1.3.2 Patient Information Leaflet

SCHEDULING STATUS

S4

VIDAZA (powder for suspension for Injection)

Azacytidine, 100 mg

Contains sugar: Mannitol

Read all of this leaflet carefully before you start receiving VIDAZA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- VIDAZA 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 VIDAZA is and what it is used for.

2. What you need to know before you receive VIDAZA**.**

3. How to receive VIDAZA**.**

4. Possible side effects.

5. How to store VIDAZA**.**

6. Contents of the pack and other information.

1. What VIDAZA is and what it is used for

VIDAZA is an anti-cancer medicine.

VIDAZA is used in adults who are not able to have a stem cell transplantation to treat:

- higher-risk myelodysplastic syndromes (MDS), a group of bone marrow disorders in which the bone marrow does not produce enough healthy blood cells;
- chronic myelomonocytic leukemia (CMML) a type of cancer of the blood-forming cells of the bone marrow;
- acute myeloid leukaemia (AML), a cancer of the blood cells, characterised by the rapid growth of abnormal white blood cells that accumulate in the bone marrow and interfere with the production of normal blood cells.

2. What you need to know before receiving VIDAZA

Do not receive VIDAZA if:

- you are hypersensitive (allergic) to azacitidine, or to any other ingredient in VIDAZA;
- you have liver cancer;
- you are pregnant and breastfeeding.

VIDAZA is not recommended for use in children and adolescents below the age of 18.

Do not receive live vaccines while being treated with VIDAZA.

Warnings and precautions

Take special care with VIDAZA if:

- you are a male you should not father a child while receiving treatment with VIDAZA. Suitable contraception should be used during and up to 3 months after treatment. You should seek counselling on sperm storage;
- you have decreased counts of platelets, red or white blood cells;
- you have kidney disease;
- you have liver disease;
- you have ever had a heart condition or heart attack or any history of lung disease.

VIDAZA can cause a serious immune reaction called `differentiation syndrome'

(*see section 4*).

Blood tests: You will have blood tests before you begin treatment with VIDAZA and at the start of each period of treatment (called a 'cycle'). This is to check that you have enough blood cells and that your liver and kidneys are working properly.

Children and adolescents

Do not give VIDAZA to children and adolescents below the age of 18 years because it is unlikely to be safe.

Other medicines and VIDAZA

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

Pregnancy and breastfeeding and fertility

Pregnancy

- You should not use VIDAZA during pregnancy, as it may be harmful to the baby.
- A woman should use highly effective contraception while being treated with VIDAZA.
- If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking VIDAZA.
- **If you become pregnant while using VIDAZA, please consult your doctor immediately.**
- Female partners of male patients receiving VIDAZA should not become pregnant.
- Women of childbearing potential must use effective contraception during and up to 6 months after treatment.

Breastfeeding

- **You should not use VIDAZA while breastfeeding your baby.**

Fertility

- If you are a male, you should not father a child while receiving treatment with VIDAZA.
- Suitable contraception should be used.
- You should seek counselling on sperm storage.
- Men must use effective contraception during and up to 3 months after treatment.

Driving and using machinery

It is not always possible to predict to what extent VIDAZA 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 VIDAZA affects them. Do not drive or operate machines if you experience side effects, such as dizziness, impairment of vision, tiredness or sleepiness.

VIDAZA contains mannitol

VIDAZA contains mannitol, which may have an effect on the control of your blood sugar if you have diabetes mellitus.

VIDAZA contains mannitol and may have a laxative effect.

If you have been told that you have an intolerance to some sugars, you should not receive VIDAZA.

3. How to receive VIDAZA

- Do not share medicines prescribed for you with any other person.
- Your doctor will decide on an appropriate dosage to treat your disease.
- You will also receive an additional medicine to prevent nausea and vomiting.
- VIDAZA is given every day for one week, followed by a rest period of 3 weeks. This "treatment cycle" will be repeated every 4 weeks.

- You will be treated for a minimum of 6 cycles. However, your disease may require more treatment cycles.
- Your doctor will decide how long to continue treatment.
- Your doctor will monitor your blood for signs of toxicity. The dosage may then be delayed or changed.
- If you have the impression that the effect of VIDAZA is too strong or too weak, tell your doctor or pharmacist.

Administration:

- You will not be expected to give yourself VIDAZA. It will be given to you by a person who is qualified to do so.
- VIDAZA will be administered under the supervision of a doctor qualified in the use of anticancer agents.
- Reconstituted VIDAZA will be injected under your skin by a doctor or nurse.

If you received more VIDAZA than you should

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

If you forget to use VIDAZA

Since a healthcare professional will administer VIDAZA, it is unlikely that the dose will be missed.

4. Possible side effects

VIDAZA may cause side effects.

Not all side effects reported for VIDAZA are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking VIDAZA and tell your doctor immediately or go to the casualty department at 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.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to VIDAZA. 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 could be due to an infection as a result of having low levels of white blood cells, which 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 your lungs, called “pneumonia”, and can be life-threatening.

- Bleeding, such as blood in your stools due to bleeding in your stomach or gut, or bleeding inside your head. These may be symptoms of having low levels of platelets in your blood.
- An infection of the blood caused by bacteria (sepsis). This may be due to low levels of white cells in your blood.
- 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.
- 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.
- Tumour lysis syndrome - Metabolic complications that can occur during treatment of cancer and sometimes even without treatment. These complications are caused by the product 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, heartbeat, seizures and sometimes death.
- Infection of the deeper layers of skin, which spreads quickly, damaging the skin and tissue, which can be life-threatening (necrotizing fasciitis)
- Inflammation of the lining around the heart (pericarditis).
- Serious immune reaction (differentiation syndrome) that may cause fever, cough, difficulty breathing, rash, decreased urine, low blood pressure (hypotension), swelling of the arms or legs and rapid weight gain.

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

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- 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 (infection of the lungs).
- 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.
- Having trouble sleeping (insomnia).
- Nosebleeds (epistaxis).
- Muscle aches.
- Weakness (asthenia).
- Weight loss.

- Low levels of potassium in your blood.
- Bleeding inside your head.
- Bone marrow failure. This can cause low levels of red and white blood cells and platelets.
- An infection in your urine.
- A viral infection causing cold sores (herpes).
- Ulcers of your mouth or tongue.
- Redness of your skin.
- An infection of the nose and throat, or sore throat.
- Sore or runny nose or sinuses (sinusitis).
- High or low blood pressure (hypertension or hypotension).
- Being short of breath when you move.
- Pain in your throat and voice box.
- Indigestion.
- Lethargy.
- Feeling generally unwell.
- Anxiety.
- Being confused.
- Hair loss.
- Kidney failure.
- Dehydration.
- White coating covering tongue, inner cheeks, and sometimes on the roof of your mouth, gums and tonsils (oral fungal infection).
- Fainting.
- A fall in blood pressure when standing (orthostatic hypotension) leading to dizziness when moving to a standing or sitting position.

- Sleepiness, drowsiness (somnolence).
- Bleeding due to a catheter line.
- A disease affecting the gut, which can result in fever, vomiting and stomach pain (diverticulitis).
- Fluid around the lungs (pleural effusion).
- Shivering (chills).
- Muscle spasms.
- Raised itchy rash on the skin (urticaria).
- Collection of fluid around the heart (pericardial effusion).

The following side effects have been reported less frequently:

- Shaking.
- Liver failure.
- Large plum coloured raised painful patches on the skin with fever.
- Painful skin ulceration (pyoderma gangrenosum).
- Dry cough.
- Painless swelling in the fingertips (clubbing).

The following side effects have been reported with the frequency not known:

- Inflammation of blood vessels in the skin which may result in rash (cutaneous vasculitis).

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 or nurse. This includes any possible side effects not listed in this leaflet. Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions 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 VIDAZA.

5. How to store VIDAZA:

- Store all medicines out of reach of children.
- **Powder for injection:** Store at or below 25 °C.
- **After reconstitution:** Reconstituted VIDAZA may be stored for up to 8 hours between 2 °C and 8 °C. When reconstituted with refrigerated (2 °C and 8 °C) water for injections, the reconstituted suspension can be kept in the refrigerator (2 °C and 8 °C) for a maximum of 22 hours.
- If administration is to be delayed, the reconstituted product may be kept in the vial or drawn into a syringe. The product must be refrigerated (2 ºC – 8 ºC) immediately. After removal from refrigerated conditions, the suspension may be allowed to equilibrate to room temperature (25 ºC) for up to 30 minutes prior to administration.
- When stored at 25 ºC, the reconstituted product should be administered within 1 hour.
- If you don't need to use this medicine anymore, take it to your doctor or nearest pharmacy who will dispose of it.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label / carton / bottle.

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

6. Contents of the pack and other information

What VIDAZA contains

The active substance is:

Each vial contains 100 mg azacitidine as the active ingredient. The reconstituted suspension contains 25 mg/ml azacitidine.

The inactive ingredients are:

Mannitol and water for injection.

Contains sugar (mannitol).

What VIDAZA looks like and contents of the pack

A white to off-white, sterile lyophilised powder, packed in a colourless single use Type I glass vial sealed with butyl rubber stopper and aluminium seal with plastic button.

Holder of Certificate of Registration and Manufacturer

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Access to the corresponding Professional Information

Can be obtained on the SAHPRA website.