1.3.2 Patient Information Leaflet

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APPROVED PATIENT INFORMATION LEAFLET

TOCENAR (powder for concentrate for solution for infusion)

Decitabine 50 mg.

Sugar free.

Contains sodium: 11.60 mg.

Read all of this leaflet carefully before you start taking TOCENAR.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet:

1. What TOCENAR is and what it is used for

[PRODUCT NAME is an anti-cancer medicine. It contains the active substance ‘decitabine’.

TOCENAR is used to treat a type of cancer called 'acute myeloid leukaemia' (AML), a type of cancer that affects your blood cells. TOCENAR works by stopping cancer cells from growing and it also kills cancer cells.

2. What you need to know before you use TOCENAR

TOCENAR should not be administered to you:

- if you are allergic to decitabine or any of the other ingredients of this medicine (listed in section 6).
- if you are breastfeeding.

Warnings and precautions

TOCENAR may only be administered to you under the supervision of a medical practitioner, who specialised in oncology and has the facilities for regular monitoring, during and after therapy.

Special care with TOCENAR should be taken:

- If you suffer from a condition of low platelets in your blood, low white or red blood cells
- If you suffer from lung problems
- If you suffer from liver or kidney disease
- If you suffer from heart problems

Other medicines and TOCENAR:

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

Tell your doctor or pharmacist if you are currently using, have recently used or might use another medicines. TOCENAR does not interfere with other medicines that you may be taking. However, some medicines may affect how TOCENAR works, or TOCENAR may affect how your other medicines work.

Pregnancy, breastfeeding and fertility

- You should not be given TOCENAR if you are pregnant as it may harm your baby. Tell your doctor immediately if you become pregnant during treatment with TOCENAR.
- Do not breastfeed if you are receiving TOCENAR. This is because it is not known if TOCENAR passes into the mother's milk.
- If you are male and receiving TOCENAR you should not father a child and you should use effective contraception during treatment and for 2 months after treatment had stopped.
- You should talk to your doctor if you wish to conserve your sperm before starting treatment.
- If you are female and receiving TOCENAR you should use effective contraception during treatment. It is unknown when it is safe for female patients to become pregnant after treatment has stopped.
- Talk to your doctor if you wish to freeze your eggs before starting treatment.

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 healthcare professional for advice before being given TOCENAR.

Driving and using machines

You may feel tired or weak after treatment with TOCENAR. If this happens, do not drive or use any tools or machines.

3. How to take TOCENAR

You will not be expected to give yourself TOCENAR. TOCENAR will be administered to you under the direction of a doctor specialised in oncology (cancer treatment). How much to receive:

- Your doctor will work out your dose of TOCENAR. This depends on your height and weight (body surface area).
- The dose is 20 mg/m^2 body surface area. You will receive TOCENAR by intravenous infusion over 1 hour repeated daily for 5 consecutive days.
- This is called a 'treatment cycle'
- The treatment cycle is repeated every 4 weeks. You will usually receive at least 4 treatment cycles.
- Your dose and number of cycles can change, depending on how you respond to treatment.

If you receive more TOCENAR than you should:

Since a healthcare provider will administer [PROUCT NAME], he/she will control the dosage. However, in the event of overdosage, your doctor will manage any symptoms of the overdosage.

If you forget to use TOCENAR:

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

4. Possible side effects

TOCENAR can have side effects.

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

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

- Fever: this may be a sign of an infection caused by low levels of white blood cells (neutropenia, febrile neutropenia, leukopenia)
- Low blood pressure, pale and cool arms and legs, chills, difficulty breathing and decreased urine output. You could be experiencing something called septic shock.
- Allergic reactions, causing breathing problems or closing of the throat
- Sudden fever and rash which consists of multiple tender red or bluish-red lesions or bumps (Sweets' Syndrome).

These are all very serious side effects. If you have them, you may have had a serious reaction to TOCENAR. You may need urgent medical attention or hospitalisation.

The below side effects occur frequently:

- Pneumonia (chest pain or shortness of breath (with or without fever or cough)
- Urinary tract infection
- Viral, bacterial or fungal infections
- Septic shock, sepsis (an infection of the blood caused by bacteria – this could be due to a low level of white blood cells)
- Sinusitis
- Bleeding from gums or nose, blue or purple bruises on skin. This could be due to low platelets in your blood (thromobocytopenia).
- Low levels of iron in your blood characterised by excessive fatigue, dizziness, shortness of breath (anaemia)
- High blood sugar levels
- Headache

- Nose bleeds
- Diarrhoea
- Nausea
- Vomiting
- Mouth or tongue ulcers
- Liver problems
- Fever

The below side effects occur less frequently:

- Low red and white blood cells and platelets (pancytopenia). This will cause all of the symptoms associated with low red and white blood cells and low platelets mentioned above
- heart muscle disease
- red, raised painful patches on the skin, fever and an increase in white blood cells – these may be signs of 'Acute Febrile Neutrophillic Dermatosis' or 'Sweet's Syndrome'
- The below side effects' frequency is unknown:
- inflamed lungs (interstitial lung disease)
- inflamed gut (enterocolitis, colitis, caecitis), with symptoms of abdominal pain, bloating or diarrhoea. Enterocolitis may lead to septic complications and may be associated with a fatal outcome.

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. 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 TOCENAR.

5. How to store TOCENAR

Your doctor, nurse or pharmacist is responsible for storing

TOCENAR.

Do not store above 25°C. Do not freeze. Protect from moisture.

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, before administration

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What TOCENAR contains

The other ingredients of TOCENAR are:

- Potassium dihydrogen phosphate
- Sodium Hydroxide
- Acetonitrile

What TOCENAR looks like and contents of the pack

TOCENAR:

Before reconstitution:

White to almost white lyophilized powder.

After reconstitution:

A clear colourless solution free from visible particles.

TOCENAR:

Clear glass vial stoppered with gray rubber stopper and sealed with aluminium seal having sky blue colour PP disc.

Pack size: 1 vial.

HOLDER OF THE CERTIFICATE OF REGISTRATION

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Registration number

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