

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS:** **S4****SPALGEM 200 mg powder for injection****SPALGEM 1000 mg powder for injection**

Gemcitabine

Sugar Free

Read all of this leaflet carefully before you are given SPALGEM

- 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 this leaflet:

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

1. What SPALGEM is and what it is used for

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

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

SPALGEM 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, together with carboplatin.
- bladder cancer, together with cisplatin.

2. What you need to know before you use SPALGEM

SPALGEM should not be administered to you:

- if you are allergic (hypersensitive) to gemcitabine or any of the other ingredients (see section 5) of **SPALGEM**.
- if you are pregnant or breast-feeding

Warnings and precautions

Before the first infusion you will have samples of your blood taken to check if your liver and kidneys are working well enough for you to receive **SPALGEM**. Before each infusion you will have samples of your blood taken to check if you have enough blood cells to receive **SPALGEM**. 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 check how well your kidneys and liver are working.

Tell your doctor or healthcare professional before being given SPALGEM:

If you have, or have previously had liver disease, heart disease, vascular disease (any abnormal condition of the blood vessels) or problems with your kidneys.

If you have recently had, or are going to have radiotherapy, as there may be an early or late radiation reaction with **SPALGEM**.

If you have been vaccinated recently, as this can possibly cause bad effects with **SPALGEM**.

If during treatment with **SPALGEM**, you get symptoms such as headache with confusion, seizures (fits) or changes in vision, call your doctor right away. This could be a very rare nervous system side effect named posterior reversible encephalopathy syndrome.



If 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.

If 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.

Children and adolescents

This medicine is not recommended for use in children under 18 years of age due to insufficient data on safety and efficacy.

Other medicines and SPALGEM

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

Pregnancy, breast-feeding and fertility

Pregnancy

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

Breast-feeding

If you are breast-feeding, tell your doctor.

You must discontinue breast-feeding during **SPALGEM** treatment.

Fertility

Men are advised not to father a child during and up to 6 months following treatment with **SPALGEM**. If you would like to father a child during the treatment or in the 6 months following treatment, seek advice from your doctor or pharmacist. You may want to seek counselling on sperm storage before starting your therapy.

Driving and using machines



SPALGEM 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 **SPALGEM** treatment has not made you feel sleepy.

3. How **SPALGEM** powder for injection is given

The usual dose of **SPALGEM** is 1000-1250 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 **SPALGEM** infusion depends on the type of cancer that you are being treated for.

A hospital pharmacist or doctor will have dissolved the **SPALGEM** powder before it is given to you.

You will always receive **SPALGEM** by infusion into one of your veins. The infusion will last approximately 30 minutes.

If you have further questions on the use of **SPALGEM** ask your doctor or pharmacist.

If you are given more **SPALGEM** than you should

Since a healthcare professional will administer **SPALGEM**, he/she will control the dosage.

However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use **SPALGEM**

Since a healthcare professional will administer **SPALGEM**, it is unlikely that the dose will be missed.



4. Possible side effects

SPALGEM can have side effects.

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

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

- Bleeding from the gums, nose or mouth or any bleeding that would not stop, reddish or pinkish urine, unexpected bruising.
- Tiredness, feeling faint, becoming easily breathless or if you look pale..
- Mild to moderate skin rash / itching, or fever (allergic reactions).
- Temperature of 38°C 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) .
- Pain, redness, swelling or sores in your mouth (stomatitis).
- Irregular heart rate (arrhythmia)
- 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.
- Difficulty breathing (it is common to have mild breathing difficulty soon after the **SPALGEM** infusion which soon passes, however uncommonly or rarely there can be more severe lung problems)
- Severe chest pain (myocardial infarction).
- Severe hypersensitivity/allergic reaction with severe skin rash including red itchy skin, swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause



difficulty in swallowing or breathing), wheezing, fast beating heart and you may feel you are going to faint (anaphylactic reaction).

- Generalised swelling, shortness of breath or weight gain, as you might have fluid leakage from small blood vessels into the tissues (capillary leak syndrome)
- Headache with changes in vision, confusion, seizures or fits (posterior reversible encephalopathy syndrome)
- Severe rash with itching, blistering or peeling of the skin (Stevens-Johnson syndrome, toxic epidermal necrolysis)

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

Tell your doctor if you notice any of the following:

Frequent side effects

Low white blood cells

Difficulty breathing

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

Insomnia



Sleepiness

Cough

Runny nose

Constipation

Diarrhoea

Itching

Sweating

Muscle pain

Back pain

Fever

Weakness

Chills

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)

Heart failure

Kidney failure

Serious liver damage, including liver failure

Stroke

Frequency unknown side effects

Low blood pressure

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 (peripheral vasculitis)

Increased platelet count

Inflammation of the lining of the large bowel, caused by reduced blood supply (ischaemic colitis)

Low haemoglobin level (anaemia), low white blood cells and low platelet count will be detected by a blood test.

You might have any of these symptoms and/or conditions. You must tell your doctor as soon as possible when you start experiencing any of these side effects.

If you are concerned about any side effects, talk to your doctor.

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

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. 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 SPALGEM

5. How to store SPALGEM

Store all medicines out of reach of children.

Store at or below 30 °C



Store in the original package to protect from light.

Contents of the pack and other information

What SPALGEM contains

- The active substance is gemcitabine
- The other ingredients are:
- Sodium acetate, sodium hydroxide, water for injection

What SPALGEM looks like and contents of the pack

SPALGEM 200 mg is a White to off white coloured lyophilized cake or powder filled in 10 mL clear tubular vial with 20 mm lyo stopper grey bromobutyl (single slotted) and sealed with 20 mm easy to open C/L alu seals with matt finish plastic german blue botton in mono cartons.

SPALGEM 1000 mg is a White to off white coloured lyophilized cake or powder filled in 50 mL clear tubular vial with 20 mm lyo stopper grey bromobutyl (single slotted) and sealed with 20 mm easy to open C/L alu. seals with matt finish plastic german blue botton in mono cartons.

Holder of Certificate of Registration

Ruby Pharmaceuticals (Pty) Ltd

Unit 1, 96 Hartley Road

Durban, 4091

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