Applicant/PHRC: ***Hetero Drugs SA (Pty) Ltd***

Product proprietary name: ***DITICAZA 100 mg/vial***

Dosage form and strength: Injection, each vial contains 100 mg azacitidine

PATIENT INFORMATION LEAFLET FOR DITICAZA 100 mg/vial

SCHEDULING STATUS

S4

DITICAZA 100 mg/vial

Azacitidine

Contains sugar: mannitol

Each vial contains 100 mg mannitol

Read all of this leaflet carefully before you are given DITICAZA:

- 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 DITICAZA is and what it is used for

DITICAZA is an anti-cancer medicine which belongs to a group of medicines called anti-metabolites.

DITICAZA contains the active ingredient azacitidine. It works by preventing the growth of cancer cells.

DITICAZA is used in adults who are not able to have a 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), 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 you receive DITICAZA

DITICAZA should not be administered to you:

- if you are hypersensitive (allergic) to azacitidine (active ingredient) or any of the other ingredients of DITICAZA (listed in section 6).
- if you have advanced liver cancer.
- if you are pregnant or breastfeeding.
- DITICAZA is not recommended for use in children and adolescents below the age of 18.
- Do not receive live vaccines while being treated with DITICAZA.

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

- if you have kidney disease.
- if you have liver disease.
- if you have decreased counts of platelets, red or white blood cells.
- if you have ever had a heart condition or heart attack or any history of lung disease.
- DITICAZA can cause a serious immune reaction called `differentiation syndrome'.

Blood test

You will have blood tests before you begin treatment with DITICAZA 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

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

Other medicines and DITICAZA

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

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 health care provider for advice before using DITICAZA.

- You should not use DITICAZA if you are pregnant or breastfeeding your baby.
- You should not use DITICAZA during pregnancy, as it may be harmful to the baby.
- A woman should use highly effective contraception while being treated with DITICAZA.
- **If you become pregnant while using DITICAZA, please consult your doctor immediately**.
- **You should not use DITICAZA while breastfeeding your baby**.
- If you are a male, you should not father a child while receiving treatment with DITICAZA. Suitable contraception should be used. You should seek counselling on sperm storage.
- Female partners of male patients receiving DITICAZA should not become pregnant.
- Women of childbearing potential and men have to use effective contraception during and up to 3 months after treatment.

Driving and using machines

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

DITICAZA contains mannitol and may have a laxative effect.

3. How to use DITICAZA

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

- Your doctor will decide on an appropriate dosage to treat your disease.
- You will also receive additional medicine to prevent nausea and vomiting.
- DITICAZA 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 DITICAZA is too strong or too weak, tell your doctor or pharmacist.

Administration:

DITICAZA will be administered under the supervision of a doctor qualified in the use of anticancer medicines.

Reconstituted DITICAZA will be injected under your skin.

If you receive more DITICAZA than you should

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

If you forget to use DITICAZA

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

4. Possible side effects

DITICAZA can have side effects.

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

If any of the following happens, stop taking DITICAZA 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.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to DITICAZA. 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 maybe 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, or such as bleeding inside your head. These may be symptoms of having low levels of platelets in your blood.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Reduced red blood count (anaemia). You may feel tired and pale.
- Constipation, diarrhoea.
- Pneumonia (infection of the lungs).
- Injection site reaction including redness, pain or a skin reaction.
- Joint aches.
- Bruising.
- Red or purple spots under your skin.
- Pain in your belly (abdominal pain).
- Sore nose and throat.
- 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.
- 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.
- 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).

Less frequent side effects:

- Allergic (hypersensitivity) reaction.
- Drowsiness.

- Shaking.
- Liver failure.
- Dry cough.
- Painless swelling in the finger tips (clubbing).
- Large plum-coloured, raised painful patches on the skin with fever.
- Painful skin ulceration (pyoderma gangrenosum).
- Inflammation of the lining around the heart (pericarditis).
- 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, heartbeat, seizures, and sometimes death.

Frequency unknown:

- Infection of the deeper layers of skin, which spreads quickly, damaging the skin and tissue, which can be life-threatening (necrotising fasciitis).

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. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website or to the Holder of certificate of registration through the mail: pvg.cdma@heterogroups.com. By reporting side effects, you can help provide more Information on the safety of **DITICAZA**.

5 How to store DITICAZA

Store all medicines out of reach of children.

Store at or below 25 °C

Store in the original package.

Protect from light/ moisture.

Do not use this medicine after the expiry date which is stated on the vial label and the carton. The expiry date refers to the last day of that month.

Your doctor, pharmacist or nurse are responsible for storing DITICAZA.

They are also responsible for preparing and disposing of any unused

DITICAZA correctly.

For unopened vials of this medicine – there are no special storage conditions.

When using immediately

Once the suspension has been prepared it should be administered within 60 minutes.

When using later

If the DITICAZA suspension is prepared using water for injections that has not been refrigerated, the suspension must be placed in the refrigerator (2 °C – 8 °C) immediately after it is prepared and kept refrigerated for up to a maximum of 8 hours.

If the DITICAZA suspension is prepared using water for injections that has been stored in the refrigerator (2 °C – 8 °C), the suspension must be placed in the refrigerator (2 °C – 8 °C) immediately after it is prepared and kept refrigerated for up to a maximum of 22 hours.

The suspension should be allowed up to 30 minutes prior to administration to reach room temperature (20 °C – 25 °C).

If large particles are present in the suspension, it should be discarded.

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

6. Contents of the pack and other information

What DITICAZA contains

- The active substance is azacitidine

The other ingredients are:

- Mannitol
- Acetonitrile
- Water for injection
- Nitrogen

What DITICAZA looks like and contents of the pack

DITICAZA 100 mg/ vial

30 ml clear moulded glass vials, type I with 20 mm neck with 5 ml 20 mm igloo rubber GBB stopper with a white flip off seals 20 mm matte top finish.

Pack size: 1 x 30 mL

Holder of Certificate of Registration

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Access to the corresponding Professional Information

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