Patient Information Leaflet

Read all of this leaflet carefully before you receive MYLAN GEMCITABINE.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **MYLAN GEMCITABINE** 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.

SCHEDULING STATUS:

S4

PROPRIETARY NAME AND DOSAGE FORM:

MYLAN GEMCITABINE 200 mg (Powder for solution for injection)

MYLAN GEMCITABINE 1 g (Powder for solution for injection)

Gemcitabine

WHAT MYLAN GEMCITABINE CONTAINS:

Active ingredient:

Each 10 ml vial of **MYLAN GEMCITABINE 200 mg** contains gemcitabine hydrochloride equivalent to 200 mg of gemcitabine free base.

Each 50 ml vial **of MYLAN GEMCITABINE 1 g** contains gemcitabine hydrochloride equivalent to 1 g gemcitabine free base.

The inactive ingredients are:

Mannitol, sodium acetate trihydrate, sodium hydroxide and hydrochloric acid.

WHAT MYLAN GEMCITABINE IS USED FOR:

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MYLAN GEMCITABINE belongs to a group of medicines called "cytotoxics".

These medicines kill dividing cells, including cancer cells.

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

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

- lung cancer
- pancreatic cancer
- bladder cancer
- breast cancer
- ovarian cancer

BEFORE YOU RECEIVE MYLAN GEMCITABINE:

You must not receive MYLAN GEMCITABINE:

- If you know that you are allergic to the active ingredient gemcitabine, or any of the other ingredients (see above)
- If you are pregnant or breast-feeding (see **PREGNANCY AND LACTATION**)
- Not to be used in children younger than 12 years

Take special care with MYLAN GEMCITABINE:

MYLAN GEMCITABINE should be administered only by a doctor experienced with cancer chemotherapeutic agents.

You are allowed to be treated with **MYLAN GEMCITABINE** under special precautions when your doctor is informed on the diseases you suffer from listed below and has agreed that you receive **MYLAN GEMCITABINE:**

- If your have an infection

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- If you have liver disease
- If you have kidney disease
- If you have asthma or other lung disease If your bone marrow is depressed

Other precautions before or during receiving treatment with MYLAN GEMCIT ABINE:

It will be necessary for your doctor to carefully monitor you by performing regular blood tests to monitor blood counts, before or during treatment with **MYLAN GEMCITABINE.** It will also be necessary for your doctor to do regular liver and kidney function checks.

Do not have any immunisations without your doctor's approval and avoid any contact with persons with infections, especially during periods of low blood counts.

Before you begin using any new medicine (prescription or non-prescription) or if you develop any new medical problem while you are using this medicine, check with your doctor, nurse, or pharmacist.

Pregnancy and breast-feeding:

If you are of childbearing age, it is very important for you to make use of contraceptive measures during and for at least three months after stopping treatment with **MYLAN GEMCITABINE.**

If you are pregnant or breast-feeding your baby while taking MYLAN GEMCITABINE please consult your doctor, pharmacist or other health care professional for advice.

USING MYLAN GEMCITABINE WITH OTHER MEDICINES:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **MYLAN GEMCITABINE** with these medicines may cause undesirable

interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

Caution is necessary if you receive other medication, especially other bone marrow depressants, other immunosuppressants, or other cytotoxic medication or radiation therapy.

INSTRUCTIONS ON HOW TO INJECT MYLAN GEMCITABINE:

Patients receiving MYLAN GEMCITABINE should be under the supervision of a doctor experienced in cancer chemotherapy.

You will never be expected to give yourself **MYLAN GEMCITABINE.** It will always be given to you by a qualified health professional and under carefully controlled conditions.

FOR ADULTS ONLY:

Dosing

MYLAN GEMCITABINE will be administered only by intravenous infusion by your doctor who is experienced in cancer chemotherapy or under his supervision. It is also recommended that equipment and medications necessary for treatment of complications be readily available.

Your doctor will determine the exact dosage that you will need. The dosage may vary according to your body mass, if you are an elderly patient, or if you suffer from kidney or liver disease. The recommended dose is administered by intravenous infusion over a 30 minute period and depending on the type of cancer you have or the combination treatment that has been prescribed for you, the dosage will be repeated in weekly cycles as determined by your doctor.

Patients with kidney disease:

Your dosage will need to be adjusted if you suffer from kidney disease.

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Patients with liver disease:

Your dosage will need to be adjusted if you have liver disease.

Elderly patients:

No dosage adjustment may be necessary if you are an elderly patient.

Paediatric Use:

The safety and effectiveness of MYLAN GEMCITABINE in children have not been established.

Do not share medicines prescribed for you with others.

If you receive more MYLAN GEMCITABINE than you should:

As **MYLAN GEMCITABINE** is most likely to be given to you in hospital, under the supervision of a doctor, it is unlikely that you will receive an incorrect dose. However if you have any concerns about the dose you receive, please tell your doctor.

POSSIBLE SIDE-EFFECTS:

MYLAN GEMCITABINE may cause unwanted effects. Although not all of these side-effects may occur, if they do occur they may need medical attention.

The following side-effects may occur frequently:

Nausea; vomiting; diarrhoea; constipation; stomatitis (sores, ulcers, or white spots on lips and in mouth); allergic skin rash, frequently associated with itching; mild proteinuria (cloudy urine) and haematuria (blood in the urine); oedema (swelling of fingers, feet, or lower legs); fever, usually in conjunction with other flu-like symptoms; blood disorders such as leucopenia

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(usually without symptoms), thrombocytopenia (decreased blood platelets manifested by black tarry stools, blood in urine or stools, pinpoint red spots on skin, unusual bleeding or bruising) and anaemia (manifested by unusual tiredness or weakness); somnolence (drowsiness); dyspnoea (shortness of breath); alopecia (loss of hair).

The following side-effects may occur less frequently:

Allergic/hypersensitivity reaction; myocardial infarct (pain in chest, arm or back; pressure or squeezing in chest); heart failure; dysrhythmia (fast or irregular heartbeat); hypotension (dizziness, fainting, lightheadedness); bronchospasm (shortness of breath, troubled breathing, tightness in chest, and/or wheezing); pulmonary oedema (coughing; noisy, rattling, or troubled breathing); interstitial pneumonitis (coughing; shortness of breath); kidney failure.

Not all side-effects reported for [MYLAN GEMCITABINE are included in this leaflet. Should your general health worsen while receiving MYLAN GEMCITABINE, please consult your doctor, pharmacist or other health care professional for advice.

STORAGE AND DISPOSAL INFORMATION:

KEEP OUT OF THE REACH OF CHILDREN.

Store at or below 25 °c. Reconstituted solutions (vials) and infusion solutions (in sodium chloride 0,9 %) must be used immediately or within 12 hours when stored at or below 25 °C. **Reconstituted solutions must not be refrigerated as crystallisation may occur.**

PRESENTATION:

Clear colourless glass vial, with a grey bromobutyl stopper and a lavender aluminium flip-off seal, packed in a carton.

Or

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Clear tubular glass vial with a 20 mm grey siliconised bromobutyl rubber stopper and a 20 mm aluminium flip-off seal.

IDENTIFICATION:

A white to off-white lyophilised powder.

REGISTRATION NUMBERS:

MYLAN GEMCITABINE 200 mg: 43/26/0068

MYLAN GEMCITABINE 1 g: 43/26/0046

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Viatris South Africa (Pty) Ltd

4 Brewery Street,

Isando

Johannesburg,

1609

DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

20 April 2012

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