

# Gemcitabine Kabi

Gemcitabine hydrochloride

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about Gemcitabine Kabi Injection. It does not contain all the available information. It does not take the place of talking to your doctor.

All medicines have benefits and risks. Your doctor has weighed the risks of using Gemcitabine Kabi against the benefits it is expected to have for you.

**If you have any concerns about taking this medicine, ask your doctor or health care professional.**

**Keep this leaflet.**

You may need to read it again.

### What Gemcitabine Kabi is used for

Gemcitabine Kabi is used to treat patients with:

- lung cancer
- cancer of the pancreas
- bladder cancer
- breast cancer
- ovarian cancer

Gemcitabine Kabi belongs to a group of anticancer drugs known as antineoplastic or cytotoxic medicines. It works by killing cancer cells and preventing cancer cells from growing and multiplying, and is used for different types of cancer. The active ingredient in Gemcitabine Kabi is gemcitabine hydrochloride.

Your doctor will be able to tell you about the specific condition for which you have been prescribed Gemcitabine Kabi. Ask your doctor or health care professional if you have any questions why it has been prescribed for you. Gemcitabine is only available on a prescription from your doctor.

Your doctors have decided to treat you with Gemcitabine because they believe that the benefit of Gemcitabine treatment will be greater than any unwanted side effects.

Many of the side effects from anti cancer drugs are predictable and can be prevented or lessened. Your doctor and other staff will take all of the precautions needed to reduce the unwanted effects of treatment.

### Before you are given Gemcitabine Kabi

#### When you must not receive it

#### Do not use Gemcitabine Kabi if:

- you have an allergy to Gemcitabine or any of the ingredients listed at the end of this leaflet
- you have kidney disease or poor kidney function
- you have liver disease or poor liver function
- you are pregnant or planning to get pregnant
- you are breastfeeding

If you are not sure whether any of these apply to you, check with your doctor.

#### Before you are given it

Tell your doctor if:

1. **you have any allergies to:**
  - any other medicine
  - any other substance, such as foods, preservatives or dyes

2. **if you are pregnant or intend to become pregnant.**

Gemcitabine may affect your developing baby if you take use it during pregnancy. If it is necessary for you to be given it, your doctor or pharmacist will discuss the risks and benefits of taking/using it during pregnancy.
3. **you are breastfeeding or plan to breastfeed.**

Gemcitabine passes into breast milk and should not be used when breastfeeding.

**If you have not told your doctor or pharmacist about any of the above, tell them before you are given Gemcitabine Kabi.**

#### Taking other medicines

**Tell your doctor or health care professional if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.**

Some medicines may be affected by Gemcitabine Kabi, or may affect how it works.

Your doctor or health care professional will advise you about continuing to take other medicines while you are receiving Gemcitabine. You may need different amounts of your medicine, or you may need to use different medicines.

### How Gemcitabine Kabi is given

Gemcitabine Kabi is given as an infusion (drip) into your veins over a 30 minute period. Gemcitabine must only be given by a doctor or nurse. Never inject Gemcitabine Kabi yourself, always let your doctor or nurse do this.

#### How much Gemcitabine Kabi will be given

Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight.

#### How often will Gemcitabine Kabi be given

##### For Lung Cancer

Gemcitabine Kabi can be given once a week for three consecutive weeks, followed by one week without treatment or once a week for two consecutive weeks, followed by one week without treatment. Your doctor will decide how many of these cycles you will need.

##### For Pancreatic Cancer

Initially, Gemcitabine Kabi is given once a week for up to seven weeks followed by a week without treatment. Subsequent cycles of Gemcitabine Kabi are given once a week for three consecutive weeks followed by a week without treatment. Your doctor will decide how many of these cycles you will need.

##### For Bladder Cancer

Gemcitabine Kabi is given once a week for three consecutive weeks, followed by one week without treatment. Your doctor will decide how many of these cycles you will need.

##### For Breast Cancer

Gemcitabine Kabi is given once a week for two consecutive weeks, followed by one week without treatment. Your doctor will decide how many of these cycles you will need.

### For Ovarian Cancer

Gemcitabine Kabi can be given once a week for two consecutive weeks, followed by one week without treatment. Your doctor will decide how many of these cycles you will need.

#### If you are given too much (overdose)

This rarely happens as Gemcitabine Kabi is administered under the care of a highly trained doctor. However, if you are given too much Gemcitabine, you may experience some of the effects listed under side effects below.

If you experience any side effects after being given Gemcitabine Kabi, tell your doctor immediately. Your doctor has information on how to recognise and treat an overdose. Ask your doctor if you have any concerns.

### While you are using Gemcitabine Kabi

#### Things you must do

Be sure to keep all your appointments with your doctor so your progress can be checked.

Your doctor may do some blood tests and other tests from time to time to check on your progress and detect any unwanted side effects.

**Tell all doctors and health care professionals who are treating you that you are being given Gemcitabine Kabi.**

**If you are about to be started on any new medicine, tell your doctor or health care professional that you are being given Gemcitabine Kabi.**

**Tell your doctor if you become pregnant while you are being given Gemcitabine Kabi.**

#### Things to be careful of

**Do not drive or operate machinery until you know how Gemcitabine affects you.**

Gemcitabine may cause dizziness or tiredness in some people and therefore may affect alertness.

### Side Effects

Gemcitabine Kabi is being given to you.

Like other medicines that treat cancer, Gemcitabine Kabi may have unwanted side effects, some of which may be serious. You may need medical treatment if you experience some of the side effects.

**Ask your doctor or health care professional to answer any questions you may have. Tell your doctor or health care professional if you notice any of the following side effects and they worry you:**

- sleepiness, drowsiness
- itchy rash
- swelling of the hands, feet or face
- unusual hair loss or thinning
- soreness in the mouth
- scaling, ulceration, sore formation on the skin
- pain at the site of injection
- dizziness, light-headedness
- itching.

Stomach or bowel problems such as:

- feeling sick
- vomiting
- diarrhoea
- constipation.

Influenza-like symptoms such as:

- fever
- headache
- back-pain
- cold shivers
- cough
- sweating
- muscle pain
- unusual tiredness or weakness
- loss of appetite
- generally feeling unwell
- inability to sleep
- runny or blocked nose, sneezing

**Tell your doctor as soon as possible if you notice any of the following side effects:**

- frequent infections such as fever, severe chills, sore throat or ulcers
- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips or tongue or other parts of the body, shortness of breath, wheezing or trouble breathing
- difficulty in breathing; wheezing or coughing
- shortness of breath
- bruising or bleeding more easily than normal
- tiredness, headaches, being short of breath when exercising, dizziness and looking pale.

Skin reactions such as:

- skin lesions
- small, solid, raised areas of skin
- raised bumps on the skin that contain fluid (blisters)
- open sores on the skin (ulcers)
- peeling of skin

These may be serious side effects.

You may need medical attention.

**Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if any of the following happen:**

- rapid laboured breathing; extreme shortness of breath; slightly bluish, greyish or dark purple discolouration of the skin; cold extremities
- quick shallow breathing followed by shortness of breath and difficulty in breathing
- tiredness, headaches and bruising or bleeding more easily than normal; yellowing of the skin and/or eyes; passing less urine than is normal
- chest pain, changes in the rhythm or rate of the heart beat
- discolouration or loss of sensation in the extremities

These are very serious side effects. You may need urgent medical attention or hospitalisation.

**Other side effects not listed above may occur in some patients. Tell your doctor or health care professional if you notice anything that is making you feel unwell. Other side effects may be only seen by blood tests. Your doctor will carry out any necessary tests.**

**Do not be alarmed by this list of possible side effects.**

You may not experience any of them.

The benefits and side effects of Gemcitabine Kabi may take some time to occur. Therefore, even after you have finished your Gemcitabine Kabi treatment, you should tell your doctor or health care professional immediately if you notice any of the side effects listed in this section.

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### After Gemcitabine Kabi has been given

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#### Storage

Gemcitabine Kabi will be stored in the pharmacy or on the ward.

The Powder for Injection is stored in a cool dry place where the temperature stays below 25°C.

The Concentrated Injection is stored in refrigeration where the temperature stays at 2°C to 8°C. Do not freeze.

**It must not be used after the expiry date (Exp) printed on the vial.**

This is not all the information that is available on Gemcitabine. If you have any more questions or are not sure about anything speak to your doctor or health care professional.

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### Product Description

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#### What it looks like

Gemcitabine Kabi Powder for Injection is a white to off-white powder which is supplied in a glass vial with a rubber stopper.

Gemcitabine Kabi Concentrated Injection is a clear, colourless to slightly yellow solution supplied in a glass vial with a rubber stopper.

Each box contains 1 vial.

Gemcitabine Kabi is available in the following presentations:

Gemcitabine Kabi Powder for Injection:

- 200 mg
- 1000 mg
- 2000 mg

Gemcitabine Kabi Concentrated Injection:

- 200 mg/5.26 mL
- 1000 mg/26.3 mL
- 2000 mg/52.6 mL

#### Ingredients

Gemcitabine Kabi **Powder for injection** contains either 200 mg, 1000 mg or 2000 mg of gemcitabine hydrochloride as the active ingredient. It also contains the inactive ingredients mannitol, sodium acetate, sodium hydroxide and hydrochloric acid.

Gemcitabine Kabi **Concentrated injection** contains 38 mg/mL of gemcitabine hydrochloride as the active ingredient. It also contains the inactive ingredients sodium hydroxide, hydrochloric acid and water for injections.

#### Sponsor

Gemcitabine Kabi is supplied in Australia by:

**Fresenius Kabi Australia Pty Limited**

964 Pacific Highway

Pymble NSW 2073

Telephone: (02) 9391 5555

#### Australian Registration Number

- Gemcitabine Kabi 200 mg Powder for Injection  
AUST R 162336
- Gemcitabine Kabi 1 g Powder for Injection  
AUST R 162337
- Gemcitabine Kabi 2 g Powder for Injection  
AUST R 162338

- Gemcitabine Kabi 200 mg/5.26 mL Concentrated Injection  
AUST R 214724
- Gemcitabine Kabi 1000 mg/26.3 mL Concentrated Injection  
AUST R 220681
- Gemcitabine Kabi 2000 mg/52.6 mL Concentrated Injection  
AUST R 220682

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