APPROVED PATIENT INFORMATION LEAFLET:

SCHEDULING STATUS: S4

VINBLASTINE TEVA 10, 1 mg/ml solution for injection

Vinblastine sulphate

Sugar free

Please read this leaflet carefully before VINBLASTINE TEVA 10 is administered to you:

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet:

1. What VINBLASTINE TEVA 10 is and what it is used for
2. What you need to know before you use VINBLASTINE TEVA 10
3. How to use VINBLASTINE TEVA 10
4. Possible side effects
5. How to store VINBLASTINE TEVA 10
6. Contents of the pack and other information

1. What VINBLASTINE TEVA 10 is and what it is used for:

Vinblastine sulphate belongs to the group of the cytostatics (products to fight cancer). Vinblastine sulphate prevents cancer cells from growing which ultimately kills them.

- Certain forms of lymph node cancer (such as Hodgkin's and Non-Hodgkin's lymphoma).
- Testicular cancer.
- Breast cancer.

2. What you need to know before you use VINBLASTINE TEVA 10:

VINBLASTINE TEVA 10 should not be administered to you:

- If you are hypersensitive (allergic) to vinblastine sulphate, the active ingredient, or any other vinca alkaloids, to or any of the other ingredients of VINBLASTINE TEVA 10 listed in **section 6**.
- If you have depressed bone marrow function caused by tumours, cytostatics or irradiation.
- If you have a bacterial infection.
- If you suffer from porphyria.
- If you have a bad nutritional state.

Warnings and precautions:

VINBLASTINE TEVA 10 should be used under strict supervision of doctors experienced in the treatment with cytostatics (products against cancer).

Take special care with VINBLASTINE TEVA 10:

- If after administration of a dose of VINBLASTINE TEVA 10 a white blood cell deficiency occurs (leucopoenia), the doctor will monitor you carefully until the number of white blood cell has increased to a safe number because otherwise an infection can possibly occur.
- If you have cancer cells in the bone marrow, the production of blood in the bone marrow is sometimes strongly reduced due to the administration of VINBLASTINE TEVA 10.
- If you are of childbearing age, VINBLASTINE TEVA 10 can affect the foetus or your fertility. Both men and women must take precautions to prevent a pregnancy during, and for at least 3 months and 6 months after the treatment, respectively.
- If your liver does not function well, the excretion of VINBLASTINE TEVA 10 can be delayed. In that case the doctor will adjust the dose of VINBLASTINE TEVA 10.
- If mitomycin C is also prescribed for you there may be an increased risk of sudden shortness of breath and breathlessness (see also **Other medicines and VINBLASTINE TEVA 10**).
- If you are being vaccinated during treatment with TEVA VINBLASTINE 10, vaccination with

specific kind of vaccines (so called live vaccines) may result in serious disease. The doctor will use a so called inactivated vaccine or postpone the vaccination.

- If you stand up after a prolonged period of rest this may cause a sudden fall in blood pressure (orthostatic hypotension) with dizziness or fainting, especially in the elderly.
- If you suffer from cardiac disorders such as angina.
- If you are an elderly patient in poor health or with skin sores, your doctor will adjust your dose of VINBLASTINE TEVA 10.

Other medicines and VINBLASTINE TEVA 10:

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

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of VINBLASTINE TEVA 10 with these medicines may cause undesirable interactions.

Please consult your doctor, pharmacist or other healthcare professional for advice if you are using any of the following medicines:

- medicines such as erythromycin (antibiotic), of which it is known that they have an inhibiting effect on the breakdown of medicines by the liver, concomitant use can lead to the faster occurrence of side effects and/or an increase in the severity of the side effects.
- mitomycin C or bleomycin (products used to fight cancer).
- the combination can lead to vascular events like Raynaud's phenomenon (see **section 4**).
- other medicines that are administered for cancer (cytostatics) or suppress your immune system, such as methotrexate and cisplatin. The combination can make the effects and the side effects of VINBLASTINE TEVA 10 to be more pronounced.
- vaccines (vaccinations); VINBLASTINE TEVA 10 suppresses the immune system of the body and may have an effect on the ability of the body to react to the vaccine (see **Take special care with VINBLASTINE TEVA 10**).
- if you are receiving radiation treatment your doctor may decide to adjust your dose of VINBLASTINE

TEVA 10.

- paracetamol (medicine used for pain and fever) can increase the side effects of VINBLASTINE TEVA 10 on the liver.
- VINBLASTINE TEVA 10 may reduce the effectiveness of:
  - allopurinol, colchicine, probenecid or sulfinpyrazone (medicines used to treat gout).
  - medicines used to treat epilepsy, such as phenytoin.

Pregnancy, breastfeeding and fertility:

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 healthcare provider for advice before being treated with VINBLASTINE TEVA 10.

VINBLASTINE TEVA 10 should not be administered to you if you are pregnant or breastfeeding your baby. Due to the possible risk of birth defects, if you are a woman of childbearing age, you must use effective methods of contraception during treatment and for at least 6 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 VINBLASTINE TEVA 10, genetic counselling is recommended.

If you are a man, you should avoid fathering a child during treatment with VINBLASTINE TEVA 10 and for at least 3 months after treatment has stopped. There is a risk that treatment with VINBLASTINE TEVA 10 will lead to male and female infertility. Male patients are advised to seek advice about sperm storage before the treatment starts.

Driving and using machinery:

VINBLASTINE TEVA 10 can cause dizziness or seizures (see **section 4**). If you experience any of these side effects, do not drive and/or use machines that require your full attention.

VINBLASTINE TEVA 10 contains sodium:

VINBLASTINE TEVA 10 contains 35,40 mg sodium (main component of cooking/table salt) in each 10

ml vial. This is equivalent to 1,77 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use VINBLASTINE TEVA 10:

Do not share medicines prescribed to you with any other person.

You will not be expected to give yourself VINBLASTINE TEVA 10. It will be given to you by a person who is qualified to do so.

VINBLASTINE TEVA 10 is administered in the vein by your doctor by means of an injection or with the aid of an infusion. VINBLASTINE TEVA 10 is sometimes used by itself, but usually it is administered in combination with other products to fight cancer.

The dose of VINBLASTINE TEVA 10 and the number of treatments, are determined by your doctor and is not the same for all patients. The dose may be increased with weekly intervals until the desired effect on the cancer is reached or until the number of white blood cells has reduced to a certain level.

If you receive more VINBLASTINE TEVA 10 than you should:

Since a healthcare professional will administer VINBLASTINE TEVA 10, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use VINBLASTINE TEVA 10:

If you have missed a dose of VINBLASTINE TEVA 10, it should be administered as soon as possible. Contact your doctor immediately to discuss when the missed injection can be administered.

You should check with your doctor or other healthcare professional if you are not sure.

4. Possible side effects

VINBLASTINE TEVA 10 can have side effects.

Some of these side effects may be serious and must be reported to your doctor. Other effects, like hair loss, may not be serious but may cause concern. Some side effects may occur after treatment with

VINBLASTINE TEVA 10 has been stopped.

Not all side effects reported for VINBLASTINE TEVA 10 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving VINBLASTINE TEVA 10, please consult your healthcare provider for advice.

If any of the following happens, tell your doctor or healthcare provider immediately or go to the casualty department of your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting
- sudden shortness of breath/wheezing, chest/left arm pains, confusion, seizures, slurred speech, weakness on one side of the body
- black or tarry stools, yellowing of the skin and eyes, vomit that looks like ground coffee.

These are all very serious side effects. If you have them, you may have had a serious reaction to VINBLASTINE TEVA 10. You may need urgent medical attention or hospitalisation.

If you experience any of the following, tell your doctor immediately:

- fever, sore throat, chills, or other signs of infection; these are symptoms of leucopoenia (decrease in the number of white blood cells found in the blood, which places individuals at increased risk of infection)
- reduced effect of the bone marrow, to be noticed as symptoms like fatigue (unusual tiredness or weakness) and often occurring infections due to reduced immunity
- observation of tickling, itching or tingling without there being a cause for it (paraesthesia), reduced reflexes
- inflammation of the mucous lining in the mouth (or sores in the mouth), bleeding of the intestines, rectal bleeding and bleeding from existing peptic ulcers, anorexia, diarrhoea, constipation, abdominal

pain

- difficult or painful urination, passing pink or bloody urine
- unusual bleeding or bruising.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- nausea and vomiting
- hair loss.

Less frequent side effects:

- pigmentation of the skin and nails, dermatitis, blistering of the skin, sensitivity of the skin to sunlight
- pain and inflammation at the injection site, vocal cord paralysis, fever, tender glands in the face and neck (parotic glands)
- decreased fertility, absence of a menstrual period in women and complete lack of semen in men
- development of abnormally large mammary gland in males resulting in breast enlargement
- light-headedness or dizziness, headache, irregular heartbeat, nausea, or sweating when standing after sitting or lying down
- fast, pounding heartbeat
- abnormal liver function tests.

Side effects with unknown frequency:

- other cancers.

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, pharmacist or nurse. 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 VINBLASTINE TEVA 10.

5. How to store VINBLASTINE TEVA 10:

Store all medicines out of reach of children.

Store between 2 to 8 °C (in a refrigerator). Do not freeze.

Store in original outer carton to protect from light.

Discard any residual solution.

Do not use this medicine after expiry date printed on the carton or vial.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets)

6. Contents of the pack and other information:

What VINBLASTINE TEVA 10 contains:

- The active substance vinblastine sulphate. Each vial contains 10 mg vinblastine sulphate (1 mg/ml).
- The other ingredients are sodium chloride and water for injection (see **section 2, VINBLASTINE TEVA 10 contains sodium**).

What VINBLASTINE TEVA 10 looks like and contents of the pack:

VINBLASTINE TEVA 10 is a sterile, clear, colourless or slightly yellow solution essentially free from particulate matter.

Solution for injection is packed in a 10 R (approx. 13,5 ml) clear, colourless type 1 glass vial. The vial is sealed with a dark grey bromobutyl rubber stopper, an aluminium seal and a white polypropylene cap.

One vial is packed in an outer carton.

Holder of Certificate of Registration:

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