

## Patient package insert according to Pharmacists' Regulations (Preparations)-1986

This medicine can be sold with a physician's prescription only

## Navelbine 20 mg capsules

The active ingredient and its quantity:

Each capsule contains: Vinorelbine as tartrate 20 mg

For a list of inactive ingredients, please see section 6.

### Read this entire leaflet carefully before using this medicine.

This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if you think that their illness is similar.

### 1. What is the medicine intended for?

Navelbine capsules are intended for the treatment of non-small cell lung cancer, treatment of advanced breast cancer.

**Therapeutic group:** A medicine belonging to the group of medicines extracted from the vinca plant (vinca-alkaloids).

### 2. Before using the medicine

#### **⚠ Do not use the medicine if:**

- you are hypersensitive (allergic) to the active ingredient vinorelbine, or to any other substance from the vinca alkaloids family or to any of the other ingredients this medicine contains (for additional information, please see section 6).
- you are pregnant or think that you are pregnant.
- you are breastfeeding.
- you suffer from a serious liver disease.
- you have had gastric or small intestine surgery or if you suffer from intestinal problems that affect the absorption of food. This may affect how Navelbine is absorbed in your body.
- low white blood cell counts (leukocytes, neutrophils), either in the case of an existing severe infection or occurring up to two weeks

before taking the medicine.

- low platelet count (thromocytopenia).
  - You have recently received or are planning to receive a vaccine against Yellow Fever.
  - You need long-term oxygen therapy.
- In case of doubt, consult your doctor or pharmacist.

### Special warnings regarding the use of the medicine

#### **⚠ Before treatment with the medicine, tell the doctor if:**

- you have a history of heart attack or severe chest pain.
- your ability to perform daily activities of daily living is strongly reduced.
- you have problems with your liver or have undergone radiotherapy where the treated area included the liver.
- the doctor has told you that you have an intolerance to some sugars; consult your doctor before taking this medicine.
- you show signs of infection (such as fever, chills, joint pain and cough).
- you take, or have recently taken, any other medicines, including non-prescription medicines.
- you are planning to receive a vaccination or have recently received a vaccination.

#### **⚠ Children and adolescents**

The capsules are not recommended for treatment in children and adolescents under the age of 18 years, as the safety and efficacy of using the medicine in these ages have not been established.

#### **⚠ Tests and follow-up**

Blood tests should be performed before and during treatment with this medicine to make sure that you can take the medicine. If the blood test results are abnormal, treatment may be delayed and performing further tests may be required until your blood test results show normal values.

#### **⚠ Drug interactions**

**If you are taking, have recently taken or might take other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.** Combining the medicine with other medicines that affect bone marrow may make some side effects worse. In particular, tell the doctor or pharmacist if you are taking: **Your doctor should take special attention if you are taking any of the following medicines:**

- Medicine used to thin your blood (anticoagulants)
  - Phenytoin (to treat epilepsy)
  - antifungal medicines, such as itraconazole and ketoconazole
  - An anti-cancer medicine called mitomycin C
  - Immunosuppressants such as cyclosporin and tacrolimus
- Many vaccines (live attenuated vaccine) are not recommended during treatment. Tell your doctor if you are required to get vaccinations.

#### **⚠ Use of this medicine and food**

The capsule should be swallowed whole with water. Do not chew or suck the capsule. It is preferable to take the medicine with a light meal. Do not take the medicine with a hot drink, as it may dissolve the capsule too quickly.

#### **⚠ Pregnancy, breastfeeding and fertility**

Consult a doctor or pharmacist before taking medicines.

#### *Pregnancy*

**Do not take** Navelbine if you are pregnant or think that you might be pregnant. If you must start treatment with Navelbine and you are pregnant, or in the case of becoming pregnant during treatment with the medicine, do not stop taking the medicine. Ask your doctor immediately about any potential risks for the unborn child.

#### *Breastfeeding*

**Do not take** Navelbine if you are breastfeeding. Stop breastfeeding if treatment with Navelbine is necessary.

#### *Fertility*

Women of childbearing age and men should use effective contraception (birth control) during treatment with Navelbine and for 3 months after taking the last capsule. Men treated with Navelbine should consult on the issue of sperm preservation before starting treatment, as Navelbine may have an effect on male fertility. It is not recommended for men who are taking Navelbine to get women pregnant for a period of 3 months after taking the last capsule.

#### **⚠ Driving and using machines**

It is unlikely that Navelbine treatment will affect your ability to drive or operate machinery, however, some of the side effects of Navelbine may affect your ability to drive or operate machinery. See

section 4 "**Side effects**" for details. Therefore, it is recommended not to drive if you feel unwell or if your doctor has advised you to avoid driving.

#### **⚠ Important information about some of the ingredients of this medicine**

This medicine contains sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, consult your doctor before taking this medicinal product.

This medicine contains small amounts of ethanol (alcohol), less than 100 mg per dose, you will not be affected by this small quantity.

### 3. How should you use this medicine?

Navelbine should be given under the medical supervision of a qualified physician experienced in the use of cancer treatment. The medicine is intended for oral use.

**Always use this medicine according to the doctor's instructions.** You should consult with the doctor or pharmacist if you are not sure about the dosage and treatment regimen with the medicine.

**The dosage and treatment regimen will be determined by the doctor only.** Before and during treatment with Navelbine, your doctor will check your blood cell count to determine when you will receive the treatment and which dose is suitable for you. Your doctor will tell you the number and strength of capsules you will need to take each week. This dosage will be determined according to your body weight and height.

Your doctor will calculate your body surface area in square meters (m<sup>2</sup>). The usual weekly dose is taken in a single dose and calculated at 60 mg per square meter of your body's surface area for the first 3 doses of treatment. After the third dose, your doctor will decide whether to increase the dosage and calculate the dose at 80 mg per square meter of your body's surface area. In any case, your doctor may adjust the dose of Navelbine.

**Do not exceed a total dosage of 160 mg per week.**

**Do not take Navelbine more than once a week.**

**Do not exceed the recommended dose.**

#### **Frequency of administration**

Usually Navelbine treatment is scheduled once a week. The

frequency will be determined by your doctor.

#### **Duration of treatment**

The duration of treatment will be determined by your doctor.

#### **If you take an anti-sickness medicine**

Vomiting can occur with Navelbine: see section 4 "**Side effects**". If your doctor has prescribed an anti sickness medicine, take it according to the doctor's instructions.

Taking Navelbine with a light meal can help to reduce the feeling of nausea.

#### **Method of administration**

Before opening the blister containing Navelbine, make sure that the capsule is not damaged 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.

#### Instruction for opening the 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.

#### **Using the medicine**

- Swallow the capsule whole with water, preferably with a light meal. Do not take the medicine with a hot drink, as it may dissolve the capsule too quickly.
- **Do not** chew or suck the capsule.
- If you chew or suck a capsule by mistake, rinse your mouth with water and contact your doctor **immediately**.
- If you vomit within a few hours after taking the medicine, contact your doctor; **do not repeat the dose**.

#### **If you have accidentally taken a higher dosage**

If you have taken more Navelbine than the doctor prescribed, refer to a doctor **immediately**.

Your dose of Navelbine is carefully monitored and checked by your doctor and pharmacist, however, even if you have received the correct amount of chemotherapy your body may sometimes

react giving severe symptoms. Some of these symptoms that may develop are 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 forgot to take the medicine**

**Do not** take a double dose to make up for a forgotten dose. Refer to your doctor who will set a new time for taking the dose. Continue with the treatment as recommended by the doctor.

#### **If you stop taking the medicine**

Your doctor will decide when to stop the treatment. However, if you want to stop the treatment earlier, you should consult your doctor about other options.

**Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.**

**If you have further questions regarding the use of this medicine, consult the doctor or pharmacist.**

### 4. Side effects

Like all medicines, the use of Navelbine may cause side effects in some users. Do not be alarmed when reading the list of side effects. **You may not suffer from any of them.**

**Contact your doctor immediately** if you experience any of the following symptoms during treatment with Navelbine:

- Symptoms indicating severe infection, such as cough, fever and chills.
- Severe constipation with abdominal pain, without gastric emptying for several days.
- Severe dizziness or light-headedness while standing.
- Severe chest pain which is not normal for you. It may be a symptom of a disturbance in the heart function due to insufficient blood flow; heart attack (may sometimes be fatal).
- Symptoms of allergy such as shortness of breath, rash spread over the whole body, swelling of the eyelids, face, lips or throat.

**Very common side effects** (can occur in more than one out of ten patients)

- Inflammation
- Gastric disorders
- Diarrhea
- Constipation
- Abdominal pain
- Nausea
- Vomiting
- A decrease in the white blood cell count, which makes you more vulnerable to infections
- A decrease in the red blood cell count which can make the skin pale and cause weakness or shortness of breath
- A decrease in the blood platelet count that may increase the risk of bleeding or bruising
- Loss of some reflex reactions, occasionally a difference in the perception of touch
- Inflammation in the mouth
- Hair loss, usually mild
- Tiredness
- Malaise
- Fever
- Weight loss, loss of appetite

**Common side effects** (can occur in less than one out of ten patients)

- Difficulties to coordinate muscle movement
- Differences in your eyesight
- Shortness of breath, cough
- Difficulty sleeping
- Headache
- Dizziness
- A difference in your taste of flavors
- Inflammation of the throat and esophagus
- Difficulty when swallowing food or liquids
- Skin reactions
- Joint pain
- Jaw pain
- Muscle pain
- Pain at different sites in your body and in the area of the tumour

- Chills
- Weight gain
- High blood pressure
- Abnormal liver test results
- Difficulty in urinating and additional symptoms in the genitourinary system

**Uncommon side effects** (can occur in more than one out of 100 patients)

#### **Affecting the nervous system:**

- Heart failure that may be expressed by shortness of breath and swelling of the ankles, irregular heart beats
- Lack of muscle control may be expressed by abnormal walking, changes in speech and abnormal eye movements (ataxia)

#### **Affecting the gastrointestinal system:**

- Severe constipation with abdominal pain, without gastric emptying for several days (paralytic ileus)

**The list below specifies side effects reported with the use of Navelbine capsules, with an unknown frequency:**

- Decrease in amount of blood sodium may be a result of overproduction of a hormone that causes fluid retention, may be expressed as symptoms such as weakness, tiredness, confusion, muscle twitching and coma (SIADH - Syndrome of Inappropriate Antidiuretic Hormone secretion)
- Generalized infection (sepsis) expressed in symptoms such as high fever and general deterioration of health
- Gastrointestinal bleeding
- Heart attack (myocardial infarction)
- Severe breathing difficulties

**If a side effect appears, if one of the side effects worsens or when you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.**

#### **Reporting side effects**

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting Side Effects from Drug Treatment" that can be found on the home page of the Ministry of Health website ([www.health.gov.il](http://www.health.gov.il)) that directs you to the online form for reporting side effects or by entering the link: <https://sideeffects.health.gov.il>

Additionally, you can report to Perrigo via the following address: [www.perrigo-pharma.co.il](http://www.perrigo-pharma.co.il)

### 5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store in a refrigerator (2°C-8°C).
- Do not store different medicines in the same package.

### 6. Additional information

- In addition to the active ingredient, this medicine also contains: Macrogol 400; Gelatine; Glycerol 85%; Purified water; Anidrisorb 85/70 (sorbitol, 1,4-sorbitan, superior polyols, mannitol); Ethanol anhydrous; Glycerol; Titanium dioxide E171; Yellow iron oxide E172; Medium chain triglycerides Phosal 53 MCT (phosphatidylcholine concentrate); Edible printing ink: E120, hypromellose, propylene glycol.
- What the medicine looks like and contents of the package: **Navelbine 20 mg:** a light brown colored capsule containing light yellow to orange-yellow solution, on which N20 is printed. The package contains capsule in a blister (tray). **Navelbine 30 mg:** a pink colored capsule containing light yellow to orange-yellow solution, on which N30 is printed. The package contains one capsule in a blister (tray).

- Registration holder and address: Perrigo Israel Agencies Ltd., 1 Rakefet St., Shoham.
- Manufacturer and its address: Pierre Fabre Medicament, Boulogne, France.

- Revised in November 2021 according to MOH guidelines.
- Drug registration number at the national drug registry of the Ministry of Health:

Navelbine 20 mg: 13090.30910  
Navelbine 30 mg: 13091.30911

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