PATIENT INFORMATION LEAFLET

BEFORE RECEIVING VIDAZA:

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 medicines with other people. It may harm them, even if their symptoms are the same as yours.

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

VIDAZA® (Powder for suspension for Injection)

WHAT VIDAZA CONTAINS:

Each vial contains 100 mg azacitidine. The reconstituted suspension contains 25 mg/ml azacitidine.

WHAT VIDAZA IS USED FOR:

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

- **VIDAZA** is used in adults who are not eligible for stem cell transplantation to treat: higher-risk myelodysplastic syndromes (MDS) a group of illnesses of the bone marrow resulting in the production of too few blood cells.
- chronic myelomonocytic leukaemia (CMML).
- acute myeloid leukaemia (AML).

BEFORE YOU RECEIVE VIDAZA:

You should not receive VIDAZA if:

- You are allergic to any ingredient in **VIDAZA**.

- You have a malignant liver tumour.
- You are breast feeding.

Tell your doctor or healthcare professional before you receive VIDAZA if:

- You have renal or liver function impairment.
- Men should be advised not to father a child while receiving treatment with **VIDAZA**.

Take special care with Vidaza:

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

- decreased counts of platelets, red or white blood cells.
- kidney disease.
- liver disease.

Pregnancy and breast -feeding while receiving VIDAZA:

You should not become pregnant while receiving VIDAZA.

If you become pregnant while receiving VIDAZA, please consult your doctor immediately.

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

You should not be receiving **VIDAZA** while breast -feeding.

It is not known if VIDAZA passes into the mother's milk and therefore you must not breastfed your baby during treatment.

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

Talk to your doctor if you wish to conserve your sperm before starting this treatment.

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 **VIDAZA**. If this happens to you, do not drive or use any tools or machines.

***Using other medicines with VIDAZA*:**

If you are taking medicines on a regular basis, concomitant use of **VIDAZA** may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

HOW VIDAZA IS USED:

The recommended 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. It is recommended that patients 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 the patient continues to benefit.

Your doctor will monitor your blood for signs of toxicity. The dosage may then be delayed or changed.

Administration:

VIDAZA should be administered under the supervision of a doctor qualified in the use of anticancer agents.

Reconstituted **VIDAZA** should be injected under your skin.

Rotate sites for injection (thigh, abdomen, or upper arm). New injections should be given at least one inch from an old site and never into areas were the site is tender, bruised, red, or hard.

Recommendations for safe handling:

The **VIDAZA** suspension should not be filtered after reconstitution since this could remove the active substance. It must be taken into account that filters are present in some adaptors, spikes and closed systems.

VIDAZA is a cytotoxic agent and caution should be exercised when handling and preparing azacitidine suspensions. Procedures for proper handling and disposal of anticancer agents should be applied.

If reconstituted **VIDAZA** comes into contact with the skin, immediately and thoroughly wash with soap and water. If it comes into contact with mucous membranes, flush thoroughly with water.

Disposal: Any unused product or waste material should be disposed of in accordance with local requirements.

VIDAZA is for you. Your doctor will prescribe the exact dose required for your condition.

If you have the impression that the effect of **VIDAZA** is to strong or to week, talk to your doctor or pharmacist.

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

If you receive more VIDAZA than you should:

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

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

If you miss a dose of VIDAZA:

VIDAZA will be administered under your doctor's supervision.

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

POSSIBLE SIDE EFFECTS:

VIDAZA may cause side-effects.

Tell your doctor straight away if you notice any of the following serious side effects:

- **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.
- **Difficulty breathing, swelling of the lips, itching or rash.** This may be due to an allergic (hypersensitivity) reaction.

*The following possible side-effects of **VIDAZA** are:*

More 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.

Frequent side -effects:

- 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.

Rare side-effects:

- Allergic (hypersensitivity) reaction.
- Drowsiness.
- Shaking.
- Liver failure.

Less frequent side –effects:

- 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.

STORAGE AND DISPOSAL INFORMATION:

If you don't need to receive **VIDAZA** anymore, take it to your doctor or nearest pharmacy who will dispose of it.

Store all medicines out of reach of children.

Powder for injection: Store below 25 °C.

After reconstitution: Reconstituted **VIDAZA** may be stored for up to 8 hours between 2 and 8 °C.

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.

Do not dispose of unused **VIDAZA** in drains or sewerage systems e.g. toilets.

PRESENTATION:

Colourless single use Type I glass vial sealed with butyl rubber stopper and aluminium seal with plastic button.

IDENTIFICATION:

White to off-white, sterile lyophilised powder.

REGISTRATION NUMBER

A40/26/0521

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Key Oncologics (Pty) Ltd
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