PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

DECEQ 50 mg powder for concentrate for solution for infusion Decitabine

Sugar free.

Please read this leaflet carefully before receiving DECEQ.

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

What is in this leaflet

1. What DECEQ is and what it is used for

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

DECEQ is used to treat a type of cancer called ‘acute myeloid leukaemia’

or ‘AML’. This is a type of cancer that affects your blood cells. You will be given DECEQ when you are first diagnosed with AML. It is used in adults.

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

2. What you need to know before you use DECEQ

DECEQ should not be administered to you:

- If you are hypersensitive (allergic) to decitabine or any of the other ingredients of DECEQ (listed in section 6).
- If you are breastfeeding.

Warnings and precautions:

Take special care with DECEQ if you:

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

Tests or checks

You will have blood tests before you start treatment with DECEQ and at

the start of each treatment cycle. These tests are to check that:

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

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

Children and adolescents

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

Other medicines and DECEQ:

Always tell your health care provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

This is because DECEQ can affect the way some other medicines work. Also, some other medicines can affect the way DECEQ 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 DECEQ.

You should not use DECEQ if you are pregnant as it may harm your baby.

Tell your doctor immediately if you become pregnant during treatment with DECEQ.

Do not breastfeed if you are using DECEQ. 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 DECEQ.
- Men should 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 effective contraception during treatment. 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 DECEQ. If this happens, not drive or use any tools or machines.

It is not always possible to predict to what extent DECEQ 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 DECEQ affects you.

DECEQ contains potassium and sodium:

DECEQ contains less than 1 mmol of potassium (39 mg) and sodium (23 mg) per dose, i.e. it is essentially ‘potassium-free’ and ‘sodium-free’.

3. How to use DECEQ

DECEQ will be given to you by a doctor or nurse who is trained in giving this type of medicine.

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

How much to use:

- Your doctor will work out your dose of DECEQ. This depends on your height and weight (body surface area).
- The dose is 20 mg/m^2 body surface area.
- DECEQ 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 have the impression that the effect of DECEQ is too strong or too weak, tell your doctor, health care provider or pharmacist.

If you receive more DECEQ than you should:

Since a health care provider will administer DECEQ, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdose.

If you forget to use DECEQ:

Since a health care provider will administer DECEQ it is very unlikely that a dose will be missed. If you miss an appointment, make another one as soon as possible. This is because for DECEQ to be as effective as possible, it is important to follow the dosing schedule.

4. Possible side effects

DECEQ can have side effects.

Not all side effects reported for DECEQ are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while receiving DECEQ, please consult your health care provider for advice.

If any of the following happens, stop receiving DECEQ 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.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to DECEQ. 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 side effects:

- Chest pain or shortness of breath (with or without fever or cough): These may be signs of any infection of the lung called “pneumonia”.
- Sepsis (a life-threatening infection of the blood caused by bacteria), which if left untreated can lead to septic shock (when the body's blood pressure falls, and organs shut down).
- Bleeding or bruising more easily than normal.
- Frequent infections such as fever, severe chills, sore throat or mouth ulcers.

- Cardiomyopathy (heart muscle disease) which can be accompanied with swelling of ankles, hands, legs and feet.

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

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

Frequent side effects:

- Urinary tract infection (strong and frequent urge to urinate, pain and burning sensation when urinating, cloudy, bloody or strong-smelling urine, abdominal pain, nausea and vomiting).
- Sinusitis (a condition in which the cavities around the nasal passages become inflamed).
- Other infections in any part of the body, caused by bacteria, virus or fungi.
- Feeling tired or looking pale – these may be signs of a drop in the number of red blood cells (anaemia).
- A drop in the number of red blood cells, white blood cells and platelets (pancytopenia).
- High sugar (glucose) levels in the blood (passing large amounts or

  urine, excessive thirst, dry mouth and skin).
- Headache.
- Nose bleeds.
- Diarrhoea, vomiting (being sick), nausea (feeling sick), mouth or tongue ulcers.
- Abnormal liver function.
- High level of ‘bilirubin’ in the blood.

Less frequent side effects:

- 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”.

Side effects occurring with an unknown frequency:

- Interstitial lung disease (an umbrella term used for a large group of diseases that cause scarring (fibrosis) of the lungs.
- Inflamed gut (enterocolitis, colitis and cecitis), 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, 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 Reactions Reporting Form**”, found online under SAHPRA’s publications: http://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of DECEQ.

5. How to store DECEQ

- Your doctor, nurse or pharmacist is responsible for storing DECEQ.
- Store at or below 25 °C.
- Keep 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 until administration.

- Discard any unused portion.
- From a microbiological point of view, unless the method of opening precludes the risk of microbial contamination, DECEQ should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.
- Do not use DECEQ after the expiry date stated on the packaging.
- Do not dispose of unused solution in drains or sewerage systems (e.g. toilets). Your doctor or health care provider will throw away any medicine that is no longer required.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What DECEQ contains:

The active substance is decitabine

Each vial of powder for concentrate for solution for infusion contains 50 mg decitabine.

After reconstitution with 10 mL of water for injections, each mL of concentrate contains 5 mg of decitabine.

The other ingredients are hydrochloric acid, potassium phosphate monobasic (E340) and sodium hydroxide (E524).

What DECEQ looks like and contents of the pack:

White to almost white lyophilised powder.

Clear, colourless, USP type I glass vial with a rubber stopper and a red aluminium flip-off seal, packed in an outer carton.

Pack size: 1 vial.

Holder of certificate of registration:

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0157

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