Applicant/PHRC: ***Hetero Drugs South Africa (Pty) Ltd***

Product proprietary name: ***ELODYST***

Dosage form and strength: ***Powder for concentrate for Solution for infusion and 50 mg/vial***

FINAL PATIENT INFORMATION LEAFLET FOR ELODYST

SCHEDULING STATUS

S4

ELODYST 50 mg/vial, Powder for concentrate for solution for infusion

Decitabine

ELODYST is sugar free

Read all of this leaflet carefully before you are given ELODYST

- 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 the leaflet

1. What ELODYST is and what it is used for

ELODYST contains the active substance decitabine. Decitabine is an anti-cancer medicine, used to treat patients with acute myeloid leukaemia (AML). This is a type of cancer that affects your blood cells. You will use **ELODYST** when you are first diagnosed with AML. It is used in adults for 65 years and older.

ELODYST works by stopping cancer cells from growing. It also kills cancer cells.

2. What you need to know before ELODYST is administered

ELODYST should not be administered to you:

- if you are hypersensitive (allergic) to decitabine or to any of the other ingredients of **ELODYST** (listed in section 6).
- if you are breastfeeding your baby (see **Pregnancy, breastfeeding and fertility**).

Warnings and precautions

Before you start your treatment with **ELODYST**, you will have blood tests to check that you have enough blood cells and sufficient liver and kidney functions to receive **ELODYST**.

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

- If you have low number of platelets, red blood cells or white blood cells,
- If you have an infection.
- If you have a liver disease.
- If you have a serious kidney disorder
- If you have a heart disease

If any of the above applies to you (or you are not sure), tell to your doctor or healthcare provider immediately before you are given **ELODYST**.

Children and adolescents

ELODYST is not for use in children or adolescents.

Other medicines and ELODYST

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines). This is because **ELODYST** can affect the way how other medicines work or some medicines can affect the way **ELODYST** works.

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 receiving **ELODYST**.

Pregnancy

You should not use **ELODYST** if you are pregnant as it may harm your baby. Tell your doctor immediately if you become pregnant during treatment with **ELODYST**.

Breastfeeding

Do not breastfeed if you are using **ELODYST**. This is because it is not known if the medicine passes into the mother's milk.

Fertility

You must use an effective method of contraception during treatment with **ELODYST** and for up to 2 months after treatment has stopped. Men should not father a child while using **ELODYST**. Men must use effective contraception during treatment and for up to 3 months after treatment has stopped. Talk to your doctor if you wish to conserve your sperm before starting treatment. Women must use an effective method of contraception during treatment with **ELODYST**. It is unknown when it is safe for women to become pregnant after treatment has stopped. Talk to your doctor if you wish to freeze your eggs before starting treatment.

Driving and using machines

You may feel tired or weak after using **ELODYST**. If this happens, not drive or use any tools or machines. It is not always possible to predict to what extent **ELODYST** may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or using machines until you are aware of the measure to which **ELODYST** affects you.

3. How to receive ELODYST

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

The solution is given into a vein (as an infusion).

Your doctor will work out your dose of **ELODYST**. This depends on your height and weight (body surface area).

5-Day Treatment Regimen

ELODYST is given by intravenous infusion over 1 hour, repeated daily for 5 days. This is one treatment cycle. There is a gap between treatment cycles of about 4 weeks.

Before each treatment cycle you will have a blood test to see if you are well enough for treatment.

You will usually receive at least 4 treatment cycles. Your doctor may change or delay your dose and change the total number of cycles, depending on how you respond to the treatment.

If you receive more ELODYST than you should

Since your health care provider will administer **ELODYST**, he/she will control the dosage. However, in the event of an overdosage your doctor will manage the overdosage.

If you missed a dose of ELODYST

Since health care provider will administer **ELODYST**, it is unlikely that the dose will be missed.

4. Possible side effects

ELODYST can have side effects.

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

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

- 'swelling of your hands, feet, ankles, face, lips and 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 **ELODYST**. 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:

Frequent:

- Chest pain or shortness of breath (with or without fever of cough) these may be signs of an infection of the lung called pneumonia
- Urinary tract infection
- Other infection in any part of the body, caused by bacteria, virus or fungi
- Decrease in the number of red blood cells (anaemia) – feeling tired or looking pale
- Decrease in the number of white blood cells (neutropenia, leucopaenia) – you might get a fever and are more likely to get infections
- Decrease in the number of blood platelets – which results in increased risk of bleeding or bruising
- Lack of white blood cells associated with fever and infection
- Bleeding, including blood in the stools – this may be a sign of bleeding in the stomach or gut
- Bleeding inside your head. Symptoms of this may be difficulty with moving, speaking or understanding or seeing; sudden severe headache, seizure, numbness or weakness in any part of the body
- Difficulty breathing, swelling of the lips. Itching or rash. This may be due to an allergic (hypersensitivity) reaction
- Nose bleeds
- Inflammation of the mucous membrane of the mouth (stomatitis)

Less frequent:

- Red, raised painful skin rash that appears mostly on the arms, face and neck and fever. These may be signs of acute febrile neutrophilic dermatosis or “Sweet’s Syndrome”

Frequency unknown:

- High level of sugar in the blood
- Heart muscle disease
- Abnormal liver function
- High levels of bilirubin in the blood
- Mouth or tongue ulcers
- Sore or runny nose, sore sinuses

- Interstitial lung disease (an umbrella term used for a large group of diseases that cause scarring (fibrosis) of the lungs
- Enterocolitis (an inflammation that occurs in a person's digestive tract

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

Tell your doctor as soon as possible if you notice any of the following:

Frequent:

- Headache
- Loose or watery stools (diarrhoea)
- Feeling sick (nausea)
- Being sick (vomiting)
- feeling of tension or fullness in the nose, cheeks and behind your eyes, sometimes with a throbbing ache.Sometimes may also get fever, stuffy nose and loss of the sense of smell (sinusitis)
- Septic shock (a life-threatening condition that happens when your blood pressure drops to a dangerously low level after an infection)
- Sepsis (the body's overwhelming and life-threatening response to infection that can lead to tissue damage, organ failure and 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 side effects, talk to your doctor or pharmacist. 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. 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 **ELODYST**.

5. How to store ELODYST

- Store at or below 25 °C. Do not freeze the reconstituted solution.
- Store all medicines out of reach of children.
- Protect form light and moisture.

- Keep the vial in the outer carton until required for use.
- After reconstitution, the concentrate must be further diluted within 15 minutes using cold infusion fluids. This prepared diluted solution can be stored refrigerated at 2°C - 8°C for up to a maximum of 4 hours, followed by up to 1 hour at room temperature before administration.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label / carton / vial.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
- For single use only. Discard any unused contents.

6. Contents of the pack and other information

What ELODYST contains

- The active substance is decitabine.
- The other ingredients are acetonitrile, hydrochloric acid, nitrogen gas, potassium dihydrogen phosphate, sodium hydroxide and water for injection.

What ELODYST looks like and contents of the pack

White to almost white lyophilized cake or powder. After reconstitution it is clear colorless solution.

Contents of the pack

20 mL Type-I, round clear fiolax tubular crimp neck finish and flat bottom glass vial with 20 mm grey colored bromobutyl rubber stopper with equidistant spacers and two semi circles at the center embossed on the top and 20 mm green colour aluminium flip off seal, packed in an outer carton.

Pack size: 1 vial

Holder of Certificate of Registration

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Access to the corresponding Professional Information

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