PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

ONCOGEM 200 mg and 1000 mg, Powder for Injection

Gemcitabine

Contains sugar- Mannitol

ONCOGEM 200: Gemcitabine Hydrochloride (200 mg)

ONCOGEM 1000: Gemcitabine Hydrochloride (1000 mg)

Read all of this leaflet carefully before you start receiving ONCOGEM

- 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.
- **ONCOGEM** 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 **ONCOGEM** is and what it is used for
2. What you need to know before you take/use/receive **ONCOGEM**
3. How to use **ONCOGEM**
4. Possible side effects

5. How to store **ONCOGEM**

6. Contents of the pack and other information.

1. What ONCOGEM is and what it is used for

ONCOGEM (Gemcitabine) belongs to a group of medicines called “cytotoxics”. These medicines kill dividing cells, including cancer cells.

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

ONCOGEM 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.

Talk to your doctor before using gemcitabine if:

• 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 POSSIBLE SIDE EFFECTS.

2. What you need to know before you use ONCOGEM

Do not take ONCOGEM

- if you are hypersensitive (allergic) to {*Gemcitabine*} or any of the other ingredients of ONCOGEM (listed in **section 6)**.
- 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 **ONCOGEM**. Before each infusion you will have samples of your blood taken to check if you have enough blood cells to receive **ONCOGEM**. 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 **ONCOGEM**:

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 **ONCOGEM**.

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

If during treatment with **ONCOGEM**, 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 ONCOGEM

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

Pregnancy, breastfeeding and fertility

Pregnancy

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

Breast-feeding

If you are breast-feeding, tell your doctor.

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

Fertility

Men are advised not to father a child during and up to 6 months following treatment with **ONCOGEM**. 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

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

ONCOGEM contains

Contains Sugar: Mannitol 200 mg

3. How to take ONCOGEM

Do not share medicines prescribed for you with any other person.
Always take ONCOGEM exactly as your doctor or pharmacist has told you.
You should check with your doctor or pharmacist if you are not sure.

The usual dose of **ONCOGEM** 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 **ONCOGEM** infusion depends on the type of cancer that you are being treated for.

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

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

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

Your doctor will tell you how long your treatment with ONCOGEM will last.

Do not stop treatment early because …

If you have the impression that the effect of ONCOGEM is too strong or too weak, tell your doctor or pharmacist.

If you are given more ONCOGEM than you should

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

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

If you forget to receive ONCOGEM

Do not receive a double dose to make up for forgotten individual doses.

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

4. Possible side effects

ONCOGEM can have side effects.

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

If any of the following happens, stop receiving ONCOGEM 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 38ºC 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 ONCOGEM 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 ONCOGEM. You may need urgent medical attention or hospitalisation.

Please inform your doctor immediately. 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)). Severe rash with itching, blistering or peeling of the skin (Stevens-Johnson syndrome, toxic epidermal necrolysis).

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,pharmacist or nurse. You can also report side effects to SAHPRA via the "**Adverse drug reaction and quality problem reporting form**", found online under SAHPRA's publications https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problemreporting-form/ or to Cipla Medpro (Pty) Ltd by e-mail: drugsafetysa@cipla.com

or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of ONCOGEM.

5. How to store ONCOGEM

Store at or below 30 °C.

Store all medicines out of reach of children.

Store in the original container.

Keep the container in the outer carton.

Do not use after the expiry date stated on the container.

Return all unused medicine to your pharmacist.

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

For the reconstituted solution:

The reconstituted solution must be used immediately.

Do not refrigerate as crystallisation may occur.

For single use only.

Any unused portion must be discarded.

Do not use after the expiry date stated on the packaging material.

Return all unused medicine to your pharmacist.

6. Contents of the pack and other information

What ONCOGEM contains

The active substance is Gemcitabine.

The other ingredients are…**What ONCOGEM looks like and contents of the pack**

ONCOGEM 200

White to off-white freeze dried cake in an EP type I, 10 ml transparent flint glass vial closed with a 20 mm grey bromobutyl lyophilisation stopper and polypropylene grade, red-coloured 20 mm aluminium flip-off-tear-off seal.

ONCOGEM 1000

White to off-white freeze dried cake in an EP type I, 10 ml transparent flint glass vial closed with a 20 mm grey bromobutyl lyophilisation stopper and polypropylene grade, red-coloured 20 mm aluminium flip-off-tear-off seal.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

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Customer Care: 080 222 6662

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Registration number(s)

ONCOGEM 200: 43/26/1171

ONCOGEM 1000: 43/26/1172

Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

PLACE HOLDER:

The QR Code to be generated

and included after approval.