PACKAGE LEAFLET: INFORMATION FOR THE USER

GEMCITABINE MYLAN 200mg & GEMCITABINE MYLAN 1g, powder for solution for infusion
Gemcitabine

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

Gemcitabine Mylan belongs to a group of medicines called "cytotoxics". These medicines kill dividing cells, including cancer cells.

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

Gemcitabine Mylan 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 GEMCITABINE MYLAN

Do not use Gemcitabine Mylan:
- if you are allergic to gemcitabine or any of the other ingredients of this medicine (listed in section 6).
- if you are breast-feeding

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using Gemcitabine Mylan.
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 Mylan. 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.

If you have, or have previously had liver disease, heart disease, vascular disease or problems with your kidneys talk to your doctor or hospital pharmacist as you may not be able to receive Gemcitabine Mylan.

If you have recently had, or are going to have radiotherapy, please tell your doctor as there may be an early or late radiation reaction with Gemcitabine Mylan.

If you have been vaccinated recently please tell your doctor as this can possibly cause bad effects with Gemcitabine Mylan.

If you develop breathing difficulties or feel very weak and are very pale, please tell your doctor 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, please tell your doctor as this may be a sign of fluid leaking from your small blood vessels into the tissue.

Other medicines and GEMCITABINE MYLAN
Tell your doctor or hospital pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy, breast-feeding and fertility

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

Breast-feeding
If you are breast-feeding, tell your doctor.
You must discontinue breast-feeding during Gemcitabine Mylan treatment.

Fertility
Men are advised not to father a child during and up to 6 months following treatment with Gemcitabine Mylan. 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
Gemcitabine Mylan 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 Mylan treatment has not made you feel sleepy.

Important information about some of the ingredients of Gemcitabine Mylan
Gemcitabine Mylan (200 mg and 1000 mg vials) contains less than 1 mmol sodium per vial, i.e. essentially ‘sodium-free’.
Gemcitabine Mylan (2000 mg vial) contains 1.5 mmol sodium per vial. To be taken into consideration by patients on a controlled sodium diet.

3. How to use GEMCITABINE MYLAN

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

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

You will always receive Gemcitabine Mylan 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.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You must contact your doctor immediately if you notice any of the following:
- Fever or infection (common): if you have a temperature of 38ºC or greater, sweating or other signs of infection (since you might have less white blood cells than normal which is very common).
- Irregular heart rate (arrhythmia) (uncommon).
- Pain, redness, swelling or sores in your mouth (common).
- Allergic reactions: if you develop skin rash (very common) / itching (common), or fever (very common). Contact your doctor if you get a severe rash or itching or blistering (Stevens - Johnson syndrome or Toxic epidermal necrolysis).
- Tiredness, feeling faint, becoming easily breathless or if you look pale (since you might have less haemoglobin than normal which is very common).
- 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 very common).
- Difficulty breathing (it is very common to have mild breathing difficulty soon after the Gemcitabine Mylan infusion which soon passes, however uncommonly or rarely there can be more severe lung problems)
- Generalised swelling, shortness of breath or weight gain, as you might have fluid leakage from small blood vessels into the tissues (very rare).

Side effects with Gemcitabine Mylan may include:

Very common: may affect more than 1 in 10 people
Low haemoglobin level (anaemia)
Low white blood cells
Low platelet count
Difficulty breathing
Vomiting
Nausea
Skin rash- allergic skin rash, frequently itchy
Hair loss
Liver problems: found through abnormal blood test results
Blood in urine
Abnormal urine tests: protein in urine
Flu like symptoms including fever
Oedema (swelling of ankles, fingers, feet, face)

Common: may affect up to 1 in 10 people

Fever accompanied by low white blood cell count (febrile neutropenia)
Anorexia (poor appetite)
Headache
Insomnia
Sleepiness
Cough
Runny nose
Constipation
Diarrhoea
Pain, redness, swelling or sores in the mouth
Itching
Sweating
Muscle pain
Back pain
Fever
Weakness
Chills

Uncommon: may affect up to 1 in 100 people
Interstitial pneumonitis (scarring of the air sacs of the lung)
Spasm of the airways (wheeze)
Abnormal chest X ray/scan (scarring of the lungs)
Stroke
Irregular heart beat (arrhythmia)
Heart failure
Serious liver damage, including liver failure
Kidney failure

Rare: may affect up to 1 in 1,000 people
Heart attack (myocardial infarction)
Low blood pressure
Skin scaling, ulceration or blister formation
Injection site reactions
Gangrene of fingers or toes
Fluid in the lungs
Adult respiratory distress syndrome (severe lung inflammation causing respiratory failure)
Severe skin reactions, including desquamation and bullous skin eruptions
Radiation recall (a skin rash like severe sunburn) which can occur on skin that has previously been exposed to radiotherapy

Very rare: may affect up to 1 in 10,000 people
Increased platelet count
Anaphylactic reaction (severe hypersensitivity/ allergic reaction)
Sloughing of skin and severe skin blistering
Ischaemic colitis (inflammation of the lining of the large bowel, caused by reduced blood supply)
Capillary leak syndrome (fluids from your small blood vessels leak out into the tissue)

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.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via IMB

Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.imb.ie; e-mail: imbpharmacovigilance@imb.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store GEMCITABINE MYLAN

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the vial and box. The expiry date refers to the last day of that month.

Before reconstitution: this medicinal product does not require any special storage conditions.

Reconstituted solution: The product should be used immediately. When prepared as directed, chemical and physical in-use stability of reconstituted solutions of gemcitabine were demonstrated for 24 hours at 25°C. Further dilution by a healthcare provider may be done. Solutions of reconstituted gemcitabine should not be refrigerated, as crystallisation may occur.

This medicine is for single use only; any unused solution should be discarded under the local requirements.

6. Contents of the pack and other information

What Gemcitabine Mylan contains

The active substance is gemcitabine. Each vial contains 200 mg or 1000 mg or 2000 mg of gemcitabine (as gemcitabine hydrochloride).
1 mL of solution for infusion contains 38 mg of gemcitabine.

The other ingredients are mannitol (E421), sodium acetate, hydrochloric acid and sodium hydroxide.

What Gemcitabine Mylan looks like and contents of the pack

This medicine is a powder for solution for infusion.
Vial of 200 mg of powder. Box of 1, 5, 10 or 20 vials.
Vial of 1000 mg of powder. Box of 1, 5, 10 or 20 vials.
Vial of 2000 mg of powder. Box of 1, 5, 10 or 20 vials.
Not all of the presentations may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Generics [UK] Limited, Potters Bar, Hertfordshire EN6 ITL, UK

Manufacturer:
MYLAN S.A.S, 117 allée des Parcs, 69800 Saint Priest Cedex, France
Or
CEMELOG BRS LTD, 2040 Budaörs, Vasut u.13., Hungary.

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The following information is intended for healthcare professionals only:

Handling of this cytotoxic agent by health professional requires a set of precautions to protect the handler and his/her environment.

The preparation of cytotoxic solutions for injection must be carried out by trained specialist personnel who know about the drugs involved, under conditions that ensure protection of the environment and above all protection of the staff handling the solutions. It must be done in a designated area. Smoking, eating and drinking are prohibited in this area.
The personnel preparing the solutions must be provided with all the equipment required for this task, notably long-sleeved laboratory coats, protective masks, head-covering, safety goggles, sterile single-use gloves, protective covering for the work surface, containers and sacks for waste.
Any excreta or vomit must be handled with adequate precautions.
Pregnant women should be informed and avoid handling cytotoxics.

Any broken container must be dealt with using the same precautions and considered to be contaminated waste.
The disposal of contaminated waste is carried out by incineration in labelled rigid containers provided for the purpose. See section "Disposal of waste" hereafter.
If gemcitabine comes in contact with the skin, it must be rinsed immediately with large amounts of water. Precautions must be taken to avoid any accidental spraying of the medicinal product into the eyes. If it is sprayed accidentally into the eyes, rinse the eyes immediately with large amounts of water.

Reconstitution
This medicinal product has only been shown to be compatible with an injectable solution of 9 mg/mL (0.9%) sodium chloride. Accordingly, only this diluent should be used to reconstitute the solution. Compatibility with other drugs has not been studied, and therefore, it is not advisable to mix gemcitabine with other drugs during reconstitution.
Reconstitution at concentrations greater than 38 mg/mL may result in incomplete dissolution, and should be avoided.
For the reconstitution, slower add the appropriate volume of 9 mg/mL (0.9%) Sodium Chloride Solution for Injection (as shown in the table below) and shake till completely dissolved.

Presentation	Volume of 9 mg/mL (0.9%) sodium chloride solution to add	Displacement volume	Final concentration
200 mg	5 mL	0.26 mL	38 mg/mL
1000 mg	25 mL	1.3 mL	38 mg/mL
2000 mg	50 ml	2.6 mL	38 mg/mL

The appropriate amount of the medicinal product can again be diluted in a 9 mg/mL (0.9%) sodium chloride solution.
Medicinal products administered by the parenteral route should be inspected visually for particulate matter and discolouration, prior to administration, whenever the solution and container permit.