicine to your pharmacist.

- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Shelf-life

36 months

6 Contents of the pack and other information

What NAVILIN contains

The active substance is vinorelbine.

The other ingredients are: macrogol 400, polysorbate 80 and purified water.

The 20 mg capsule shell contains gelatin 160, iron oxide yellow (E172), purified water, sorbitol liquid partially dehydrated (EP), titanium dioxide (E171), triglycerides (medium chain).

The 30 mg capsule shell contains gelatin 160, iron oxide red (E172), purified water, sorbitol liquid partially dehydrated (EP), titanium dioxide (E171), triglycerides (medium chain).

What NAVILIN looks like and contents of the pack

NAVILIN is packed in PVC/PVDC-Al blister with child-resistant safety paper layer.

The blister is further packed in an outer carton.

Pack size: 1 capsule

Holder of Certificate of Registration

Eurolab (Pty) Ltd.

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Woodmead, 2144

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This leaflet was last revised in

08 June 2021

Registration number

NAVILIN 20: A 53/26/0743

NAVILIN 30: A 53/26/0744