

Package leaflet: Information for the user

Vinorelbine medac 20 mg Soft Capsules

Vinorelbine medac 30 mg Soft Capsules

Vinorelbine medac 80 mg Soft Capsules

vinorelbine tartrate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet

1. What Vinorelbine medac is and what it is used for
2. Before you take Vinorelbine medac
3. How to take Vinorelbine medac
4. Possible side effects
5. Storing Vinorelbine medac
6. Further information

1. What Vinorelbine medac is and what it is used for

Vinorelbine medac belongs to a family of medicines used to treat cancer called the vinca alkaloid family.

Vinorelbine medac is used to treat:

- 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. Before you take Vinorelbine medac

Do not take Vinorelbine medac

- if you are allergic (hypersensitive) to the active ingredient, vinorelbine, any of the related family of cancer medicines called the vinca alkaloids
- If you are allergic to any of the other ingredients of Vinorelbine medac (refer to section 6)
- if you are pregnant or think that you might be pregnant
- if you have a severe liver disease.
- if you are breast feeding
- if you have had an operation on your stomach or small bowel, or if you have gut disorders which affect how you absorb food. These may affect how your body absorbs Vinorelbine medac.
- if you have a low white blood cell count (neutrophils, leucocytes) or a severe infection current or recent within 2 weeks
- if you plan to have a yellow fever vaccine or have just had one
- if you require long-term oxygen therapy

If in doubt, ask your doctor or pharmacist.

Take special care with Vinorelbine medac

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 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 plan to have a vaccination or have just had one
- you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- you take, or have recently taken, any other medicines including medicines obtained without a prescription.

Before and during treatment with Vinorelbine medac, 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.

Taking other medicines

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 Vinorelbine medac as well as medicines that affect your bone marrow it may make some of the side effects worse.

Your doctor should take special care 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
- Anti-cancer medicines such as mitomycin C
- Medicines that impair your immune system such as ciclosporin and tacrolimus

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

Taking Vinorelbine medac with food and drink

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

It is preferable to take Vinorelbine medac with a light meal.

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

Male fertility

Men being treated with Vinorelbine medac are advised not to father a child during and at least for 100 days after taking the last capsule, and to seek advice on conservation of sperm prior to treatment because Vinorelbine medac may alter male fertility.

Women of child-bearing age

Women of child-bearing age must use effective contraception (birth control) during treatment and for at least 190 days after treatment.

Children and adolescents

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

Pregnancy

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

Breast-feeding

Do not take Vinorelbine medac if you are breast-feeding.

Breast-feeding must be discontinued if treatment with Vinorelbine medac is necessary. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

It is unlikely that Vinorelbine medac will affect your ability to drive or operate machinery. However, some of the possible side effects of Vinorelbine medac 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.

Vinorelbine medac contains sorbitol

Each soft capsule containing 20 mg vinorelbine contains 10.54 mg sorbitol.

Each soft capsule containing 30 mg vinorelbine contains 15.96 mg sorbitol.

Each soft capsule containing 80 mg vinorelbine contains 29.35 mg sorbitol.

Vinorelbine medac contains ethanol

Each soft capsule containing 20 mg vinorelbine contains 5 mg alcohol (ethanol).

Each soft capsule containing 30 mg vinorelbine contains 7.5 mg alcohol (ethanol).

Each soft capsule containing 80 mg vinorelbine contains 20 mg alcohol (ethanol).

The amount in each capsule of this medicine (Vinorelbine medac 20 mg, 30 mg, 80 mg) is equivalent to less than 1 ml beer or 1 ml wine.

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

This medicine (Vinorelbine medac 20 mg, 30 mg, 80 mg) contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. How to take Vinorelbine medac

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

Vinorelbine medac must be taken by mouth.

Vinorelbine medac is used in patients over 18 years old.

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

<p>Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.</p>

Dosage

Before and during your treatment with Vinorelbine medac 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 (m²). The usual weekly dose, taken in a single dose, is 60 mg/m² 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/m² of body surface area. In any case, your doctor may adjust the dose of Vinorelbine medac.

If you are receiving the capsules with another medicine to treat your cancer/condition, your doctor will decide on an appropriate dose for you.

<p>The total dose should never exceed 160 mg per week.</p>

You should never take Vinorelbine medac more than once a week.

Frequency of administration

Normally Vinorelbine medac 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

Before opening the blisters containing Vinorelbine medac, 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; 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 Vinorelbine medac

- Swallow the Vinorelbine medac capsule 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**.
- If you vomit within a few hours after taking your Vinorelbine medac, contact your doctor; **do not repeat the dose**.

If you take an anti-sickness medicine

Vomiting can occur with Vinorelbine medac (refer to 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 Vinorelbine medac during a light meal; this will help to reduce the feeling of sickness.

If you take more Vinorelbine medac than you should

If you have taken more Vinorelbine medac than you should, contact a doctor immediately. Your dose of Vinorelbine medac 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 could also become severely constipated. You must immediately contact your doctor if any of these severe symptoms occur.

If you forget to take Vinorelbine medac

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 Vinorelbine medac

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.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Immediately contact your doctor, while taking Vinorelbine medac, 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 severely 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, a so called myocardial infarction (sometimes with fatal outcome)
- Difficulty in breathing, dizziness, decreased blood pressure, rash affecting your whole body, or swelling of the eyelids, face, lips or throat which may be signs of an allergic reaction
- 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

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

- Infections at different sites
- Gastric disorders, diarrhoea, 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)
- Tiredness
- Fever
- Malaise
- Weight loss, loss of appetite

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

- Difficulties in coordinating muscle movements
- Differences in your eyesight
- Shortness of breath, cough
- Difficulties urinating, other genitourinary symptoms
- Difficulty in sleeping
- Headache, dizziness, a difference in your taste of flavours
- 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 tumour 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 eye movement (ataxia)

Not known (frequency cannot be estimated from the available data)

- Blood infection (sepsis) with symptoms such as high fever and deterioration in general health
- Heart attack (myocardial infarction)
- Gastrointestinal bleeding
- Low sodium level in your blood resulting in weakness, muscle twitching, tiredness, confusion and unconsciousness. This low sodium level may be attributed in some cases to an overproduction of a hormone causing fluid retention (Syndrome of Inappropriate Antidiuretic Hormone secretion –SIADH).

Reporting of side effects:

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. Storing Vinorelbine medac

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

Do not use this medicine after the expiry date which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C - 8°C) in the original package to protect from light.

Do not throw away any medicines via wastewater or household waste. For safety reasons any unused capsules must be returned to your doctor or pharmacist for destruction. These measures will help protect the environment.

6. Further information**What Vinorelbine medac contains**

- The active substance is Vinorelbine (as tartrate) 20 mg, 30 mg or 80 mg
- The other ingredients are:

Capsule filling

anhydrous ethanol
purified water
glycerol
macrogol 400

Capsule cover

gelatin
glycerol
partially dehydrated sorbitol liquid
titanium dioxide (E171)
purified water

Vinorelbine medac 20 mg Soft Capsules: iron oxide yellow (E172)

Vinorelbine medac 30 mg Soft Capsules: iron red oxide (E172)

Vinorelbine medac 80 mg Soft Capsules: iron oxide yellow (E172)

Other ingredients

printing ink (non-volatile component: shellac glaze, black iron oxide (E172), propylene glycol)
medium chain triglycerides

What Vinorelbine medac looks like and contents of the pack

20 mg soft capsule: An oval-shaped light brown soft capsule with a size of 9.0 mm x 7.0mm with black “20” printed on the surface

30 mg soft capsule: An oblong-shaped pink soft with a size of 15.0 mm x 6.0mm capsule with black “30” printed on the surface

80 mg soft capsules: An oblong-shaped pale yellow soft capsule with a size of 20.0 mm x 8.0mm. with black “80” printed on the surface.

Vinorelbine medac 20 mg Soft Capsules:	Pack of 1 blister with 1 soft capsule Pack of 4 blisters with 1 soft capsule each
Vinorelbine medac 30 mg Soft Capsules:	Pack of 1 blister with 1 soft capsule Pack of 4 blisters with 1 soft capsule each
Vinorelbine medac 80 mg Soft Capsules:	Pack of 1 blister with 1 soft capsule

Marketing Authorisation Holder and Manufacturer

medac Gesellschaft für klinische Spezialpräparate mbH
Theaterstr. 6
22880 Wedel
Germany
Tel.: +49 4103 8006-0
Fax: +49 4103 8006-100

This leaflet was last revised in 08/2023