Patient Information Leaflet

SCHEDULING STATUS: S4

Sandoz® Vinorelbine 10 mg/1 ml

Sandoz® Vinorelbine 50 mg/5 ml

Concentrate for solution for infusion

Vinorelbine (as tartrate)

Sugar free

Read all of this leaflet carefully before you are given SANDOZ VINORELBINE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- SANDOZ VINORELBINE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT IS IN THIS LEAFLET

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

1. WHAT SANDOZ VINORELBINE IS AND WHAT IT IS USED FOR

SANDOZ VINORELBINE belongs to a family of medicines used to treat cancer called the vinca-alkaloid family.

SANDOZ VINORELBINE is used to treat some types of lung and breast cancer in patients:

- Used alone or in combination with other medicines to treat Non-small cell lung cancer.
- Advanced breast cancer that has not responded to other medicines or relapsed within 6 months of receiving chemotherapy.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE SANDOZ VINORELBINE

Do not use SANDOZ VINORELBINE:

- if you are hypersensitive (allergic) to the active substance (vinorelbine), or cancer drugs called the vinca alkaloids or any of the other ingredients of SANDOZ VINORELBINE (listed in section 6).
- if you are pregnant or think you might be pregnant or breastfeeding.
- if you have severe liver problems.
- if you have a low white blood cell or platelet count.
- if you plan on receiving or just received the yellow fever vaccine.

Warnings and precautions

Tell your doctor or health care provider before using SANDOZ VINORELBINE:

- before and during your treatment with SANDOZ VINORELBINE, 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.
- if you present signs or symptoms suggestive of infection (such as fever, chills, sore throat).
- if you suffer from swelling or clotting in a vein.
- if you develop bile in the urine causing it to go darker.
- if you have had a heart disease involving lack of blood supply to the heart (ischaemic heart disease, angina).
- if you have kidney or liver problems.

- if you are having radiotherapy and the treatment field includes the liver.
- if you just had a vaccination or plan on having one.
- do not touch your eyes or the inside of your nose, unless you have just washed your hands and have not touched anything else in the meantime.

Other medicines and SANDOZ VINORELBINE

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor if you are taking or have recently taken the following medicines:

- phenytoin (medicines for the treatment of epilepsy).
- itraconazole or ketoconazole (medicines for the treatment of fungal infections).
- antibiotics such as rifampicin, erythromycin, clarithromycin, telithromycin.
- other medicines for the treatment of cancer e.g. mitomycin C, cisplatin, lapatinib.
- ciclosporine and tacrolimus (medicine which decrease the activity of the immune system).
- other medicines which can affect the bone marrow e.g. cancer medicine (paclitaxel) or radiotherapy.
- yellow fever vaccine and other live vaccines. Please inform your doctor if you require any vaccinations, as it can cause serious side effects when used during treatment with SANDOZ VINORELBINE.
- rifampicin (medicine for the treatment bacterial infections).
- blood thinning medicines e.g. warfarin.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before you receive this medicine.

SANDOZ VINORELBINE should not be given to pregnant women, because it can cause serious birth defects.
If you are a woman of childbearing age you must use an effective method of contraception during treatment and for 3 months after treatment has stopped. If pregnancy occurs during your treatment you must immediately inform your doctor.
If you are or become pregnant during treatment with SANDOZ VINORELBINE, genetic counselling is recommended.

If you are a man, you should avoid fathering a child during treatment with SANDOZ VINORELBINE and for 3 months after treatment has stopped. There is also a risk that treatment with vinorelbine will lead to male infertility and you may wish to seek advice about sperm storage before the treatment starts.

You must discontinue breastfeeding before treatment with SANDOZ VINORELBINE starts as it is not known whether it might pass into breast milk thereby affecting the baby.

Driving and using machines
It is not always possible to predict to what extent SANDOZ VINORELBINE may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which SANDOZ VINORELBINE affects them.

3. HOW TO USE SANDOZ VINORELBINE

Do not share medicines prescribed for you with any other person.
Always use SANDOZ VINORELBINE exactly as your doctor has told you. Check with your doctor if you are not sure.

You will not be expected to give yourself SANDOZ VINORELBINE. It will be given to you by a person who is qualified to do so.

SANDOZ VINORELBINE is for intravenous use only.

The usual dosage of vinorelbine is 25 to 30 mg/m^2 of body surface area given once a week.

The dosage depends on the condition you are being treated for, your response to the therapy and other medication you are being given. Your general condition and your response to the treatment will be closely observed before, during and after the treatment with SANDOZ VINORELBINE.

If you receive more SANDOZ VINORELBINE than you should

Since a health care provider will administer SANDOZ VINORELBINE, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use SANDOZ VINORELBINE

Since a health care provider will administer SANDOZ VINORELBINE, it is unlikely that the dose will be missed.

If you stop using SANDOZ VINORELBINE

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

SANDOZ VINORELBINE can have side effects.

Not all side effects reported for SANDOZ VINORELBINE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving SANDOZ VINORELBINE, please consult your health care provider for advice.

If any of the following happens, stop using SANDOZ VINORELBINE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- cough, fever and chills which may be signs of a major infection or a general infection (septicemia) that can be severe.
- blood infection (sepsis) with symptoms such as high fever and deterioration in general health.
- severe infections with different organ failure or blood poisoning.
- fainting (severe hypotension).

These are all very serious side effects. If you have them, you may have had a serious reaction to SANDOZ VINORELBINE. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- chest pain which may spread to the back of your neck and arm, due to lack of blood supply to the heart (angina pectoris).
- heart attack (myocardial infarction).
- heart failure.
- changes in the way your heart beats, for example, if you notice it beating faster.
- difficulty breathing.
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.

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

Tell your doctor if you notice any of the following:

- low platelet count (symptoms include bleeding or bruising more easily than normal).
- lack of white blood cells (symptoms include frequent infections such as fever, severe chills, sore throat or mouth ulcers).
- inflammation of the pancreas.
- low sodium level due to an overproduction of a hormone causing fluid retention and resulting in weakness, tiredness or confusion (SIADH syndrome).
- loss of appetite.
- unusual tiredness or weakness.
- weakness of the lower extremities.
- tingling or numbness of the hands or feet.
- headache.
- dizziness.
- unsteadiness when walking.
- high blood pressure.
- cough.
- severe constipation.
- nausea.
- vomiting.
- diarrhoea may be severe.
- mouth ulcers and sores.
- slow bowel movement.
- gastrointestinal bleeding.
- stomach pain.
- irregular liver test results.
- hair loss.
- skin rash.

- reddening, swelling, numbness, skin sloughing or peeling on palms of the hands and soles of the feet (and, occasionally, on the knees, elbows, and elsewhere).
- aching or painful muscles.
- joint and jaw pain.
- pain or redness at the site of injection.
- discolouration or burning at injection site.
- tiredness.
- fever.
- pain.
- chest pain.
- chills.
- weight-loss.

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of SANDOZ VINORELBINE.

Suspected adverse reactions can also be reported directly to the Holder of the Certificate of Registration (HCR) via Patientsafety.sacg@novartis.com.

5. HOW TO STORE SANDOZ VINORELBINE

- Store in a refrigerator (2 °C - 8 °C). Do not freeze.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**

- Do not use SANDOZ VINORELBINE after the expiry date which is stated on the vial and box (after Exp). The expiry date refers to the last day of that month.
- Protect from light.
- SANDOZ VINORELBINE will be diluted and stored by hospital staff.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What SANDOZ VINORELBINE contains:

Each SANDOZ VINORELBINE 10 mg/1 ml vial contains: vinorelbine tartrate equivalent to 10,00 mg vinorelbine.

Each SANDOZ VINORELBINE 50 mg/5 ml vial contains: vinorelbine tartrate equivalent to 50,00 mg vinorelbine.

The other ingredients are water for injection and nitrogen (inert gas).

What SANDOZ VINORELBINE looks like and contents of the pack

Clear, colourless to pale yellow solution, free from visible particles.

SANDOZ VINORELBINE 10 mg/1 ml:

Carton containing a single dose 2 ml clear glass vial with a grey rubber stopper and aluminium crimp cap with brown plastic flip off cover and carton containing 10 single dose, 2 ml clear glass vials, with grey rubber stoppers and aluminium crimp caps with brown plastic flip off covers.

SANDOZ VINORELBINE 50 mg/5 ml:

Carton containing a single dose 5 ml clear glass vial with a grey rubber stopper and aluminium crimp cap with brown plastic flip off cover and carton containing 10 single dose, 5 ml clear glass vials, with grey rubber stoppers and aluminium crimp caps with brown plastic flip off covers.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

Waterfall 5-Ir

Magwa Crescent West

Waterfall City

Jukskei View

2090

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Registration number

SANDOZ VINORELBINE 10 mg/1 ml: 42/26/0132

SANDOZ VINORELBINE 50 mg/5 ml: 42/26/0133

Access to the corresponding Professional Information

Not applicable

[1]Company Reg. No.: 1990/001979/07