Package leaflet:
Information for the user

GEMCITABINE 200 mg POWDER FOR SOLUTION FOR INFUSION
GEMCITABINE 1 g POWDER FOR SOLUTION FOR INFUSION
GEMCITABINE 2 g POWDER FOR SOLUTION FOR INFUSION

Gemcitabine

Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Gemcitabine Powder for Solution for Infusion is and what it is used for

Gemcitabine Powder for Solution for Infusion belongs to a group of medicines called 'cytotoxics'. These medicines kill dividing cells, including cancer cells.

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

Gemcitabine Powder for Solution for Infusion is used in the treatment of a number of types of cancer including:
- 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 Powder for Solution for Infusion

You should not be given Gemcitabine Powder for Solution for Infusion
- If you are allergic to gemcitabine or any of the other ingredients of this medicine (listed in section 6).
- If you are breast-feeding.

Tell the doctor if you think any of the above applies to you.

Warnings and precautions

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 also have samples of your blood taken to check if you have enough blood cells to receive Gemcitabine. Your doctor may decide to change your 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 your kidney and liver function.

Talk to your doctor or nurse before using Gemcitabine if:
- you have, or have previously had liver disease, heart disease or vascular disease.
- you have recently had, or are going to have radiotherapy.
- you have been vaccinated recently.
- you develop breathing difficulties or feel very weak and are very pale (this may be a sign of lung problems or kidney failure).

Other medicines and Gemcitabine Powder for Solution for Infusion

Tell your doctor if you are taking, have recently taken or might take any other medicines, including vaccinations.

Pregnancy, breast-feeding and fertility

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

If you are breast-feeding, tell your doctor. You must discontinue breast-feeding during treatment with Gemcitabine Powder for Solution for Infusion.

Men are advised not to father a child during, and up to 6 months after treatment with gemcitabine. If you would like to father a child during the treatment or in the 6 months following treatment, please 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 treatment can make you feel drowsy. Alcohol can make this worse. Do not drive or operate machinery until you are sure that Gemcitabine Powder for Solution for Infusion has not made you feel sleepy.

Gemcitabine Powder for Solution for Infusion contains sodium

This medicinal product contains 35 mg (1.5 mmol) of sodium per 2 g dose. This should be taken into consideration by patients on a controlled sodium diet.

3. How to use Gemcitabine Powder for Solution for Infusion

The usual dose of Gemcitabine Powder for Solution for Infusion 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 infusion will depend on the type of cancer you are being treated for.

A hospital pharmacist or doctor will have dissolved the Gemcitabine Powder for Solution for Infusion powder before it is given to you.

You will always receive Gemcitabine Powder for Solution for Infusion 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, this medicine can cause side effects, although not everybody gets them.

Frequencies of the observed side effects are defined as:
- very common: affects more than 1 user in 10
- common: affects 1 to 10 users in 100
- uncommon: affects 1 to 10 users in 1,000
- rare: affects 1 to 10 users in 10,000
- very rare: affects less than 1 user in 10,000
- not known: the frequency cannot be estimated from the available data

If any of the following happen, tell your doctor immediately:
- Fever or infection (common): if you have a temperature of 38°C 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).
- 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 receiving a gemcitabine infusion but which soon passes; however uncommonly or rarely there can be more severe lung problems).
- Tiredness, looking pale, bruising easily and kidney problems which your doctor will do blood tests to investigate (uncommon).
- Worsening skin rash with sloughing of skin rash and sever skin blistering together with mouth sores (very rare).

The following information is intended for healthcare professionals only:

Reconstitution:

For single use only

This medicinal product has only been shown to be compatible with sodium chloride 9 mg/ml (0.9%) solution for injection. Accordingly, only this diluent should be used for reconstitution. Compatibility with other active substances has not been studied. Therefore, it is not recommended to mix this medicinal product with other active substances when reconstituted.

Reconstitution at concentrations greater than 38 mg/ml may result in incomplete dissolution, and should be avoided.

To reconstitute, slowly add the appropriate volume of sodium chloride 9 mg/ml (0.9%) solution for injection (as stated in the table below) and shake to dissolve.

Presentation	Volume of sodium chloride 9 mg/ml (0.9%) solution for injection to be added	Displacement volume	Final concentration
200 mg	5 ml	0.26 ml	38 mg/ml
1 g	25 ml	1.3 ml	38 mg/ml
2 g	50 ml	2.6 ml	38 mg/ml

The appropriate amount of drug may be further diluted with sodium chloride 9 mg/ml (0.9%) solution for injection.

Chemical and physical in-use stability has been demonstrated for 35 days at 25°C.

From a microbiological point of view, the product should be used immediately.

Solutions should not be refrigerated, as crystallisation may occur.

Q73592

Component Specification

Item number:	Q73592
Request number:	AS2065
Country:	UK & IE
OI template:	SVI006
Amalia version:	1
Mulgrave version:	n/a
Dimensions:	300 x 378 mm
Container(s):	Glass Vial
Supplier:	SVUS
Stock:	40 gsm
Folded dimensions:	31.5 x 150 mm
Printed both sides:	Yes
Perforated:	No
Pharma code:	n/a
Pharma code length:	n/a
Supplier Code:	n/a

Colours

Black: ■

Requester

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This artwork is in conformance with the Marketing Authorisation and can now proceed to the printing stage.

Previous Item Number: Q64439

Latest QP Release Date:

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Date:

Version 1		**Version 2**	
Technician:	KN	Technician:	JH
Date:	14/Jun/12	Date:	02/Apr/14
Version 3		**Version 4**	
Technician:	KN	Technician:	KN
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Version 5		**Version 6**	
Technician:	XX	Technician:	XX
Date:	dd/mmm/yy	Date:	dd/mmm/yy
Version 7		**Version 8**	
Technician:	XX	Technician:	XX
Date:	dd/mmm/yy	Date:	dd/mmm/yy
Version 9		**Version 10**	
Technician:	XX	Technician:	XX
Date:	dd/mmm/yy	Date:	dd/mmm/yy

Side effects that you might experience when taking Gemcitabine Powder for Solution for Infusion include:

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

Common side effects (affecting 1 to 10 users in 100):
- Fever, accompanied by a low white blood cell count (febrile neutropaenia)
- Anorexia (poor appetite)
- Headache
- Drowsiness
- Difficulty sleeping (insomnia)
- Cough
- Runny nose or nasal congestion
- Diarrhoea
- Constipation
- Pain, redness, swelling or sores in the mouth
- Itching
- Sweating
- Muscle pain
- Back pain
- Weakness
- Chills

Uncommon side effects (affecting 1 to 10 users in 1,000):
- Stroke
- Irregular heart beat (arrhythmia)
- Heart failure
- Interstitial pneumonitis (scarring of the air sacs of the lung)
- Spasm of the airways (wheezing)
- Abnormal chest X ray/scan (which show scarring of the lungs)
- Serious liver damage, including liver failure
- Kidney failure

Rare side effects (affecting 1 to 10 users in 10,000):
- Heart attack (myocardial infarction)
- Gangrene of fingers or toes
- Low blood pressure
- Fluid in the lungs
- Adult Respiratory Distress Syndrome (severe lung inflammation causing respiratory failure)
- Skin shedding
- Skin blisters
- Skin sores (ulcers)
- Soreness at the injection site after the injection
- Radiation toxicity (scarring of the air sacs of the lung associated with radiation therapy)
- Radiation recall (a skin rash like severe sunburn which can occur on skin that has previously been exposed to radiotherapy)

Very rare (affects less than 1 user in 10,000 less than 1 in 10,000 patients):
- Increased platelet count
- Ischaemic colitis (inflammation of the lining of the large bowel, caused by reduced blood supply)
- Anaphylactic reaction (severe hypersensitivity/allergic reaction)
- Sloughing of skin and severe skin blistering

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet.

5. How to store Gemcitabine Powder for Solution for Infusion

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 carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

After reconstitution:

This medicine may be stored for 35 days at 25°C. From a microbiological point of view however, it is advised that the product is used immediately.

The reconstituted solution should not be refrigerated.

The prepared solution for infusion should not be used if it contains particles or if it is strongly coloured.

This medicine will be prepared and administered to you by healthcare staff. Any unused medicine will be disposed of by healthcare staff, according to local procedures.

6. Contents of the pack and other information

What Gemcitabine Powder for Solution for Infusion contains
- The active substance is gemcitabine (as hydrochloride)
- Vials contain either 200 mg, 1 g or 2 g gemcitabine (as hydrochloride)
- The other ingredients are mannitol, sodium acetate trihydrate, hydrochloric acid (for pH adjustment) and sodium hydroxide (for pH adjustment)
- One ml of the reconstituted solution for infusion contains 38 mg gemcitabine (as hydrochloride)

What Gemcitabine Powder for Solution for Infusion looks like and contents of the pack

This medicinal product is a powder for solution for infusion (a powder which is dissolved before being injected slowly via a drip into a vein). It can also be referred to as a 'powder for infusion'.

The powder is white to off-white and when dissolved ready for infusion, it produces a colourless or slightly yellow solution.

The 200 mg, 1 g and 2 g vials are sold separately as single packs or packs of 5. Not all pack sizes may be marketed. Vials may be sheathed in protective ONCO-TAIN® sleeves.

Marketing Authorisation Holder and Manufacturer

The marketing authorisation holder and manufacturer is Hospira UK Limited, Queensway, Royal Leamington Spa, Warwickshire, CV31 3RW, United Kingdom.

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Parenteral drugs should be inspected visually for particulate matter and discolouration prior to administration, whenever solution and container permit.

Any unused solution should be discarded as described below.

Guidelines for the Safe Handling of Cytotoxic Medicinal Products:

Local guidelines on safe preparation and handling of cytotoxic medicinal products must be adhered to. Cytotoxic preparations should not be handled by pregnant staff. The preparation of injectable solutions of cytotoxic agents must be carried out by trained specialist personnel with knowledge of the medicines used. This should be performed in a designated area. The work surface should be covered with disposable plastic-backed absorbent paper.

Suitable eye protection, disposable gloves, face mask and disposable apron should be worn. Precautions should be taken to avoid the drug accidentally coming into contact with the eyes. If accidental contamination occurs, the eye should be washed with water thoroughly and immediately.

Syringes and infusion sets should be assembled carefully to avoid leakage (use of Luer lock fittings is recommended). Large bore needles are recommended to minimise pressure and the possible formation of aerosols. The latter may also be reduced by the use of a venting needle.

Actual spillage or leakage should be mopped up wearing protective gloves. Excreta and vomit must be handled with care.

Disposal:

Adequate care and precaution should be taken in the disposal of items used to reconstitute this medicinal product. Any unused dry product or contaminated materials should be placed in a high-risk waste bag. Sharp objects (needles, syringes, vials, etc) should be placed in a suitable rigid container. Personnel concerned with the collection and disposal of this waste should be aware of the hazard involved. Waste material should be destroyed by incineration. Any unused product or waste material should be disposed of in accordance with local requirements.

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Mulgrave version:	n/a
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Stock:	40 gsm
Folded dimensions:	31.5 x 150 mm
Printed both sides:	Yes
Perforated:	No
Pharma code:	n/a
Pharma code length:	n/a
Supplier Code:	n/a

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