

SCHEDULING STATUS

S4

MYLAN GEMCITABINE 200 mg, powder for solution for injection**MYLAN GEMCITABINE 1 g, powder for solution for injection****Gemcitabine****Contains sugar:****MYLAN GEMCITABINE 200 mg contains sugar: Mannitol 200 mg/10 ml vial when reconstituted with 5 ml of 0,9 % sodium chloride****MYLAN GEMCITABINE 1 g contains sugar: Mannitol 1 g/50 ml vial when reconstituted with 25 ml of 0,9 % sodium chloride****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, pharmacist, nurse or other healthcare provider.

What is in this leaflet

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

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

What MYLAN GEMCITABINE is:

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.

What it is used for:

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

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

2. What you need to know before you receive MYLAN GEMCITABINE

MYLAN GEMCITABINE should not be administered to you:

- if you are hypersensitive (allergic) to the active substance gemcitabine or any of the other ingredients of MYLAN GEMCITABINE (listed in section 6);
- if you are pregnant or breastfeeding (see section 'Pregnancy and lactation');
- if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using gemcitabine as contained in MYLAN GEMCITABINE.

Not to be used in children.

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Warnings and precautions

Tell your doctor or healthcare provider before being given the injection;

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

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

- if you have an infection;
- if you have liver disease;
- if you have kidney disease;
- if you have asthma or other lung disease;
- if your bone marrow is depressed.

Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis and acute generalised 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 (see section 4 'Possible side effects').

Other precautions before or during receiving treatment with MYLAN GEMCITABINE:

- 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.

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Children and adolescents

Do not give MYLAN GEMCITABINE to children.

Other medicines and MYLAN GEMCITABINE

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

Tell your doctor if you are taking any of the following medicines:

- Caution is necessary if you receive other medicines, especially other bone marrow depressants, other immunosuppressants, or other cytotoxic medicines or radiation therapy.
- Yellow fever and other live attenuated vaccines are not recommended.

Pregnancy and breastfeeding and fertility

The safety of MYLAN GEMCITABINE during pregnancy and whilst breastfeeding has not been established

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking MYLAN GEMCITABINE.

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

Driving and using machinery

MYLAN GEMCITABINE may cause a state of drowsiness or strong desire to fall asleep.

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

MYLAN GEMCITABINE contains mannitol

MYLAN GEMCITABINE contains mannitol which may have an effect on the control of your blood sugar if you have diabetes mellitus and may have a laxative effect.

3. How to receive MYLAN GEMCITABINE

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

Do not share medicines prescribed for you with others.

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

The usual dose is:

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 medicines 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

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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.

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.

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

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

If you receive more MYLAN GEMCITABINE than you should

Since a healthcare professional will administer MYLAN GEMCITABINE, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget or missed a dose of MYLAN GEMCITABINE

Since a healthcare provider will administer MYLAN GEMCITABINE, it is unlikely that the dose will be missed.

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4. Possible side effects

MYLAN GEMCITABINE can have side effects.

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

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

- oedema: swelling of fingers, feet, or lower legs, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- fainting,
- severe rash with itching, blistering or peeling of the skin (Stevens-Johnson syndrome, toxic epidermal necrolysis (TEN)),
- 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 Generalised Exanthematous Pustulosis (AGEP)) (frequency not known).
- myocardial infarct (pain in chest, arm or back; pressure or squeezing in chest),
- thrombocytopenia (decreased blood platelets manifested by black tarry stools, blood in urine or stools, pinpoint red spots on skin, unusual bleeding from the gums, nose or mouth or any bleeding that would not stop, or bruising),
- 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),
- extreme tiredness and weakness, purpura or small areas of bleeding in the skin (bruises), acute renal failure (low urine output/no urine output), and signs of infection (haemolytic uraemic syndrome). It may be fatal,

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- headache with changes in vision, confusion, seizures or fits (posterior reversible encephalopathy syndrome),
- generalised swelling, shortness of breath or weight gain, as you might have fluid leakage from small blood vessels into the tissues (capillary leak syndrome),
- serious damage to your liver, including liver failure and death,
- a dangerous and potentially fatal condition that happens when the blood flow to a large area of tissue is cut off (gangrene).

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

- 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),
- dysrhythmia (fast or irregular heartbeat),
- anaemia (manifested by unusual tiredness or weakness),
- pain, redness, swelling, sores, ulcers, or white spots on lips and in your mouth (stomatitis),
- mild to moderate skin rash/itching, or fever (allergic reactions),
- mild proteinuria (cloudy urine) and haematuria (blood in the urine).

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

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Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- nausea; vomiting; diarrhoea; constipation,
- fever, usually in conjunction with other flu-like symptoms,
- blood disorders such as leucopenia (usually without symptoms),
- somnolence (drowsiness),
- alopecia (loss of hair).

The following side effects have been reported less frequently:

- allergic/hypersensitivity reaction at injection site,
- hypotension (dizziness, fainting, light-headedness)
- kidney failure.

The following side effects have been reported but the frequency is unknown:

- inflammation in the blood vessels (peripheral vasculitis),
- blood flow to part of the large intestine is temporarily reduced (ischaemic colitis).

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

Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the “**6.04 Adverse Drug Reactions Reporting Form**”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>

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

5. How to store MYLAN GEMCITABINE

- 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.**
- Store all medicines out of reach of children.
- Keep the container in the outer carton.
- Do not use after the expiry date stated on the label/carton/bottle.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What MYLAN GEMCITABINE contains:

The active substance is:

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 other ingredients are:

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

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What MYLAN GEMCITABINE looks like and contents of the pack:

What MYLAN GEMCITABINE looks like:

A white to off-white lyophilised powder.

Contents of the pack:

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

or

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

Holder of Certificate of Registration and Manufacturer

Viatrix South Africa (Pty) Ltd

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MYLAN GEMCITABINE 1 g: 43/26/0046

Access to the corresponding Professional Information

Can be obtained on the SAHPRA website.