PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

DACOGEN® powder for concentrate for solution for infusion.

Each 20 mL single dose vial contains 50 mg **decitabine**.

Read all of this leaflet carefully, before you are given DACOGEN

- 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.
- DACOGEN 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 DACOGEN is and what it is used for
2. What you need to know before you use DACOGEN
3. How to use DACOGEN
4. Possible side effects
5. How to store DACOGEN
6. Contents of the pack and other information

1. What DACOGEN is and what it is used for

DACOGEN is an anti-cancer medicine. It contains the active substance ‘decitabine’.

What DACOGEN is used for

DACOGEN is used to treat patients with acute myeloid leukaemia (AML).

This is a type of cancer that affects your blood cells.

You will use DACOGEN when you are first diagnosed with AML.

It is used in adults of 65 years and older.

How DACOGEN works

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

2. What you need to know before you are given DACOGEN

You should not be administered with DACOGEN:

- if you are allergic (hypersensitive) to decitabine or any of the other ingredients of DACOGEN (see list of ingredients under ***Section 6***),
- if you are pregnant or breastfeeding your baby.

Do not use DACOGEN if any of the above applies to you. If you are not sure, talk to your doctor before you are given DACOGEN.

Warnings and precautions

Tell your doctor or health care provider before being given DACOGEN if:

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

- you have a heart disorder.

If any of the above apply to you (or you are not sure), talk to your doctor before you are given DACOGEN.

Tests

You will have blood tests before you start treatment with DACOGEN and at the start of each treatment cycle. These tests are to check that:

- you have enough blood cells,
- your liver and kidneys are working properly.

Talk to your doctor about what your blood test results mean.

DACOGEN can cause a serious immune reaction called differentiation syndrome. Tell your doctor if you experience fever, cough, difficulty breathing, rash, decreased urine, dizziness, swelling of the arms or legs, and rapid weight increase (see also section 4, Possible Side Effects).

Children and adolescents

DACOGEN is not for use in children or adolescents under the age of 18.

Other medicines and DACOGEN

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

Pregnancy and Breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before being administered this medicine.

- You should not use DACOGEN if you are pregnant as it may harm your baby.
- You must use an effective method of contraception during treatment with DACOGEN and for up to 2 months after treatment has stopped.
- Tell your doctor **immediately** if you become pregnant during treatment with DACOGEN.
- Do not breastfeed if you are using DACOGEN. This is because it is not known if the medicine passes into the mother's milk.

Male and female fertility and contraception

- Men should not father a child while using DACOGEN.
- 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 who are able to become pregnant must use an effective method of contraception during treatment with DACOGEN.
- It is unknown when it is safe for women to become pregnant after treatment has stopped.
- Women who are able to become pregnant must use an effective method of contraception for at least 6 months following completion of treatment with DACOGEN.
- Talk to your doctor if you wish to freeze your eggs before starting treatment.

Driving and using machinery

You may feel tired or weak after using DACOGEN. If this happens, not drive or use any tools or machines.

DACOGEN contains potassium and sodium

- This medicine contains potassium less than 1 mmol (39 mg) per dose, i.e., essentially 'potassium- free'.
- This medicine contains 0,29 mmol (6,67 mg) sodium (main component of cooking/table salt) in each vial. After preparing the medicine, it contains between 13,8 mg-138 mg sodium per dose, equivalent to 0,7-7 % of the recommended maximum daily dietary intake of sodium for an adult. Talk to your doctor if you are on a low salt diet.

3. How to receive DACOGEN

Do not share medicines prescribed for you with any other person. DACOGEN will be given to you by a doctor or nurse who is trained in giving this type of medicine.

How DACOGEN is given

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

5-Day Treatment Regimen

DACOGEN 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 DACOGEN than you should

Since a healthcare professional will administer this medicine, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage and take corrective action.

If you forget your appointment to have DACOGEN

If you miss an appointment, make another one as soon as possible. This is because for this medicine to be as effective as possible, it is important to follow the dosing schedule.

If you have any further questions on the use of DACOGEN, ask your doctor or pharmacist.

4. Possible side effects

DACOGEN can have side effects.

Not all side effects reported for DACOGEN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DACOGEN please consult your doctor, pharmacist or other health care professional for advice.

Tell your doctor or nurse immediately if you notice any of the following side effects:

- Fever – this may be a sign of an infection caused by low levels of white blood cells.

- Chest pain or shortness of breath (with or without fever of cough) these may be signs of an infection of the lung called “pneumonia”.
- 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.

Tell your doctor or nurse immediately if you notice any of the side effects above.

Side effects of DACOGEN include:

Frequent (affects more than 1 in 10 people)

- Lung infection (pneumonia),
- Urine infection,
- Other infection in any part of the body, caused by bacteria, virus or fungi.
- A drop in the number of white blood cells (neutropenia, leukopenia) – you might get a fever and are more likely to get infections,
- Bleeding or bruising more easily – these may be signs of a drop in the number of blood platelets (thrombocytopenia),
- Feeling tired or looking pale – these may be signs of a drop in the number of red blood cells (anaemia),
- Headache,
- Nose bleeds,
- Diarrhoea,
- Vomiting,

- Mouth or tongue ulcers,
- Nausea,
- Fever,
- An infection of the blood caused by bacteria – this may be a sign of a low level of white blood cells,
- Sore or runny nose, sore sinuses,
- A drop in the number of red blood cells, white blood cells and platelets (pancytopenia).
- High levels of 'bilirubin' in the blood.
- Abnormal liver function.
- High level of sugar in the blood

Less frequent (affects less than 1 in 100 people)

- Red, raised painful patches on the skin, fever, an increase in white blood cells. These may be signs of "acute febrile neutrophilic dermatosis" or "Sweet's Syndrome".
- Heart muscle disease.
- Serious immune reaction that may cause fever, cough, difficulty breathing, rash, decreased urine, dizziness, swelling of the arms or legs, and rapid weight increase (differentiation syndrome).

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. 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 DACOGEN.

5. How to store DACOGEN

Store all medicines out of the reach of children.

Store unopened vials at or below 25 °C. Unless used within 15 minutes of reconstitution, the diluted solution must be prepared using cold (2 °C to 8 °C) infusion fluids and stored at 2°C to 8°C for up to a maximum of 4 hours until administration.

Do not freeze the reconstituted solution.

Do not use DACOGEN after the expiry date, which is stated on the label.

The expiry date refers to the last day of that month. DACOGEN is made into a solution from a powder before being given. Your doctor, nurse or pharmacist is responsible for storing and preparing DACOGEN. They are also responsible for disposing of any unused DACOGEN correctly.

6. Contents of the pack and other information

What DACOGEN contains

The active substance is decitabine. Each 20 mL single dose vial contains 50 mg decitabine. After preparation with 10 mL of Sterile Water for Injection, each mL of the

infusion contains 5 mg of decitabine. The other ingredients are potassium dihydrogen phosphate, hydrochloric acid and sodium hydroxide.

What DACOGEN looks like and contents of the pack

DACOGEN is a white cake or powdery mass.

DACOGEN is supplied in 20 mL glass vial, stoppered with a grey bromobutyl stopper, and sealed with an aluminium crimp seal with a red plastic flip-off cap.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

Included in the carton, accompanying this patient information leaflet.