

VINOBIN SOFT CAPSULES 20 mg

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VINOBIN SOFT CAPSULES 80 mg

Vinorelbine Tartrate (20mg, 30mg, 80mg)

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What *VINOBIN* is used for

VINOBIN is used to treat non-small cell lung cancer and advanced breast cancer.

How *VINOBIN* works

VINOBIN belongs to a family of medicines called the vinca alkaloid. *VINOBIN* is an antimitotic agent, causing cell death by blocking cell division.

Before you use *VINOBIN*

-When you must not use it:

- If you are allergic (hypersensitive) to vinorelbine (active ingredient), or any of the related group of cancer drugs called the vinca-alkaloids
- If you are allergic to any other ingredients of *VINOBIN* (refer to section 'Ingredients' in this leaflet)
- If you have had an operation on your stomach or small bowel, or if you have intestinal disorders, or if you present disorder affecting absorption
- If you have a low white blood cell count (leukocytes and/or neutrophils) or a severe infection currently or recently (within 2 weeks)
- If you have a low platelet count
- If you require long-term oxygen therapy
- If you are breast feeding
- If you plan to have a yellow fever vaccine or have just had one

-Before you start to use it:

Please inform your doctor if:

- You have a history of heart attack or severe chest pain
- Your ability to carry out activities of

daily living is strongly reduced

- You have received radiotherapy treatment involving the liver
- You have symptoms of infection (such as fever, chills, cough)
- you are taking or have recently taken another medicine including one obtained without a prescription
- you are going to be vaccinated, (for the yellow fever vaccine, Never take *VINOBIN*)
- you are being treated with phenytoin, fosphenytoin, itraconazole, ketoconazole or posaconazole as combination of these substances with *VINOBIN* is not recommended (see **Taking—Other medicines**). you are suffering from a severe liver disease,
- you are pregnant.

Before and during treatment with *VINOBIN*, blood cell counts are performed to check that it is safe for you to receive treatment (check of white blood cell and platelet count). If the results of this analysis are not satisfactory, your treatment may be delayed and further checks made until these values return to normal. This medicine should not be used in people with fructose intolerance (hereditary metabolic disease).

-Taking other medicines:

This medicine must not be taken with a yellow fever vaccine. Taking this medicine with live attenuated vaccine (e.g. measles vaccine, mumps vaccine, rubella vaccine...), phenytoin, fosphenytoin (anti-seizure medicines), itraconazole, ketoconazole or posaconazole (anti-fungal medicines). Mitomycin C or Iapatinib (anticancer medicines) is not recommended. Please tell your doctor or pharmacist if you are taking, or have recently taken any other medicines, including medicines obtained without prescription.

How to use *VINOBIN*

VINOBIN should be prescribed by a qualified doctor who is experienced in the use of cancer treatments.

VINOBIN must be taken by mouth.

It is not recommended for use by children.

-How much to use

Before and during treatment with *VINOBIN*, 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 per week.

The total dose should never exceed 160 mg per week.

You should never take *VINOBIN* more than once per week.

Before opening the blisters containing *VINOBIN* 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.

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.

-When to use it

Normally, *VINOBIN* treatment is scheduled once a week. The frequency will be determined by your doctor.

-How long to use it

The duration of your treatment is decided by your doctor.

If you are taking a medicine for nausea

Vomiting can occur with *VINOBIN*. If your doctor has prescribed an anti-sickness medication, always take it exactly as the doctor has told you. Take *VINOBIN* with a light meal as

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this will help you to reduce nausea.

-If you forget to use it

Do not take a double dose to make up a forgotten dose. Contact your doctor who will reschedule your dose.

-If you use too much (overdose)

If you have taken more VINOBIN than the prescribed dose, contact a doctor immediately.

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.

If you stop using VINOBIN

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.

While you are using it

- Things you must do

VINOBIN with food and drink

The soft capsule of VINOBIN should be swallowed whole with water without chewing and sucking the capsule. It is preferable to take VINOBIN with a light meal. If you have chewed or sucked a capsule by mistake, rinse your mouth thoroughly with water and contact your doctor immediately. If you vomit within a few hours after taking VINOBIN, inform your doctor immediately: do not repeat the same dose.

- Things you must not do

Pregnancy, breast-feeding and fertility

Fertility:

Men being treated with VINOBIN are advised not to father a child during and up to 3 months after treatment, and to seek advice on conservation of sperm prior to treatment because VINOBIN may alter male fertility irreversibly.

Women of child-bearing potential

Women of child-bearing potential must use effective contraception (birth

control) during treatment, and up to 3 months after treatment.

Pregnancy

Do not take VINOBIN if you are pregnant, or think that you might be pregnant or intend to become pregnant. If you have to start treatment with VINOBIN and are pregnant or if pregnancy occurs during your treatment with VINOBIN, you must immediately contact your doctor for advice on the potential risk for harmful effects on the child.

Breast-feeding

Do not take VINOBIN if you are breast-feeding. Breast feeding must be discontinued if a treatment with VINOBIN is necessary.

• Things to be careful of

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed.

However, as in all cases you should not drive if you feel unwell or if your doctor has advised you not to drive.

Important information about some of the ingredients of VINOBIN

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

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

Side effects

Like all medicines, VINOBIN can cause side effects, although not everybody gets them.

While taking VINOBIN, if you

develop any of the following

symptoms you should contact your doctor immediately:

- signs of a major infection such as cough, fever and chills
- severe constipation with abdominal pain when your bowels have not been

open for several days,

- severe dizziness or faintness when standing up which may be a sign of a large fall in your blood pressure.
- severe chest pain which may be due to incorrect functioning of the heart because of reduced blood flow (ischaemic heart disease). signs of allergy such as itching, shortness of breath, dizziness, reduced blood pressure, skin rash over your whole body or swelling of the eyelids, lips or throat.

Below is a list of side effects that have occurred in some people following treatment with VINOBIN. This list is classified according to the frequency of side effects occurred.

Very common side effects

Nausea; Vomiting; Diarrhoea; Constipation; Gastric disturbances; Fall in red cells (anaemia) which may cause pallor, fatigue or breathlessness; Inflammation or aphthous ulcers in the mouth or throat (stomatitis); Reduced platelet count (thrombocytopenia) which may increase the risk of bleeding or haematomas; Loss of some reflexes, occasionally with reduction in touch sensation; Hair loss (alopecia), generally mild and during prolonged treatment; Fatigue; Malaise; Weight loss; Loss of appetite (anorexia).

Common side effects

- Neuromotor disturbances: Changes in vision; Respiratory difficulties (dyspnoea); Pain, burning and difficulty passing urine; Sleep disturbances; Headache; Dizziness; Altered taste for food and drinks; Inflammation of the throat and oesophagus (oesophagitis); Difficulty swallowing foods or liquids; Skin reactions; Weight gain; Joint pain; Jaw pain; Muscle pain; Pain at different sites in the body and at the site of the tumour.

Uncommon side effects

- Heart failure which may cause

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respiratory difficulties or swelling of the ankles; Irregular heart rate (cardiac arrhythmias).

Other adverse effects of not known incidence have been reported:

- Low level of sodium (severe hyponatraemia) in the blood which may cause symptoms of fatigue, confusion or muscle contractions; Gastro-intestinal bleeding; Heart attack (myocardial infarction in patients with a past medical history or cardiac risk factors).

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nprr.gov.my [Consumer Reporting → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of VINOBIN**- Storage**

Keep this medicine out of the sight and reach of children.

This medicinal product needs to be stored at 2-8°C (in a refrigerator). Store in original container. Keep the immediate packaging tightly closed

- Disposal

For safety reasons, any unused or damaged capsule should be returned to your doctor or pharmacist to be destroyed in accordance with applicable procedure for cytotoxic substances.

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.

Product Description**- What it looks like**

VINOBIN SOFT CAPSULES 20 mg: An oval-shaped light brown soft capsule filled with a transparent,

colorless to slightly yellow liquid.

VINOBIN SOFT CAPSULES 30 mg: An oblong-shaped pink soft capsule filled with transparent, colorless to slightly yellow liquid

VINOBIN SOFT CAPSULES 80 mg: An oblong-shaped pale yellow soft capsule filled with a transparent, colorless to slightly yellow liquid.

Ingredients**-Active ingredient:**

Vinorelbine 20 or 30 or 80 mg. (As Vinorelbine tartrate)
For one soft capsule

-Inactive ingredients:

The fill solution contains: purified water; macrogol 400; polysorbate 80

Vinorelbine 20 mg & 80mg soft capsule

The capsule shell contains:
Gelatin, Sorbitol Liquid, Yellow Iron oxide, Titanium dioxide & Purified Water

Vinorelbine 30 mg soft capsule

The capsule shell contains:
Gelatin, Sorbitol Liquid, Red Iron oxide, Titanium dioxide & Purified Water

MAL Numbers:

MAL23036026AZ (20 mg)
MAL23036025AZ (30 mg)
MAL23036024AZ (80 mg)

Manufacturer

Lotus Pharmaceutical Co., Ltd. Nantou Plant.
No. 30, Chenggong 1st Road., Sinsing Village, Nantou City,
Nantou County 540033,
Taiwan

Product Registration Holder

Lotus Healthcare Malaysia Sdn. Bhd.
UOA BUSINESS PARK, TOWER 3,
9TH FLOOR, K03-09-11,
1 JALAN PENGATURCARA U1/51A,
SECTION U1, 40150 SHAH ALAM
SELANGOR, MALAYSIA

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