Package leaflet: Information for the user

Vinorelbine Sandoz® 10 mg/ml, concentraat voor oplossing voor infusie

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 nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [nationally completed name] is and what it is used for

[Nationally completed name] is an anti-cancer medicine. It belongs to a group of drugs called vinca alkaloids.

[Nationally completed name] is used for certain types of advanced lung and breast cancer.

2. What you need to know before you use [nationally completed name]

Do not use [nationally completed name]:
- if you are allergic (hypersensitive) to vinorelbine, other vinca alkaloids, or any of the other ingredients of this medicine (listed in section 6)
- if you have or have recently had a serious infection, or if you have a significant reduction of your white blood cells (neutropenia)
- if you have a significant reduction of your blood platelets
- if you are breast feeding
- if you have recently had or you are going to have a vaccine against yellow fever.

If any of the above applies to you, **do not use this medicine and talk to your doctor.**

Warnings and precautions:
- Tell you doctor if you have had a heart disease called "ischemic heart disease".
- Tell your doctor if you have liver problems.
- Tell your doctor if you develop shortness of breath.
- You should not have radiotherapy in the area of your liver while you are having this medicine.
- Tell your doctor immediately if you have symptoms of an infection (such as fever, chills, or sore throat), so that he can carry out any tests which may be needed.
- Tell your doctor if you have had a vaccination recently. Special care must be taken with live attenuated vaccines such as measles, mumps, rubella, polio, varicella, and tuberculosis (BCG).
- Any contact with the eye must be strictly avoided, since there is a risk of serious irritation or even ulceration of the surface of the eye (corneal ulcers). In case of contact, immediately rinse the eye with normal saline solution and contact the doctor.
- Take special care if you use phenytoin, itraconazole, or any other medicine mentioned in the section "Using other medicines"

Before each administration of [nationally completed name], a blood sample will be taken for analysis of its components. 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
[nationally completed name] is used in patients over 18 years old. It is not recommended for use by children under 18 years old.

Other medicines and [nationally completed name]
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines.. In particular if you take one of the following medicines:
- any medicine that may affect the bone marrow, such as anti-cancer medicines
- carbamazepine, phenytoin and phenobarbital (used to treat epilepsy)
- antibiotics such as rifampicine, erythromycin, clarithromycin, telithromycin
- St. John's Wort (Hypericum perforatum)
- ketoconazole and itraconazole (medicines for fungal infections)
- antiviral medicines used for AIDS (HIV) such as ritonavir (HIV protease inhibitors)
- nefazodone (antidepressant)
- cyclosporine, tacrolimus (medicines that reduce the activity of the immune system)
- verapamil, quinidine (used for heart problems)
- an anti-cancer medicine called lapatinib
- anti-cancer medicines such as mitomycine C and cisplatine; there is an increased risk of difficulty breathing if [nationally completed name] is used with mitomycin C (see section 4)
- medicines to prevent blood clots, such as warfarin
- vaccines (see "Take special care with [nationally completed name]")

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

<u>Pregnancy</u>

You should not use this medicine during pregnancy, unless the benefit for you is higher than the risk for your baby. Your treating doctor will discuss this with you. Inform your doctor if you are pregnant or you think you might be pregnant.

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

Breast-feeding
It is not known if this medicine passes into breast milk. Therefore, you must stop breast-feeding before starting the treatment.

Male fertility
Men being treated with this medicine are advised not to father a child during treatment and for a minimum of 3 months after the end of the treatment.
You should seek advice on conservation of sperm prior to treatment because of the possibility of irreversible infertility due to therapy with vinorelbine.

Driving and using machines
No studies on the effects on the ability to drive and use machines have been performed.
However, do not drive or use machines if you feel drowsy, or if you experience any other effect which may impair your ability to drive or use machines.

3. How to use [nationally completed name]

Your doctor will decide how much [nationally completed name] you will have.
The dosage you are given will depend on your general medical condition. It will also depend on any other treatment you may have received for your cancer.

[nationally completed name] is used in patients over 18 years old. It is not recommended for use by children under 18 years old.

[nationally completed name] should not be given as an injection to the spine.
The usual dose is 25 to 30 milligrams weekly for every square metre of your body's surface area.
Before and during treatment with [nationally completed name] your doctor will check your blood cell count. The results of your blood test will decide when you receive your treatment. Your nurse will measure your height and weight and work out the surface area of your body from these measurements. Your doctor will use this body surface area to work out the right dose for you.

The medicine will be diluted with a solution such as physiologic saline or glucose 5% before it is given to you.

[Nationally completed name] is always administered intravenously. It may be infused over a 6 to 10 minute period.
At the end of the injection or infusion, the vein will be flushed with physiologic saline.

As this medicine will be given to you whilst you are in hospital it is unlikely that you will be given too little or too much, however tell your doctor or nurse if you think you were given too much of this

medicine. Some of the symptoms of being given too much may develop (such as fever, chills, joint pain). You may also become severely constipated.

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

4. Possible side effects

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

Serious side effects:
The following are all serious side effects. You may need urgent medical attention if you have any of them.
Rare (may affect up to 1 in 1,000 people):
- chest pain, heart attack which might sometimes lead to death
- severe pain in the abdomen and back, caused by inflammation of the pancreas
- shortness of breath, caused by pulmonary diseases (interstitial pneumopathy) which might sometimes lead to death. Your treating doctor might monitor you more closely for this side effect if you are Japanese, as it has been shown to happen more frequently in this population group.

Very rare (may affect up to 1 in 10,000 people):
- life threatening infections in your body with severe fever, such as chest infections and infections at other sites in your body (septicaemia)

Not known (frequency cannot be estimated from the available data):
- generalized allergic reactions. These are serious reactions which can cause severe difficulty in breathing, dizziness, rash affecting your whole body, swelling of the eyelids, face lips, throat (anaphylactic shock, anaphylaxis, anaphylactoid type reactions)
- difficulty in breathing, which may be the symptom of a condition known as acute respiratory distress syndrome and can be severe and life-threatening.
- 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
- a chest pain, breathlessness and fainting, which can be a symptom of a clot in a blood vessel in the lungs (pulmonary embolism)

If any of the above happens to you, stop using this medicine and **tell your doctor immediately** or go to the casualty department at your nearest hospital

Other possible side effects:
Tell your doctor if any of the following side effects become troublesome.

Very common (may affect more than 1 in 10 patients):
- shortage of white blood cells, which makes infections more likely.
- shortage of red blood cells which can make the skin pale and cause weakness or breathlessness.
- inflammation of mouth or throat, nausea and vomiting, constipation
- hair loss, pain and/or redness at the site of injection
- loss of deep tendon reflexes, weakness in the legs
- blood tests which show changes in the way the liver is working.

Common (may affect up to 1 in 10 people):
- shortage of blood platelets which increases risk of bruising and bleeding
- infections
- diarrhoea
- joint pain, muscle pain, pain in the jaw
- weakness, tiredness, fever and pain

Uncommon (may affect up to 1 in 100 people):
- severe signs of a major infection such as cough, fever, chills and blood infection.
- severe difficulties with your body movements and abnormal sensation of touch
- reduced blood pressure (hypotension with symptoms such as dizziness or feeling faint)
- raised blood pressure (hypertension) with symptom such as a headache
- a sudden feeling of heat and skin redness of the face and neck (flushing)
- feeling cold in the hands and feet (peripheral coldness)
- difficulty in breathing or wheezing

Rare (may affect up to 1 in 1,000 people):
- severe drop in blood pressure causing dizziness, fainting (severe hypotension, collapse)
- bowel obstruction
- skin rashes on your body such as rashes and eruptions (generalised cutaneous reactions)
- skin reactions at site of injection (ulcer, necrosis)
- decrease of the level of sodium in the blood (hyponatraemia).

Very rare (may affect up to 1 in 10,000 people):
- irregular heartbeats (tachycardia, palpitation and heart rhythm disorders)

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

- a fall in white blood cell count with fever (febrile neutropenia), a general infection in combination with a fall in white blood cell count (neutropenic sepsis, neutropenic infection), a fall of white blood cells (leukopenia) or a fall of white and red blood cells and platelets (pancytopenia)
- 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).
- loss of appetite (anorexia)
- headache, dizziness, lack of muscle control may be associated with abnormal gait, speech changes and abnormalities in eyes movement (ataxia)
- heart failure
- cough
- gastrointestinal bleeding, severe diarrhoea, abdominal pain
- liver disorder
- skin redness (erythema) on the hands and feet (hand-foot syndrome)
- chills,
- weight loos
- darker colour of skin that follows the path of veins

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [to be completed nationally]. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store [nationally completed name]

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 on the outer carton and vial after 'EXP'. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C - 8°C).
Do not freeze.
Store in the original package in order to protect from light.

In-use stability after dilution:
After opening, the contents should be reconstituted and used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user. If prepared aseptically, the stability of the diluted solution in normal saline or glucose has been demonstrated for 48 hours when stored in a refrigerator (2°C – 8°C).

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. Contents of the pack and other information

What [Nationally completed name] contains

- The active substance is vinorelbine.

Each vial of 1 ml contains vinorelbine tartrate equivalent to 10 mg vinorelbine.
Each vial of 5 ml contains vinorelbine tartrate equivalent to 50 mg vinorelbine.

- The other ingredient is water for injection.

What [nationally completed name] looks like and contents of the pack

[Nationally completed name] is a clear, colourless or pale yellow solution.

[Nationally completed name] is packed in clear, colourless glass vials (type I) with fluoropolymer coated bromobutyl rubber stoppers and aluminium crimp caps.

Pack sizes:
1 x 1 ml, 5 x 1 ml and 10 x 1 ml
1 x 5 ml, 5 x 5 ml and 10 x 5 ml

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Vergunninghouder:
Sandoz B.V., Veluwezoom 22, 1327 AH Almere, Nederland

Fabrikanten:
Lek Pharmaceuticals d.d.
Verovskova 57
1526 Ljubljana
Slovenië

Salutas Pharma GmbH
Otto-von-Guericke Allee 1
39179 Barleben
Duitsland

EBEWE Pharma Ges.m.b.H. Nfg.KG
Mondseestrasse 11
4866 Unterach
Oostenrijk

Fareva Unterach GmbH
Mondseestrasse 11
4866 Unterach am Attersee
Oostenrijk

Dit middel is in het register ingeschreven onder:
Vinorelbine Sandoz® 10 mg/ml, concentraat voor oplossing voor infusie - RVG 35140

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte en in het Verenigd Koninkrijk (Noord-Ierland) onder de volgende namen:

Nederland:	Vinorelbine Sandoz 10 mg/ml, concentraat voor oplossing voor infusie
Polen:	NEOCITEC
Spanje:	Vinorelbina Sandoz 10 mg/ml concentrado para solución para perfusión EFG
Verenigd Koninkrijk (Noord-Ierland):	Vinorelbine 10mg/ml Concentrate for Solution for Infusion

Deze bijsluiter is voor het laatst goedgekeurd in augustus 2023.

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

Special precautions

- Only trained staff should carry out the preparation and administration of [Nationally completed name].
- As with all cytotoxic agents, precautions should be taken to avoid exposing staff during pregnancy
- Suitable safety equipment, such as eye protection, disposable gloves, facemask and disposable apron, should be worn. Spills and leakages must be wiped up.
- All contact with the eye must be strictly avoided. Immediate washing of the eye with normal saline solution should be undertaken if any contact occurs.
- On completion, any exposed surface should be thoroughly cleaned and hands and face washed.

Only for intravenous administration. Must be diluted before use immediately after opening the vial.

Incompatibility

[Nationally completed name] should not be diluted in alkaline solutions (risk of precipitation)
[Nationally completed name] must not be mixed with other medicinal products except normal saline or glucose (5%) solution
There is no incompatibility between [Nationally completed name] and clear glass vials, PVC or vinyl acetate bags, or infusion sets with PVC tubing.

Administration

[Nationally completed name] may be administered by slow bolus (6-10 minutes) after dilution in 20-50 ml of normal saline or glucose 50 mg/ml (5%) solution. Administration should always be followed with at least 250 ml of a normal saline infusion to flush the vein.

[Nationally completed name] should only be given intravenously. It is very important to make sure that the cannula is accurately placed in the vein before the injection is commenced. If [Nationally completed name] infiltrates the surrounding tissue during intravenous administration, a substantial irritation may occur. In this case, the injection should be stopped, the vein flushed with saline solution and the rest of the dose should be administered in another vein. In the event of extravasation, glucocorticoids could be given intravenously to reduce the risk of phlebitis.

Storage and shelf life:

Store in a refrigerator (2°C - 8°C).
Do not freeze.
Store in the original package in order to protect from light.
Do not use after the expiry date stated on the carton and label after “EXP”.

In-use stability after dilution:
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 the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

For more information read the SmPC.