

Package leaflet: Information for the user

Vinorelbine Accord 20 mg soft capsules **Vinorelbine Accord 30 mg soft capsules** vinorelbine

Read all of this leaflet carefully before you start using 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 or pharmacist.
- 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 you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Vinorelbine Accord is and what it is used for
2. What you need to know before you take Vinorelbine Accord
3. How to take Vinorelbine Accord
4. Possible side effects
5. How to store Vinorelbine Accord
6. Contents of the pack and other information

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

Vinorelbine Accord contains the active substance vinorelbine and belongs to a family of medicines called the vinca-alkaloid family, used to treat cancer.

Vinorelbine Accord is used to treat some types of lung cancer and some types of breast cancer in patients over 18 years old.

2. What you need to know before you take Vinorelbine Accord

Do not take Vinorelbine Accord

- If you are allergic to vinorelbine, to any of the related family of cancer drugs called the vinca alkaloids, or any of the other ingredients of this medicine (listed in section 6).
- If you are breast feeding.
- If you have had an operation where a part of your stomach or small bowel has been removed, or if you have gut disorder which affects how you absorb food. These may affect how your body absorbs Vinorelbine Accord.
- 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 require long-term oxygen therapy.

Warnings and precautions

Talk to your doctor or pharmacist before taking Vinorelbine Accord 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, cough).
- You plan to have a vaccination. Many vaccines (live attenuated vaccines) are not recommended during treatment.
- You have a severe hepatic disease unrelated to your cancer.
- You are pregnant.

Before starting and during your treatment with Vinorelbine Accord, 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

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

Other medicines and Vinorelbine Accord

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

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
- anti-cancer medicines such as mitomycin C or lapatinib,
- medicines that impair your immune system such as ciclosporin and tacrolimus
- ant-tuberculosis medicine called rifampicin

The combination of Vinorelbine Accord with other medicines with known bone marrow toxicity (affecting your white and red blood cells and your platelet) could also worsen some side effects.

Pregnancy, breast-feeding and fertility

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine because there are potential risks for the unborn child. You should not take Vinorelbine Accord if you are pregnant. Do not breast-feed if you are taking Vinorelbine Accord.

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

Men being treated with Vinorelbine Accord 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 Vinorelbine Accord as male fertility may be altered.

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.

Vinorelbine Accord contains sorbitol, ethanol and sodium

Vinorelbine Accord 20 mg contains 8.03 mg of sorbitol (as sorbitol liquid partially dehydrated) in each soft capsule.

Vinorelbine Accord 30 mg contains 13.65 mg of sorbitol (as sorbitol liquid partially dehydrated) in each soft capsule.

Vinorelbine Accord 80 mg contains 24.09 mg of sorbitol (as sorbitol liquid partially dehydrated) in each soft capsule.

Vinorelbine Accord 20 mg contain 2.89 mg of alcohol in each soft capsule.

Vinorelbine Accord 30 mg contain 4.35 mg of alcohol in each soft capsule.

Vinorelbine Accord 80 mg contain 11.56 mg of alcohol in each soft capsule.

The amount in each soft capsule is equivalent to less than 1 ml beer or 1 ml wine.

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

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to take Vinorelbine Accord

Before and during your treatment with Vinorelbine Accord your doctor will check your blood cell count. Your doctor will tell you the number and strength of capsules which you should take, how often you should take the capsules and for how long. This will depend on your body weight and body height, the results of your blood samples and your well-being.

The total dose should never exceed 160 mg per week.

You should never take Vinorelbine Accord more than once a

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Before opening the blisters containing Vinorelbine Accord, 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.

Taking Vinorelbine Accord:

- Swallow Vinorelbine Accord 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 Accord, contact your doctor; **do not repeat the dose**.

If you take an anti-sickness medicine

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

If you take more Vinorelbine Accord than you should

If you may have taken more Vinorelbine Accord than the prescribed dose, contact a doctor **immediately**.

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 Vinorelbine Accord

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 Accord

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, this medicine can cause side effects, although not everybody gets them.

Immediately contact your doctor while taking Vinorelbine Accord, if you develop any of the following symptoms:

- 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, lightheadedness when you stand up, sign of 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 infraction (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 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 (anaemia) 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 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 eyes movement (ataxia).

Not known: frequency cannot be estimated from the available data

- 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 resulting in weakness, muscle twitching, tiredness, confusion and unconsciousness. This low sodium level may be attributed in some cases due to an overproduction of a hormone causing fluid retention and (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 HPRC Pharmacovigilance; Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Vinorelbine Accord

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 carton and blister after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C – 8 °C).

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. Contents of the pack and other information

What Vinorelbine Accord contains

The active substance is vinorelbine. Each soft capsule contains 20 mg, 30 mg or 80 mg vinorelbine (as tartrate).

The other ingredients are:

The solution contains: macrogol, glycerol, anhydrous ethanol and purified water.

The capsule shell contains: gelatin, glycerol, sorbitol liquid partially dehydrated (E 420), titanium dioxide (E 171), iron oxide yellow (E 172) [Only for 20 mg and 80 mg], iron oxide red (E 172) [Only for 30 mg]

Imprinting ink: shellac(E 904), iron oxide black (E 172), ammonium hydroxide (E 527) and propylene glycol (E 1520).

What Vinorelbine Accord looks like and contents of the pack

Vinorelbine Accord 20 mg are Light brown, opaque, oval shaped (9.3 mm x 6.7 mm) soft gelatin capsule, free from surface defect, imprinted "JJ1" in black, containing a clear colourless liquid.

Vinorelbine Accord 30 mg are Pink, opaque, oblong shaped (15 mm x 6.2 mm) soft gelatin capsule, free from surface defect, imprinted "JJ2" in black, containing a clear colourless liquid.

Vinorelbine Accord 80 mg are Pale yellow, opaque, oblong shaped (20.5 mm x 8 mm) soft gelatin capsule, free from surface defect, imprinted "JJ3" in black, containing a clear colourless liquid.

Vinorelbine Accord are available in blisters containing 1, 2, 3, or 4 soft capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Accord Healthcare Ireland
Euro House, Euro
Business Park, Little
Island, Cork, T45 K857,
Ireland

Manufacturer

Accord Healthcare Polska Sp. z o.o.,
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95-200, Poland

Or

Accord Healthcare B.V.
Winthontlaan 200, Utrecht, 3526KV,
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Or

Pharmadox Healthcare Limited
KW20A Kordin Industrial Park,
Paola PLA 3000, Malta

Or

Laboratori Fundació Dau,
C/ C, 12-14 Pol. Ind. Zona

Franca, Barcelona, 08040, Spain

This medicine is authorised in the Member States of the European Economic Area under the followings names:

Name of Member State	Name of medicinal product
Austria	Vinorelbine Accord 20 mg & 30 mg weichkapsel
Czech Republic	Vinorelbine Accord
Denmark	Vinorelbine Accord
Finland	Vinorelbine Accord 20 mg, 30 mg & 80 mg kapseli, pehmeä
France	VINORELBINE ACCORD 20 mg & 30 mg, capsule molle
Germany	Vinorelbine Accord 20 mg, 30 mg & 80 mg weichkapsel
Ireland	Vinorelbine Accord 20 mg & 30 mg soft capsules
Italy	Vinorelbine Accord Healthcare
Norway	Vinorelbine Accord
Poland	Vinorelbine Accord
Portugal	Vinorelbina Accord 20 mg, 30 mg & 80 mg cápsula mole
Romania	Vinorelbina Accord 20 mg, 30 mg & 80 mg capsulă moale
Slovenia	Vinorelbina Accord
Spain	Vinorelbine Accord 20 mg & 30 mg cápsula blanda EFG
Sweden	Vinorelbine Accord

This leaflet was last revised in March 2023