1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

SPALZACT 100 mg powder for suspension for injection

Azacitidine

Contains sugar (mannitol 100 mg / vial)

Read all of this leaflet carefully before you are given SPALZACT 100

- 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.

What is in this leaflet:

1. What SPALZACT 100 is and what it is used for

SPALZACT 100 contains the active substance azacitidine. It works by preventing the growth of cancer cells.

- **SPALZACT 100** is used for treatment of patients with myelodysplastic syndromes (MDS) a group of illnesses of the bone marrow resulting in the production of too few blood cells.
- chronic myelomonocytic leukaemia (CMML).

2. What you need to know before you receive SPALZACT 100

You should not receive SPALZACT 100 if:

- You are allergic to any ingredient in **SPALZACT 100**.
- You have a malignant liver tumour.

Warnings and precautions

Check with your doctor or nurse before you receive **SPALZACT 100** if you have:

- decreased counts of platelets, red or white blood cells.
- kidney disease.
- liver disease.
- if you have ever had a heart condition or heart attack or any history of lung disease.
- Men should be advised not to father a child while receiving treatment with SPALZACT 100.

Other medicines and SPALZACT 100

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

Pregnancy, breast-feeding 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 health care provider for advice before taking this medicine.

Pregnancy

You should not use SPALZACT 100 during pregnancy as it may be harmful to the baby.

Use an effective method of contraception during and up to 3 months after treatment.

Tell your doctor straight away if you become pregnant during treatment.

Breast-feeding

You should not breast-feed when using SPALZACT 100. It is not known if this medicine passes into human milk.

Fertility

Men should not father a child while receiving treatment with SPALZACT. Use an effective method of contraception during and up to 3 months after treatment with this medicine.

Driving and using machines

No studies of the effects on the ability to drive and use machines have been performed.
Some people may feel tired after being given SPALZACT 100. If this happens to you, do not drive or use any tools or machines.

3. How SPALZACT 100 powder for injection is given

You will not be expected to give yourself SPALZACT 100. It will be given to you by a person who is qualified to do so.
Your doctor will prescribe the specific dosage regimen required for your condition.
The usual starting dose is 75 mg/m^2 injected under the skin, daily for seven days, every four weeks. You should also receive additional medication to prevent nausea and vomiting. The dose may be increased to 100 mg/m^2 if no beneficial effect is seen after two treatment cycles and if no toxicity other than nausea and vomiting has occurred. You will usually be treated for a minimum of 4 cycles. However, complete or partial response may require more than 4 treatment cycles. Treatment may be continued as long as you continue to benefit.
Your doctor will monitor your blood for signs of toxicity. The dosage may then be delayed or changed.

Administration:

SPALZACT 100 will be administered under the supervision of a doctor qualified in the use of anticancer medicines.
SPALZACT 100 will be given to you as an injection under the skin (subcutaneously). It may be given under the skin on your thigh, tummy or upper arm.

If you have the impression that the effect of SPALZACT 100 is too strong or too week, talk to your doctor or pharmacist.

If you develop any new medical problem while you are receiving SPALZACT 100 check with your doctor, nurse, or pharmacist.

If you receive more SPALZACT 100 than you should:

Since a healthcare professional will administer **SPALZACT 100,** he/she will control the dosage.

In the event of overdosage, the doctor will treat you.

If you miss a dose of SPALZACT 100:

SPALZACT 100 will be administered under your doctor's supervision.

If you think you have not been given a dose of **SPALZACT 100**, tell your doctor or other healthcare professional immediately.

4. Possible side effects

SPALZACT 100 may cause side-effects.

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

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

- Difficulty breathing, swelling of the lips, swollen tongue or throat, itching or rash including hives, low blood pressure, a weak and rapid pulse, nausea, vomiting, diarrhoea, dizziness or fainting. This may be due to a serious allergic (hypersensitivity) reaction.

These are all very serious side effects. If you have them, you may have had a serious reaction to SPALZACT. 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:

- **Drowsiness, shaking, jaundice, abdominal bloating and easy bruising**. These may be symptoms of liver failure and can be life-threatening.
- **Swelling of the legs and feet, back pain, reduced passing of water, increased thirst, rapid pulse, dizziness and nausea, vomiting or reduced appetite and feelings of confusion, restlessness or fatigue.** These may be symptoms of kidney failure and can be life-threatening.
- **A fever**. This may be due to an infection as a result of having low levels of white blood cells and can be life-threatening.
- **Chest pain or shortness of breath which may be accompanied with a fever.** This may be due to an infection of the lung called “pneumonia” and can be life-threatening.
- **Bleeding.** Such as blood in the stools due to bleeding in the stomach or gut.

These are all serious side effects. You may need urgent medical attention.
*Other possible side-effects of **SPALZACT 100**:*
Frequent side-effects:

- Reduced red blood count (anaemia). You may feel tired and pale.
- Reduced white blood cell count. This may be accompanied by a fever. You are also more likely to get infections.
- A low blood platelet count (thrombocytopenia). You are more prone to bleeding and bruising.
- Constipation, diarrhoea, nausea, vomiting.
- Pneumonia.
- Chest pain, being short of breath.
- Tiredness (fatigue).
- Injection site reaction including redness, pain or a skin reaction.
- Loss of appetite.
- Joint aches.
- Bruising.

- Rash.
- Red or purple spots under your skin.
- Pain in your belly (abdominal pain).
- Itching.
- Fever.
- Sore nose and throat.
- Dizziness.
- Headache.
- Bleeding inside your head.
- An infection of the blood caused by bacteria (sepsis). This may be due to low levels of white cells in your blood.
- Bone marrow failure. This can cause low levels of red and white blood cells and platelets.
- A type of anaemia where your red and white blood cells and platelets are reduced.
- An infection in your urine.
- A viral infection causing cold sores (herpes).
- Bleeding gums, bleeding in the stomach or gut, bleeding from around your back passage due to piles (haemorrhoidal haemorrhage), bleeding in your eye, bleeding under your skin, or into your skin (haematoma).
- Blood in your urine.
- Ulcers of your mouth or tongue.
- Changes to your skin at the injection site. These include swelling, a hard lump, bruising, bleeding into your skin (haematoma), rash, itching and changes in the skin colour.
- Redness of your skin.
- Skin infection (cellulitis).

- An infection of the nose and throat, or sore throat.
- Sore or runny nose or sinuses (sinusitis).
- Low levels of potassium in your blood.
- High or low blood pressure (hypertension or hypotension).
- Being short of breath when you move.
- Pain in your throat and voice box.
- Indigestion.
- Weight loss.
- Lethargy.
- Feeling generally unwell.
- Muscle aches.
- Anxiety or having trouble sleeping (insomnia).
- Being confused.
- Hair loss.
- Kidney failure.
- Dehydration.

Frequency unknown:

- Allergic (hypersensitivity) reaction.
- Drowsiness.
- Shaking.
- Liver failure.
- Dry cough.
- Painless swelling in the finger tips (clubbing).

- Tumour lysis syndrome - Metabolic complications that can occur during treatment of cancer and sometimes even without treatment. These complications are caused by the break-down products of dying cancer cells and may include the following: changes to blood chemistry; high potassium, phosphorus, uric acid, and low calcium consequently leading to changes in kidney function, heart beat, seizures, and sometimes death.

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

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 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 SPALZACT 100

5. How to store SPALZACT 100

Store all medicines out of reach of children.

Store at or below 25 °C

Do not freeze. Store in the original package to protect from moisture.

Contents of the pack and other information

What SPALZACT 100 contains

- The active substance is azacitidine
- The other ingredients are:
- Mannitol, pyrogen free, water for injection

What SPALZACT 100 looks like and contents of the pack

SPALZACT 100 mg is a white to off white lyophilised powder filled in clear single use Type I glass vial sealed with 20 mm grey bromobutyl rubber stopper and white coloured flip off seals in a unit carton

Holder of Certificate of Registration

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