

# Winobin®

## Vinorelbine

Soft Gelatin Capsule

Concentrate for Solution for Infusion

Read this leaflet carefully before you start taking Winobin®. This leaflet provides answers to the most common questions. If you have any further questions, ask your doctor or pharmacist. This medicine has been prescribed for your current illness only. Do not take it in similar conditions and do not pass it on to others. The information in this leaflet was last updated on the date listed on the bottom of the page. More recent information on the medicine may be available. You should ensure that you speak to your doctor or pharmacist to obtain the most up-to-date scientific information on the medicine. The latest version of this leaflet is available on [www.nanoalvand.com](http://www.nanoalvand.com).

### What is in this leaflet

1. What Winobin® is and what it is used for
2. What you need to know before you take Winobin®
3. How to take Winobin®
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### 1. What Winobin® is and what it is used for

Winobin® belongs to a family of medicines used to treat cancer called the vinca-alkaloid family.

Winobin® is used to treat some types of lung and breast cancer in patients over 18 years of age:

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

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

### 2. What do you need to know before you take Winobin®

#### Do not take Winobin®

- If you are allergic (hypersensitive) to the active ingredient, vinorelbine, or any of the related family of cancer drugs called the vinca alkaloids.
- If you are allergic to any of the other ingredients in Winobin® (refer to section 6 of this leaflet).
- If you are pregnant or think that you might be pregnant.
- If you are breast feeding.
- If you have a severe liver disease.
- If you have a low white blood cell count (neutrophils, leucocytes) 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 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 Winobin®. (Just in case of Winobin® soft gelatin capsule)
- If you require long-term oxygen therapy. (Just in case of Winobin® soft gelatin capsule)

If in doubt, ask your doctor or pharmacist.

#### Warnings and precautions

Please inform your doctor 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 included the liver.
- You have symptoms of infection (such as fever, chills, joint pain, cough).
- You take, or have recently taken, any other medicines including medicines obtained without a prescription.
- You plan to have a vaccination or have just had one.
- Your ability to carry out activities of daily living is strongly reduced. (Just in case of Winobin® soft gelatin capsule)
- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. (Just in case of Winobin® soft gelatin capsule)

Before and during your treatment with Winobin® 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.

#### Other medicines and Winobin®

Please inform your doctor or pharmacist if you are taking, or have recently taken, any other medicines, including medicines obtained without a prescription.

If you are given Winobin® as well as medicines that affect your bone marrow it may make some of the side effects worse.

Your doctor should take special attention if you are taking 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 cyclosporine and tacrolimus

Many vaccines (live attenuated vaccines) are not recommended during treatment. Please inform your doctor if you require any vaccinations.

#### Winobin® with food and drink

##### Winobin® soft gelatin capsule

It is preferable to take Winobin® with a light meal.

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

##### Winobin® concentrate for solution for infusion

There are no known interactions with food and drink when using Winobin®. However, you should check with your doctor if taking alcohol is advisable for you.

#### Pregnancy, breast-feeding and fertility

##### Pregnancy

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

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

Men being treated with Winobin® are advised not to father a child during and up to 3 months after the end of the treatment.

##### Fertility

Men should discuss sperm banking with their doctor before starting treatment with Winobin®.

##### Breast-feeding

Do not take Winobin® if you are breast-feeding.

Breast-feeding must be discontinued if treatment with Winobin® is necessary.

#### Driving and using machines

It is unlikely that Winobin® will affect your ability to drive or operate machinery.

However, some of the possible side effects of Winobin® 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 drive.

#### Winobin® soft gelatin capsule contains sorbitol and alcohol

Winobin® soft gelatin capsule contains sorbitol. If you are intolerant to some sugars, contact your doctor before taking this medicinal product.

Winobin® 20 mg, 30 mg, and 80 mg contains 5 mg, 7.5 mg, and 20 mg of alcohol (ethanol) in each capsule, respectively.

The small amount of alcohol in this medicine will not have any noticeable effects.

### 3. How to take Winobin®

Winobin® should be given under the supervision of a qualified doctor who is experienced in the use of cancer treatments.

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

#### Dosage

Before and during your treatment with Winobin® your doctor will check your blood cell count to determine when you receive your treatment and which dose is suitable for you. The dose will depend on your height and weight and your general condition. Your doctor will calculate your body surface area and will determine the dose you should receive.

##### Winobin® soft gelatin capsule

Your doctor will tell you the number and strength of capsules which you should take.

Your doctor will calculate your body surface area in square meters (m<sup>2</sup>). The usual weekly dose, taken in a single dose, is 60 mg/m<sup>2</sup> of body surface area for the first 3 doses. After the third dose, your doctor will decide if the dose will be increased to 80 mg/m<sup>2</sup> of body surface area. In any case, your doctor may adjust the dose of Winobin®.

If you are receiving the capsules 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 Winobin® more than once a week.

#### Frequency of administration

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

#### Duration of treatment

The duration of your treatment is decided by your doctor.

#### Method of administration

##### Winobin® soft gelatin capsule

- Before opening the blisters containing Winobin®, 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 with water. Do not swallow any damaged capsules.
- Swallow Winobin® 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 with water and tell your doctor immediately.
- Vomiting can occur with Winobin® (see section 4, Possible side effects).
- If your doctor has prescribed an anti-sickness medication, always take it exactly as the doctor has told you.
- Take Winobin® during a light meal; this will help to reduce the feeling of sickness.
- If you vomit within a few hours after taking your Winobin®, contact your doctor; do not repeat the dose.

##### Winobin® concentrate for solution for infusion

- Winobin® must be diluted before administration.
- Winobin® must only be administered into a vein. It will be given by an infusion into one of your veins. It will take between 6 to 10 minutes.
- After administration the vein will be rinsed thoroughly with a sterile solution.

#### If you take more Winobin® than you should

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

#### If you forget to take Winobin® soft gelatin capsule

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

Like all medicines, Winobin® can have side effects although not everybody gets them.

**Immediately contact your doctor, while taking Winobin®, if you develop any of the following symptoms:**

- Cough, fever and chills which may be signs of a major infection or a general infection (septicemia) that can be severe.
- Severe constipation with abdominal pain when your bowels have not been open for several days.
- Severe dizziness, lightheadedness 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 myocardial infarction (sometimes with fatal outcome).
- Difficulty in breathing, which may be the symptom of a condition known as acute respiratory distress syndrome and can be severe and life-threatening.
- Dizziness, rash affecting your whole body, or swelling of the eyelids, face, lips or throat which may be signs of an allergic reaction.

Side effects with Winobin® may include:

##### Winobin® soft gelatin capsule

**Very common side effects** (may affect more than 1 in 10 people)

- Infections at different sites
- Gastric disorders; diarrhea; constipation, abdominal pain; nausea, vomiting
- Inflammation in the mouth
- A fall in red blood cells which can make the skin pale and cause weakness or breathlessness
- A fall in platelets which can increase the risk of bleeding or bruising
- A decrease in white blood cells which makes you more vulnerable to infection
- Loss of some reflex reactions, occasionally difference in the perception of touch

- Hair loss usually mild form
- Tiredness
- Fever
- Malaise
- Weight loss, loss of appetite

**Common side effects** (may affect up to 1 in 10 people)

- Difficulties to coordinate muscle movements
- Differences in your eyesight
- Shortness of breath, cough
- Difficulties to urinate, other genitourinary symptoms
- Difficulty in sleeping
- Headache, dizziness, a difference in your taste of flavors
- Inflammation of the gullet, difficulty when swallowing food or liquids
- Skin reactions
- Chills
- Weight gain
- Joint pain, jaw pain, muscle pain
- Pain at different sites in your body and pain where your tumor is
- High blood pressure
- Liver disorders (abnormal liver test)

**Uncommon side effects** (may affect up to 1 in 100 people)

- Heart failure which can cause shortness of breath and ankle swelling, irregular heartbeats
- Lack of muscle control may be associated with abnormal gait, speech changes and abnormalities in eyes movement (ataxia)
- Blood infections (sepsis) with symptoms such as high fever and deterioration in general health
- Heart attack (myocardial infarction)
- Gastrointestinal bleeding
- Low sodium level in your blood. This low sodium level may be attributed in some cases to an overproduction of a hormone causing fluid retention resulting in weakness, muscle twitching, tiredness, confusion or unconsciousness (Syndrome of Inappropriate Antidiuretic Hormone secretion (SIADH)).

##### Winobin® concentrate for solution for infusion

**Very common side effects** (may affect more than 1 in 10 people):

- Nausea; vomiting, constipation
- A decrease in red blood cells which can make the skin pale and cause weakness or breathlessness
- A decrease in white blood cells which makes you more vulnerable to infection
- Weakness of lower extremities

- Loss of some reflex reactions, occasionally difference in the perception of touch
- Hair loss, normally not severe for long treatment
- Inflammation or sores in the mouth or throat
- Reactions at the site where Winobin® was administered such as redness, burning pain, vein discoloration, inflammation of the veins
- Liver disorders (abnormal liver test)

**Common side effects** (may affect up to 1 in 10 people)

- A decrease in platelets which can increase the risk of bleeding or bruising; joint pain
- Jaw pain; muscle pain
- Tiredness (asthenia, fatigue)
- Fever
- Pain at different sites in your body such as chest pain and pain where your tumor is
- Diarrhea
- Infections at different sites

**Uncommon side effects** (may affect up to 1 in 100 people)

- Severe difficulties with your body movements and sense of touch
- Dizziness
- Sudden feeling of heat and skin redness of the face and neck
- Feeling cold in the hands and feet
- Difficulty in breathing or wheezing (dyspnea and bronchospasm)
- Blood infection (sepsis) with symptoms such as high fever and deterioration in general health
- High blood pressure

**Rare side effects** (may affect up to 1 in 1 000 people)

- Heart attack (ischemic heart disease, angina pectoris, myocardial infarction, sometimes fatal)
- Lung toxicity (inflammation and fibrosis, sometimes fatal)
- Severe abdominal and back pain (inflammation in pancreas)
- Low blood levels of sodium in your blood (which can cause symptoms of tiredness, confusion, muscle twitching and unconsciousness)
- Ulcers at the injection site where the Winobin® was given (local necrosis)
- Skin rashes on your body such as rashes and eruptions (generalized cutaneous reactions)

**Very rare side effects** (may affect up to 1 in 10,000 people)

- Irregular heartbeat (tachycardia), palpitations, heart rhythm disorders
- **Not known** (frequency cannot be estimated from the available data)
- Abdominal pain, gastrointestinal bleeding
- Heart failure which can cause shortness of breath and ankle swelling
- Redness of hands and feet (erythema)
- Low sodium level due to an overproduction of a hormone causing fluid retention and resulting in weakness, tiredness or confusion (Syndrome of Inappropriate Antidiuretic Hormone secretion (SIADH))
- Lack of muscle control may be associated with abnormal gait, speech changes and abnormalities in eyes movement (ataxia)

- Headache
- Chills with fever
- Cough
- Loss of appetite
- Weight loss

### 5. How to store Winobin®

- Keep out of the reach and sight of children.
- Do not use after the expiry date.
- Store in a refrigerator (2°C to 8°C). Do not freeze.
- Store in the original package in order to protect from light and moisture.
- Cytotoxic agent. Must be transported, stored, and used according to guidelines for handling of cytotoxic compounds.
- 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.

### 6. Content of the pack and other information

#### What Winobin® contains

##### Winobin® soft gelatin capsule

The active substance is vinorelbine (as tartrate).

The other ingredients are:

Ethanol, glycerol, polyethylene glycol, gelatin, sorbitol, and titanium dioxide.

##### Winobin® concentrate for solution for infusion

The active substance is vinorelbine (as tartrate). Each 1 ml of solution contains 10 mg of vinorelbine as vinorelbine tartrate.

The other ingredient is water for injection.

#### What Winobin® looks like and contents of the pack

Winobin® soft gelatin capsules of 20, 30 and 80 mg are available as packs of 1 blister of 1 soft gelatin capsule with a leaflet.

Winobin® concentrate for solution for infusion is a clear colorless to pale yellow solution.

This medicinal product is a concentrate for solution for infusion, in clear glass vials of 1 or 5 ml. Each vial is packed in a box with a leaflet.

Not all strengths may be marketed.

#### For medical or healthcare professionals only

- Winobin® concentrate for solution for infusion
- For single use only, discard any unused contents.
- Winobin® must be diluted prior to administration in a 50 ml infusion bag with sodium chloride 9 mg/ml (0.9%) solution for injection or in dextrose 50 mg/ml (5%) solution for injection.
- Winobin® should not be diluted in alkaline solutions as there is a risk of precipitation.
- After diluting Winobin® in sodium chloride 9 mg/ml (0.9%) solution for injection or in dextrose 50 mg/ml (5%) solution for injection, chemical and physical in-use stability has been demonstrated for 48 hours at room temperature.
- From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are under the responsibility of the user.
- Intra-thecal administration of Winobin® may be fatal. The use of intrathecal route is contra-indicated.
- It is recommended to infuse Winobin® over 6-10 minutes after dilution in a 50 ml infusion bag with sodium chloride 9 mg/ml (0.9%) solution for injection or in dextrose 50 mg/ml (5%) solution for injection.
- After administration the vein should be thoroughly flushed with at least 250 ml of saline solution.
- Winobin® must be given strictly intravenously. It is very important to make sure that the cannula is accurately placed in the vein before starting to infuse Winobin®.
- If the drug extravasates into the surrounding tissue during the administration considerable local irritation may occur. In this case, the administration should be stopped, the vein flushed with normal saline solution and the remaining dose administered in another vein.
- Do not infuse concomitantly with another cytotoxic agent. It should be given as the first drug where the patient is treated with combination chemotherapy due to the risk of venous irritation.

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