PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

GEMCITABINE SANDOZ 40 mg/mL (concentrate for solution for infusion)

Gemcitabine hydrochloride

Sugar free

Please read this leaflet carefully before you are given GEMCITABINE SANDOZ.

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

1. What GEMCITABINE SANDOZ is and what it is used for

GEMCITABINE SANDOZ belongs to a group of medicines called “cytotoxics”. These medicines kill dividing cells, including cancer cells.

GEMCITABINE SANDOZ may be given alone or in combination with other anti-cancer medicines, depending on the type of cancer.

GEMCITABINE SANDOZ is used in the treatment of the following types of cancer:

- Non-small cell lung cancer (NSCLC), alone or together with cisplatin.
- Pancreatic cancer.
- Breast cancer, together with paclitaxel.
- Ovarian cancer, alone or together with carboplatin.
- Bladder cancer, together with cisplatin.

2. What you need to know before you use GEMCITABINE SANDOZ

GEMCITABINE SANDOZ should not be administered to you:

- If you are hypersensitive (allergic) to gemcitabine or any of the other ingredients of GEMCITABINE SANDOZ (listed in section 6).
- If you are pregnant or breastfeeding.

Warnings and precautions:

Before the first infusion you will have samples of your blood taken to evaluate if you have sufficient kidney and liver function. Before each infusion you will have samples of your blood taken to evaluate if you have enough blood cells to receive GEMCITABINE SANDOZ. Your doctor may decide to change the dose or delay treating you depending on your general condition and if your blood cell counts are too low. Periodically you will have samples of your blood taken to evaluate your kidney and liver function.

Tell your doctor or health care provider before being given GEMCITABINE SANDOZ, if:

- You have, or have previously had liver disease, heart disease or vascular disease, problems with your lungs or your kidneys as you may not be able to receive GEMCITABINE SANDOZ.
- You have recently had, or are going to have radiotherapy as there may be an early or late radiation reaction with GEMCITABINE SANDOZ.
- You have been vaccinated recently (especially against yellow fever) as this can possibly cause bad effects with GEMCITABINE SANDOZ 40 mg/mL
- You develop breathing difficulties or feel very weak and are very pale as this may be a sign of kidney failure or problems with your lungs.
- You develop generalised swelling, shortness of breath or weight gain as this may be a sign of fluid leaking from your small blood vessels into the tissue.
- During treatment with this medicine, you get symptoms such as headache with confusion, seizure (fits) or changes in vision, call your doctor immediately. This could be a very rare nervous system side effect named posterior reversible encephalopathy syndrome.
- You have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using gemcitabine.

Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis and acute generalized exanthematous pustulosis (AGEP) have been reported in association with gemcitabine treatment. Seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Children

Do not give GEMCITABINE SANDOZ to children under the age of 18 years due to the insufficient data on safety and efficacy.

Other medicines and GEMCITABINE SANDOZ

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

- If you are receiving radiotherapy, also called radiation therapy (used to treat patients with cancer).
- If you are given vaccinations (a treatment which makes the body stronger against a particular infection) e.g. yellow fever.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask a pharmacist or another healthcare professional for advice before taking this medicine.

Pregnancy:

If you are pregnant, or thinking about becoming pregnant, tell your doctor. The use of GEMCITABINE SANDOZ should be avoided during pregnancy. Your doctor will discuss with you the potential risk of taking GEMCITABINE SANDOZ during pregnancy.

Breastfeeding:

If you are breastfeeding, tell your doctor.

You must discontinue breastfeeding during GEMCITABINE SANDOZ treatment.

Fertility:

Males are advised not to father a child during and up to 6 months following treatment with GEMCITABINE SANDOZ. If you would like to father a child during the treatment or in the 6 months following treatment, please consult your doctor, pharmacist or health care provider. You may want to seek counselling on sperm storage before starting your therapy.

Driving and using machinery

GEMCITABINE SANDOZ may make you feel sleepy, particularly if you have consumed any alcohol.

Do not drive a car or use machinery until you are sure that GEMCITABINE SANDOZ has not made you feel sleepy.

It is not always possible to predict to what extent GEMCITABINE SANDOZ 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 GEMCITABINE SANDOZ affects them.

3. How to use GEMCITABINE SANDOZ

GEMCITABINE SANDOZ will be administered in hospital, by a healthcare professional with an injection.

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

The usual dose of GEMCITABINE SANDOZ is 1 000 to 1 250 mg for every square metre of your body’s surface area. Your height and weight are measured to work out the surface area of your body. Your doctor will use this body surface area to work out the right dose for you. This dosage may be adjusted, or treatment may be delayed depending on your blood cell counts and on your general condition.

How frequently you receive your GEMCITABINE SANDOZ infusion depends on the type of cancer that you are being treated for.

You will always receive GEMCITABINE SANDOZ only after dilution by infusion into one of your veins. The infusion will last approximately 30 minutes.

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

If you take more GEMCITABINE SANDOZ than you should

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

If you forget to take of GEMCITABINE SANDOZ

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

4. POSSIBLE SIDE EFFECTS

GEMCITABINE SANDOZ can have side effects.

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

Should your general health worsen or if you experience any untoward effects while taking GEMCITABINE SANDOZ please consult your doctor, pharmacist or other healthcare professional for advice.

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

- Serious reaction where swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing, rash or itching (anaphylactic reaction).

- Fainting.

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

- Bleeding from the gums, nose or mouth or any bleeding that would not stop, reddish or pinkish urine, unexpected bruising (since you might have less platelets than normal which is frequent).
- Tiredness, feeling faint, becoming easily breathless or if you look pale (since you might have less haemoglobin than normal which is frequent).
- Mild to moderate skin rash/ itching, or fever (frequent); (allergic reactions).
- Temperature of 38 ºC or greater, sweating or other signs of infection (since you might have less white blood cells than normal accompanied by fever also known as febrile neutropenia) (frequent).
- Pain, redness, swelling or sores in your mouth (stomatitis) (frequent).
- Irregular heart rate (arrhythmia) (less frequent).
- Extreme tiredness and weakness, purpura or small areas of bleeding in the skin (bruises), acute renal failure (low urine output or no urine output), and signs of infection (haemolytic uraemic syndrome). It may be fatal (less frequent).
- Difficulty breathing.
- Severe chest pain (myocardial infarction) (less frequent).
- Generalised swelling, shortness of breath or weight gain, as you might have fluid leakage from small blood vessels into the tissues (capillary leak syndrome) (less frequent).

- Headache with changes in vision, confusion, seizures or fits (posterior reversible encephalopathy syndrome) (less frequent).
- Severe rash with itching, blistering or peeling of the skin (Stevens-Johnson syndrome, toxic epidermal necrolysis) (less frequent).
- Extreme tiredness and weakness, purpura or small areas of bleeding in the skin (bruises), acute renal failure (low urine output or no urine output), and signs of infection. These may be features of thrombotic microangiopathy (clots forming in small blood vessels) and haemolytic uraemic syndrome, which may be fatal.
- A red, scaly widespread rash with bumps under the swollen skin (including your skin folds, trunk, and upper extremities) and blisters accompanied by fever (Acute Generalized Exanthematous Pustulosis (AGEP)) (frequency not known).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Low white blood cells,
- Vomiting,
- Nausea,
- Hair loss,
- Liver problems: Found through abnormal blood test results,
- Blood in urine,
- Abnormal urine tests: Protein in urine,
- Flu like symptoms including fever,
- Swelling of ankles, fingers, feet, face (oedema),

- Poor appetite (anorexia),
- Headache,
- Sleeping problems,
- Sleepiness,
- Cough,
- Runny nose,
- Constipation,
- Diarrhoea,
- Itching,
- Sweating,
- Muscle pain,
- Back pain,
- Fever,
- Weakness,
- Chills,
- Increased liver values (bilirubin),
- Infections.

Less frequent side effects:

- Scarring of the air sacs of the lung (interstitial pneumonitis),
- Wheeze (spasm of the airways),
- Scarring of the lungs (abnormal chest X-ray/scan),
- Stroke,
- Heart failure,
- Kidney failure,

- Serious liver damage, including liver failure and death,
- Skin scaling, ulceration or blister formation,
- Sloughing of the skin and severe skin blistering,
- Injection site reactions,
- Severe lung inflammation causing respiratory failure (adult respiratory distress syndrome),
- A skin rash like severe sunburn which can occur on skin that has previously been exposed to radiotherapy (radiation recall),
- Fluid in the lungs,
- Scarring of the air sacs of the lung associated with radiation therapy (radiation toxicity) ,
- Gangrene of fingers or toes,
- Inflammation of the blood vessels,
- Increased liver values (GGT),
- Increased platelet count,
- Inflammation of the lining of the large bowel, caused by reduced blood supply (ischaemic colitis),
- *Thrombotic microangiopathy:* Clots forming in small blood vessels.

Frequency unknown side effects:

- *Sepsis:* When bacteria and their toxins circulate in the blood and starts to damage the organs,
- *Pseudocellulitis:* Skin redness with swelling,
- Low haemoglobin level (anaemia), will be detected by a blood test.

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, 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 GEMCITABINE SANDOZ. Suspected adverse reactions can also be reported directly to the HCR via https://pvi1j.solutions.iqvia.com or the e-mail address: adverse.event.sac@sandoz.com.

5. How to store GEMCITABINE SANDOZ

Store all medicines out of reach of children.

- Do not use after the expiry date stated on the label or carton.
- Store at or between 2 °C to 8 °C (in a refrigerator).
- Do not freeze.
- Do not use GEMCITABINE SANDOZ, if the solution appears discoloured or contains visible particles, 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 GEMCITABINE SANDOZ contains:

The active substance is gemcitabine (as hydrochloride).

Each mL concentrate for solution for infusion contains 40 mg gemcitabine (as hydrochloride).

Each vial of 5 mL contains 200 mg gemcitabine (as hydrochloride).

Each 25 mL vial contains 1000 mg gemcitabine (as hydrochloride).

Each 50 mL vial contains 2000 mg gemcitabine (as hydrochloride).

The other ingredients are: Water for injections and diluted hydrochloric acid (for pH adjustment).

What GEMCITABINE SANDOZ looks like and contents of the pack

GEMCITABINE SANDOZ is a clear, colourless to pale yellow concentrated solution for infusion.

The container closure system for GEMCITABINE SANDOZ consists of colourless glass vials of glass type I, with a capacity of 5 mL and 50 mL with dimensions according to DIN ISO 8362.

The vials are closed with rubber stoppers according to Ph. Eur. and to DIN ISO 8362 with an aluminium crimp cap. All type of vials use stopper of the same quality and size.

Pack sizes:

5 mL vial: 1 vial, 5 vials, 10 vials

25 mL vial: 1 vial

50 mL vial: 1 vial

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

Waterfall 5-Ir

Magwa Crescent West

Waterfall City

Jukskei View

2090

This leaflet was last revised in

20 December 2024

Registration number

45/26/1159

[1]Company Reg. No.: 1990/001979/07