PACKAGE LEAFLET: INFORMATION FOR THE USER

VINORELBINE TEVA 10 mg/ml, CONCENTRATE FOR SOLUTION FOR INFUSION
Vinorelbine

Read all of this leaflet carefully before you start using this medicine.
- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT VINORELBINE TEVA 10 mg/ml, CONCENTRATE FOR SOLUTION FOR INFUSION IS AND WHAT IT IS USED FOR

- Vinorelbine is used in the treatment of cancer and belongs to a group of medicines called vinca-alkaloids.
- It is used to treat certain forms of lung and breast cancer.

2. BEFORE YOU USE VINORELBINE TEVA 10 mg/ml, CONCENTRATE FOR SOLUTION FOR INFUSION

Do not use Vinorelbine Teva 10 mg/ml, concentrate for solution for infusion
- Vinorelbine will not be given to you as an injection into your spine
- if you are allergic (hypersensitive) to vinorelbine or any other vinca alkaloids or to any of the ingredients (see section 6)
- if you have or recently have had a severe infection or have a severely reduced number of white blood cells (neutropenia)
- if you have a severely reduced number of a type of blood cell called platelets in your blood
- if you are pregnant
- if you are breast-feeding.
- in combination with yellow fever vaccine (see section Taking or Using other medicines).

Take special care with Vinorelbine Teva 10 mg/ml, concentrate for solution for infusion
Warning

Tell your doctor if:
- you have previously had heart disease called ischaemic heart disease
- you are receiving radiotherapy over an area that includes the liver
- you have signs or symptoms of an infection (such as fever, chills, sore throat etc), tell your doctor as soon as possible so that they may arrange any tests that may be necessary
- you have reduced liver function
- you are taking phenytoins, fosphenytoins, itraconazole or posaconazole. Their concomitant use with Vinorelbine Teva is not recommended (see section Taking or Using other medicines).

Concomitant use of Vinorelbine Teva with live attenuated vaccines (for yellow fever vaccine, see concomitant use contraindicated) is not recommended (see section Taking or Using other medicines).

All contact with the eye must be strictly avoided, there is a risk of serious irritation or even ulceration of the surface of the eye (cornea) if this happens. Immediate washing of the eye with saline should be undertaken if any contact occurs.

Before you have each treatment with Vinorelbine Teva, you will have a blood test. If the results are too low, your treatment may be delayed until they return to a satisfactory level.

Taking or Using other medicines

Vinorelbine Teva should not be used in combination with yellow fever vaccines (see Contra-indications).

Vinorelbine Teva should be avoided in combination with live attenuated vaccines (except yellow fever, for which concomitant use is contraindicated), phenytoine, fosphenytoin (anticonvulsants), itraconazole or posaconazole (anti-fungal drugs) (see Warnings).

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

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking any medicine. Vinorelbine Teva causes birth defects and should not be used during pregnancy. Women of childbearing potential must use effective contraception during and up to 3 months after treatment. Tell your doctor if you are pregnant or suspect that you are pregnant.

It is not known if vinorelbine passes over into breast milk. Breast-feeding should therefore be discontinued before treatment starts.

Men undergoing treatment with Vinorelbine Teva should avoid fathering children during and up to minimum 3 months after treatment has stopped.

Driving and using machines
No studies on the effects on the ability to drive have been performed.
Discuss with your doctor, nurse or pharmacist if you are unsure of anything.

3. HOW TO USE VINORELBINE TEVA 10 mg/ml, CONCENTRATE FOR SOLUTION FOR INFUSION

The preparation and administration of Vinorelbine Teva must only be carried out by a trained healthcare professional - please refer to the information for healthcare professionals (below) for detailed information.
Vinorelbine Teva is normally administered once a week. The usual dose of vinorelbine is 25-30 mg/m^2 of body surface area given once a week. The dose depends on your medical condition, your general state of health and if you are using other drugs at the same time.

Dosage will be reduced if you have severe liver problems.

Vinorelbine Teva should always be administered into a vein.

This medicine will be diluted with a solution such as sodium chloride 9 mg/ml (0.9%) solution for injection or glucose 50 mg/ml (5%) solution before it is given to you. This may be by an injection over 6 to 10 minutes after dilution. After completion of the slow injection or infusion the vein should be flushed with saline solution.

Your doctor will ensure that the correct dose for your condition is given, however tell your doctor or pharmacist if you have any concerns.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Vinorelbine Teva 10 mg/ml, concentrate for solution for infusion can cause side effects, although not everybody gets them.

Frequency:
Very common (Side effects that occur in more than 1 out of 10 patients)
Common (Side effects that occur in less than 1 out of 10 patients but in more than 1 out of 100 patients)
Uncommon (Side effects that occur in less than 1 out of 100 patients but in more than 1 out of 1,000 patients)
Rare (Side effects that occur in less than 1 out of 1,000 patients but in more than 1 out of 10,000 patients)
Very rare (Side effects that occur in less than 1 out of 10,000 patients)

Serious side effects – if any of the following side effects happen, please tell your doctor immediately:

Common: Narrowing of the airways, shortness of breath, respiratory reactions due to allergy.
Rare: Chest pain which spreads to the back of the neck and arm, due to the lack of blood supply to the heart, heart attack, lung disease

These are very serious side effects. You may need urgent medical attention

Other side effects - if you experience any of the following tell your doctor as soon as possible.

Very common	• Decrease in the number of white blood cells, which can increase your chance of getting an infection. Decrease in the number of red blood cells (anaemia), which can make you feel tired. • Inflammation in the mouth or throat. Nausea and vomiting (feeling and being sick), constipation. • Hair loss, tiredness, abnormal physical weakness, loss of some reflex reactions, weakness of legs. • Swelling, soreness, pain and/or skin rash where the injection was given. • Abnormal liver function test results.
Common	• Low levels of blood platelets which increases risk of bruising and bleeding. A reduction in a special type of white blood cell, which can result in fever. • Weakness, jaw pain, muscle pain, infection in lungs, kidneys or stomach. Diarrhoea. • Fatigue, fever and pain at different places including chest pain and pain at the site of the tumour being treated.
Uncommon	• Severe infections with organ failure, possibly leading to death. • Feeling of tingling or prickling, increased or decreased muscle tension shortness of breath, breathing difficulties. • Low blood pressure, high blood pressure. • Flushing and peripheral coldness.
Rare	• Severe decrease of a salt in the blood called sodium. • Blockage of the gut, inflammation of the pancreas (organ which regulates glucose in the blood). • Heart disease like angina pectoris (severe chestpain), heart attack, irregular heart beat.

	• Inflammation of the lung tissue • Generalised skin reactions, breakdown of the skin around the injection site. • Severe disorders of the skin at the injection site. • Severe drop in blood pressure causing dizziness and fainting (severe hypotension, collapse)
Very rare	• Heart disorders (Faster heart beat): irregular heartbeats including tachycardia, palpitations and heart rhythm disorders. • Complicated severe infections possibly leading to death.
Not known	• Loss of appetite (Anorexia) • 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). • A reduction in white blood cell, which can result in fever or infection. • Redness of skin of hands and feet.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE VINORELBINE TEVA 10 mg/ml, CONCENTRATE FOR SOLUTION FOR INFUSION

Keep out of the reach and sight of children.

Do not use Vinorelbine Teva after the expiry date which is stated on the carton/vial. The expiry date refers to the last day of that month.

Before opening: store in a refrigerator (2°C - 8°C). Do not freeze.
Store in the original packaging, in order to protect from light.

After first opening/dilution :
Chemical and physical in-use stability has been demonstrated for 24 hours at 25°C. From a microbiological point of view, the product should be used immediately.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment

6. FURTHER INFORMATION

What Vinorelbine Teva 10 mg/ml, concentrate for solution for infusion contains

The active substance is:
Vinorelbine (10 mg per 1 ml of concentrate for solution for infusion), in the form of vinorelbine (as tartrate).

The other ingredients are:
Water for injections

What Vinorelbine Teva 10 mg/ml, concentrate for solution for infusion looks like and contents of the pack
This medicinal product is presented in the form of a concentrate for solution for infusion in a vial (1 ml or 5 ml); carton of 1 and 10.
- A 1 ml vial contains 10 mg of vinorelbine.
- A 5 ml vial contains 50 mg of vinorelbine.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Teva Pharma B.V.
Computerweg 10
3542DR Utrecht
The Netherlands

Manufacturer:

PHARMACHEMIE B.V.
Swensweg 5, 2031 GA Haarlem
P.O. Box 552, 2003 RN Haarlem
NETHERLANDS

This leaflet was last approved in 01/2014.

The following information is intended only for for medical or healthcare professionals:

As with any cytotoxic, the preparation and handling of this product requires a set of precautions that will make it possible to ensure the protection of the handler and his or her environment and the safety conditions required for the patient.

In addition to the usual precautions to maintain the sterility of preparations for injection, it is necessary to:

- wear a long-sleeved smock with tight cuffs, in order to avoid the projection of the solution onto the skin,
- wear a single-use surgical mask and wrap-around goggles,
- wear single-use PVC (not latex) gloves, after aseptic hand washing,
- prepare the solution on a work drape,
- stop the infusion in the case of injection outside the vein,
- dispose of all equipment that was used in preparing the solution (syringes, compresses, work drape, vial) in a container designed for this purpose,
- destroy toxic waste,
- handle excreta and vomit with precaution.

Pregnant women must avoid handling cytotoxic substances.

After opening: the product must be used immediately.

Nonetheless, the physical/chemical stability of the solution when diluted in infusion fluids has been demonstrated for 24 hours at room temperature or in the refrigerator, away from light.

From a microbiological standpoint, the product must be used immediately.