PACKAGE LEAFLET: INFORMATION FOR THE USER

Gemzar 200 mg powder for solution for infusion
Gemzar 1000 mg 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 further questions, please ask your doctor, nurse or pharmacist.
- 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 GEMZAR IS AND WHAT IT IS USED FOR

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

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

Gemzar 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 GEMZAR

Do not use Gemzar:
- if you are allergic (hypersensitive) to gemcitabine or any of the other ingredients of Gemzar.
- if you are 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 this medicine. Before each infusion you will have samples of your blood taken to check if you have enough blood cells to receive Gemzar. 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.

Talk to your doctor, nurse or hospital pharmacist before using Gemzar

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 Gemzar.

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 Gemzar.

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

If during treatment with this medicine, 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, 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.

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 Gemzar
Please tell your doctor or hospital pharmacist if you are taking or have recently taken any other medicines, including vaccinations and medicines obtained without a prescription.

Pregnancy, breast-feeding and fertility
Pregnancy
If you are pregnant, or thinking about becoming pregnant, tell your doctor. The use of Gemzar should be avoided during pregnancy. Your doctor will discuss with you the potential risk of taking Gemzar during pregnancy.

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

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

Gemzar contains sodium
Gemzar contains 3.5 mg (< 1 mmol) of sodium in each 200 mg vial and 17.5 mg (< 1 mmol) sodium in each 1000 mg vial ie essentially sodium free.

3. HOW TO USE GEMZAR

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

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

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

If you have further questions on the use of this product ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

You must contact your doctor immediately if you notice any of the following:

- 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).
- Tiredness, feeling faint, becoming easily breathless or if you look pale (since you might have less haemoglobin than normal which is very common).
- Mild to moderate skin rash (very common) / itching (common), or fever (very common); (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) (common).
- Pain, redness, swelling or sores in your mouth (stomatitis) (common).
- Irregular heart rate (arrhythmia) (uncommon)
- 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 (uncommon).
- Difficulty breathing (it is common to have mild breathing difficulty soon after the Gemzar infusion which soon passes, however uncommonly or rarely there can be more severe lung problems)
- Severe chest pain (myocardial infarction) (rare).
- 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) (very rare).
- Generalised swelling, shortness of breath or weight gain, as you might have fluid leakage from small blood vessels into the tissues (capillary leak syndrome) (very rare)
- Headache with changes in vision, confusion, seizures or fits (posterior reversible encephalopathy syndrome) (very rare)
- Severe rash with itching, blistering or peeling of the skin (Stevens-Johnson syndrome, toxic epidermal necrolysis) (very rare).

Other side effects with Gemzar may include:

Very common side effects (may affect more than 1 in 10 people)
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)

Common side effects (may affect up to 1 in 10 people)
Poor appetite (anorexia)
Headache
Insomnia
Sleepiness
Cough
Runny nose
Constipation
Diarrhoea
Itching
Sweating
Muscle pain
Back pain
Fever
Weakness
Chills

Uncommon side effects (may affect up to 1 in 100 people)
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

Rare side effects (may affect up to 1 in 1,000 people)
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)

Very rare side effects (may affect up to 1 in 10,000 people)
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.

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 the leaflet.
You can also report side effects directly via

HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE GEMZAR

Keep out of the reach and sight of children.
Do not use after the expiry date (EXP) which is stated on the carton and the vial.

Unopened vial: Store below 30°C.

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 30°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 Gemzar contains

The active substance is gemcitabine. Each vial contains 200 or 1000 mg of gemcitabine (as gemcitabine hydrochloride).
The other ingredients are mannitol (E421), sodium acetate, hydrochloric acid and sodium hydroxide.

What Gemzar looks like and contents of the pack

Gemzar is a white to off-white powder, for solution for infusion in a vial. Each vial contains 200 or 1000 mg of gemcitabine. Each pack of Gemzar contains 1 vial.

Marketing Authorisation Holder and Manufacturer

Eli Lilly and Company Limited
Lilly House
Priestley Road
Basingstoke
Hampshire
RG24 9NL
United Kingdom

Manufacturer:
Lilly France S.A.S., rue du Colonel Lilly, F-67640, Fegersheim, France

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The following information is intended for medical or healthcare professionals only:

Instructions for use, handling and disposal.

1. Use aseptic techniques during the reconstitution and any further dilution of gemcitabine for intravenous infusion administration.

2. Calculate the dose and the number of Gemzar vials needed.

3. Reconstitute 200 mg vials with 5 ml of 9 mg/ml (0.9 %) sterile sodium chloride solution for injection, without preservative, or 25 ml sterile sodium chloride solution for injection, without preservative to the 1000 mg vial. Shake to dissolve. The total volume after reconstitution is 5.26 ml (200 mg vial) or 26.3 ml (1000 mg vial) respectively. This dilution yields a gemcitabine concentration of 38 mg/ml, which includes accounting for the displacement volume of the lyophilised powder. Further dilution with sterile sodium chloride 9 mg/ml (0.9%) solution for injection, without preservative may be done. The resulting solution is clear and ranges in colour from colourless to light straw-coloured.

4. Parenteral medicinal products should be inspected visually for particulate matter and discolouration prior to administration. If particulate matter is observed, do not administer.

5. Solutions of reconstituted gemcitabine should not be refrigerated, as crystallisation may occur. Chemical and physical in-use stability has been demonstrated for 24 hours at 30°C. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at room temperature, unless reconstitution/dilution has taken place in controlled and validated aseptic conditions.

6. Gemcitabine solutions are for single use only. Any unused product or waste material should be disposed of in accordance with local requirements.

Preparation and administration precautions

The normal safety precautions for cytostatic agents must be observed when preparing and disposing of the infusion solution. Handling of the solution for infusion should be done in a safety box and protective coats and gloves should be used. If no safety box is available, the equipment should be supplemented with a mask and protective glasses.
If the preparation comes into contact with the eyes, this may cause serious irritation. The eyes should be rinsed immediately and thoroughly with water. If there is lasting irritation, a doctor should be consulted. If the solution is spilled on the skin, rinse thoroughly with water.

Disposal
Any unused product should be disposed of in accordance with local requirements.