

DBL™ Gemcitabine Injection (Solution for Injection)

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about being treated with this medicine, speak to your doctor or pharmacist.

1. Why am I being treated with DBL Gemcitabine Injection?

DBL Gemcitabine Injection contains the active ingredient gemcitabine hydrochloride. DBL Gemcitabine Injection is used to treat the following cancers: lung cancer, pancreatic cancer, bladder cancer, breast cancer and ovarian cancer.

For more information, see Section [1. Why am I being treated with DBL Gemcitabine Injection?](#) in the full CMI.

2. What should I know before being treated with DBL Gemcitabine Injection?

You will not be given DBL Gemcitabine Injection if you have ever had an allergic reaction to DBL Gemcitabine Injection or any of the ingredients listed at the end of the CMI. Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I am treated with DBL Gemcitabine Injection?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DBL Gemcitabine Injection and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How will I be given DBL Gemcitabine Injection?

DBL Gemcitabine Injection will be given to you by a doctor or a nurse, by infusion into a vein.

More instructions can be found in Section [4. How will I be given DBL Gemcitabine Injection?](#) in the full CMI.

5. What should I know while being treated with DBL Gemcitabine Injection?

Things you should do	• Remind any doctor, nurse, pharmacist and dentist who are treating you that you are being given this medicine. • If you become pregnant while you are being given DBL Gemcitabine Injection, tell your doctor immediately. • Females should use effective contraception during treatment and for at least 7 months after stopping treatment. Males should use effective contraception during treatment and for at least 4 months after stopping treatment. • Keep all of your doctor's appointments so your progress can be checked. • Make sure you have all the blood tests asked by your doctor to check your blood cell count, general condition, kidney and liver function as you are at an increased risk of getting an infection during treatment.
Things you should not do	• Do not breastfeed during treatment and for 3 weeks after stopping treatment.
Driving or using machines	• Do not drive or operate machinery until you know how DBL Gemcitabine Injection affects you. This medicine may affect your ability to drive or operate machinery as it can cause sleepiness or drowsiness in some people.

For more information, see Section [5. What should I know while being treated with DBL Gemcitabine Injection?](#) in the full CMI.

6. Are there any side effects?

Side effects may include nausea, vomiting, diarrhoea, constipation, difficulty breathing, shortness of breath, skin rash, suburn, redness, swelling, itching, swelling of ankles, hands, feet, face, flu like symptoms including fever, chills, headache, weakness, loss of appetite, back and/or muscle pain, cough, runny or blocked nose, sneezing, sweating, generally feeling unwell, fatigue, sleepiness, drowsiness, difficulty sleeping, unusual hair loss or thinning, soreness, swelling or ulcers in the mouth, scaling, ulceration or sore formation on the skin.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

DBL™ Gemcitabine Injection (Solution for Injection)

Active ingredient(s): gemcitabine hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about being treated with DBL Gemcitabine Injection. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about being treated with DBL Gemcitabine Injection.**

Where to find information in this leaflet:

1. [Why am I being treated with DBL Gemcitabine Injection?](#)
2. [What should I know before I am treated with DBL Gemcitabine Injection?](#)
3. [What if I am taking other medicines?](#)
4. [How will I be given DBL Gemcitabine Injection?](#)
5. [What should I know while being treated with DBL Gemcitabine Injection?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I being treated with DBL Gemcitabine Injection?

DBL Gemcitabine Injection contains the active ingredient gemcitabine hydrochloride. DBL Gemcitabine Injection belongs to a group of medicines called antineoplastic or cytotoxic medicines. You may also hear of these being called chemotherapy medicines.

This medicine works by killing cancer cells and stopping cancer cells from growing and multiplying.

DBL Gemcitabine Injection is used to treat the following cancers: lung cancer, pancreatic cancer, bladder cancer, breast cancer and ovarian cancer.

2. What should I know before I am treated with DBL Gemcitabine Injection?

Warnings

DBL Gemcitabine Injection should not be given if:

1. you are allergic to gemcitabine, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you have any:

- liver problems.
- kidney problems.
- bone marrow/blood disorder with low numbers of red blood cells, white blood cells, or platelets.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Talk to your doctor if you are pregnant or plan to become pregnant.

You should not be given gemcitabine if you are pregnant or intend to become pregnant.

Gemcitabine may cause birth defects.

It is recommended for females to use effective contraception during treatment and for at least 7 months after stopping treatment. Your doctor will discuss this with you.

It is recommended that males should use effective contraception during treatment and for at least 4 months after stopping treatment. Your doctor will discuss this with you.

You should seek advice from your doctor with respect to fertility preservation prior to treatment.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

You should not breastfeed while you are being treated with gemcitabine and for 3 weeks after stopping treatment.

It is not known whether gemcitabine passes into breast milk.

Use in children

The safety and effectiveness of this medicine in children has not been established.

3. What if I am taking other medicines?

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

Some medicines/treatments may interfere with DBL Gemcitabine Injection and affect how it works.

- other medicines used to treat cancer (such as oxaliplatin, bevacizumab or cisplatin).
- radiation therapy.
- certain vaccines (live vaccines such as yellow fever).

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DBL Gemcitabine Injection.

4. How will I be given DBL Gemcitabine Injection?

How much is given

Your doctor will decide what dose, how often and how long you will receive it. This depends on your condition and other factors, such as your weight, height, how well

your kidneys and liver are working and whether you are being given any other medicines at the same time.

How long it is given for

Several courses of gemcitabine therapy may be needed, depending on your response to treatment. Additional treatment may not be repeated until your blood cell numbers return to acceptable levels and any uncontrolled effects have been controlled.

How it is given

DBL Gemcitabine Injection may be given alone or in combination with other drugs.

DBL Gemcitabine Injection is given as an infusion (a slow injection via a drip) into a vein. The infusion will last approximately 30 minutes.

DBL Gemcitabine Injection must only be given by a doctor or nurse.

If too much DBL Gemcitabine Injection is given

As DBL Gemcitabine Injection will be given to you in hospital or under the supervision of your doctor, it is very unlikely that you will receive an overdose.

If you think that you have been given too much DBL Gemcitabine Injection or experience severe side effects, you may need urgent medical attention.

Symptoms of an overdose may include the side effects listed in section 6, but are usually of a more severe nature affecting your blood, stomach, liver or kidneys.

You should immediately:

- alert the doctor or nurse in the treatment centre
- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while being treated with DBL Gemcitabine Injection?

Things you should do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being given DBL Gemcitabine Injection.

Tell any other doctors, dentists, and pharmacists who are treating you that you are being given this medicine.

If you are going to have surgery, tell the surgeon, anaesthetist or dentist that you are taking this medicine. It may affect other medicines used during surgery.

If you become pregnant while you are being given gemcitabine, tell your doctor immediately.

Keep all of your doctor's appointments so your progress can be checked.

Before each dose of gemcitabine, your doctor will do a blood test to check you have enough blood cells to receive this medicine.

Your doctor will also do blood tests to check your kidney and liver function from time to time while being treated with DBL Gemcitabine Injection.

Things you should not do

You should not breastfeed while you are being treated with gemcitabine.

Things to be careful of

Gemcitabine can lower the number of white blood cells and platelets in your blood. This means that you have an increased chance of getting an infection or bleeding. The following precautions should be taken to reduce your risk of infection or bleeding:

- Avoid people who are unwell or have infections.
- Be careful when using a toothbrush, dental floss or toothpick. Your doctor, dentist or nurse may recommend other ways to clean your teeth and gums. Check with your doctor before having any dental work done.
- Be careful not to cut yourself when you are using sharp objects such as a safety razor or fingernail or toenail cutters.
- Avoid contact sports or other situations where bruising or injury may occur.

Your body breaks down gemcitabine and uses it to fight cancer. The breakdown products may be excreted in body fluids and waste, including blood, urine, faeces, vomit and semen.

In general, precautions to protect other people should be taken while you are receiving chemotherapy and for one week after the treatment period by:

- Flushing the toilet twice to dispose of any body fluids and waste.
- Wearing gloves to clean any spill of body fluid or waste. Use paper towels or old rags, a strong solution of non-bleaching detergent and large amounts of water to mop up the spill. Discard the towels or rags into a separate waste bag and dispose of fluids in the toilet.
- Wash linen or clothing that is heavily contaminated by body fluids or waste separately from other items. Use a strong solution of non-bleaching detergent and large amounts of water.
- Place soiled disposable nappies and other pads in a plastic bag, seal and dispose into the garbage.
- For sexual intercourse, use a barrier method such as a condom.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how DBL Gemcitabine Injection affects you.

DBL Gemcitabine Injection may cause sleepiness or drowsiness in some people. If you have any of these

symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

No information is available.

Looking after your medicine

DBL Gemcitabine Injection will be stored appropriately under refrigeration in the pharmacy or on the hospital ward.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention. See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects

Side effects	What to do
• nausea, vomiting • diarrhoea, constipation • difficulty breathing, shortness of breath • skin rash, sunburn, redness, swelling, itching • swelling of ankles, hands, feet, face • flu like symptoms including fever, chills, headache, weakness, loss of appetite, back and/or muscle pain • cough, runny or blocked nose, sneezing, sweating • generally feeling unwell, fatigue • sleepiness, drowsiness, difficulty sleeping • unusual hair loss or thinning • soreness, swelling or ulcers in the mouth • scaling, ulceration, sore formation on the skin	Speak to your doctor if you have any of these side effects and they worry you.

Serious side effects

Serious side effects	What to do
• 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 • fever, with other signs of infection such as feeling unwell, shivers, shakes, sore throat or ulcers	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of

Serious side effects	What to do
• difficulty in breathing, fast shallow breathing, wheezing, discolouration in skin or nails, fast heart rate, tiredness, cough, chest pain • fever, bruising or bleeding more easily than normal, yellowing of the skin and/or eyes, passing less urine than is normal, swollen legs • headache with changes in vision, confusion, seizures or fits • severe rash with itching, blistering, peeling of the skin with widespread skin pain often with fever • severe chest pain, pain or discomfort in the arm, back or neck (usually on the left side), changes in the rhythm or rate of the heart beat • sudden swelling of the body, rapid drop in blood pressure, lightheadedness and weakness, nausea, abdominal pain, increased thirst or sudden weight gain	these serious side effects

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Some of these side effects (for example, changes in blood cell count, kidney and liver function) can only be found when your doctor does tests from time to time to check your progress.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What DBL Gemcitabine Injection contains

Active ingredient (main ingredient)	gemcitabine hydrochloride
Other ingredients (inactive ingredients)	hydrochloric acid sodium hydroxide

	water for Injections
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You should not be given this medicine if you are allergic to any of these ingredients.

What DBL Gemcitabine Injection looks like

DBL Gemcitabine Injection is a clear, colourless to light straw-coloured solution supplied in a clear glass vial. It is available in single packs of 1 vial.

DBL Gemcitabine Injection is available in the following strengths:

- 1 g/ 26.3 mL AUST R 160202
- 2 g/ 52.6 mL AUST R 160204

Who distributes DBL Gemcitabine Injection

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedical.com.au

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