

DBL™ Gemcitabine for Injection

Gemcitabine Hydrochloride (jem-sie-ta-been)

Consumer Medicine Information

What is in this leaflet

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

All medicines have risks and benefits. Your doctor has weighed the risks of you being given DBL™ Gemcitabine for Injection against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What DBL™ Gemcitabine for Injection is used for

This medicine is used to treat the following types of cancer:

- lung cancer
- pancreatic cancer
- bladder cancer
- breast cancer
- ovarian cancer.

This medicine 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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

DBL™ Gemcitabine for Injection may be used alone or in combination with other medicines to treat cancer.

This medicine is not addictive.

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

Before you are given DBL™ Gemcitabine for Injection

When you must not be given it

You must not be given DBL™ Gemcitabine for Injection if you have an allergy to:

- any medicine containing gemcitabine hydrochloride
- any of the ingredients listed at the end of this leaflet
- if the packaging is torn or shows sign of tampering.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching, or hives on the skin.

Tell your doctor or pharmacist if you are pregnant or intend to become pregnant.

Like most cytotoxic medicines, DBL™ Gemcitabine for Injection is not recommended for use during pregnancy. If there is any need to consider DBL™ Gemcitabine for Injection during your pregnancy,

your doctor or pharmacist will discuss with you the benefits and risks of using it.

DBL™ Gemcitabine for Injection may cause birth defects if either the male or female is using it at the time of conception. It is recommended that you use some kind of birth control while you are being treated with DBL™ Gemcitabine for Injection.

Tell your doctor or pharmacist if you are breast-feeding while being treated with this medicine.

DBL™ Gemcitabine for Injection may pass into breast milk and there is a possibility that your baby may be affected.

You must not be given this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:

- liver problems
- kidney problems.

If you have not told your doctor about any of the above, tell him/her before you are given DBL™ Gemcitabine for Injection.

Taking other medicines

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

These medicines may be affected by DBL™ Gemcitabine for Injection, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while you are being treated with this medicine.

How DBL™ Gemcitabine for Injection is given

How much is given

Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight, liver function, kidney function and other chemotherapy medicines you are being given.

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

Several courses of DBL™ Gemcitabine for Injection 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.

Ask your doctor if you want to know more about the dose of DBL™ Gemcitabine for Injection you receive.

How it is given

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

This medicine is usually given as a slow injection into a vein over 30 minutes.

How often is it given

For Lung Cancer

DBL™ Gemcitabine for Injection 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, DBL™ Gemcitabine for Injection is given once a week for up to seven weeks followed by a week without treatment. Subsequent cycles of DBL™ Gemcitabine for Injection 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

DBL™ Gemcitabine for Injection 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

DBL™ Gemcitabine for Injection 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

DBL™ Gemcitabine for Injection 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 take too much (overdose)

As DBL™ Gemcitabine for Injection is given to you under the supervision of your doctor, it is very unlikely that you will receive

too much. However, if you experience any severe side effects after being given DBL™ Gemcitabine for Injection, tell your doctor immediately or go to Accident and Emergency at the nearest hospital.

In case of overdose, immediately contact the Poisons Information Centre for advice (telephone 13 11 26 in Australia, or call 0800 764 766 in New Zealand).

You may need urgent medical attention.

While you are being treated with DBL™ Gemcitabine for Injection

Things you must do

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

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

If you become pregnant while being given this medicine, or soon after, tell your doctor immediately.

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

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

Keep follow up appointments with your doctor.

It is important to have your follow-up doses of DBL™ Gemcitabine for Injection at the appropriate times to get the best effects from your treatments.

Things to be careful of

Be careful driving or operating machinery until you know how DBL™ Gemcitabine for Injection affects you.

This medicine 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.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are being treated with DBL™ Gemcitabine for Injection.

Like other medicines that treat cancer, DBL™ Gemcitabine for Injection may have unwanted side effects, some of which may be serious. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor, nurse or pharmacist if you notice any of the following 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
- 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
- wheezing or coughing
- bruising or bleeding more easily than normal
- tiredness, headaches, being short of breath when exercising.

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:

- 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
- 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
- bruising or bleeding more easily than normal; yellowing of the skin and/or eyes; passing less urine than is normal
- confusion
- visual disturbance
- seizures, fits or convulsions
- chest pain, changes in the rhythm or rate of the heart beat.

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.

Tell your doctor, nurse or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may occur in some people. Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

The benefits and side effects of DBL™ Gemcitabine for Injection may take some time to occur.

Therefore even after you have finished your DBL™ Gemcitabine for Injection treatment you should tell your doctor immediately if you notice any of the side effects listed in this section.

After using DBL™ Gemcitabine for Injection

Storage

DBL™ Gemcitabine for Injection will be stored in the pharmacy or on the ward. The injection should be stored below 25°C

Product description

What it looks like

DBL™ Gemcitabine for Injection is a white to off-white powder.

Ingredients

DBL™ Gemcitabine for Injection contains 200mg, 1g or 2g of gemcitabine hydrochloride as the active ingredient.

Inactive ingredients:

It also contains:

- mannitol
- sodium acetate

This medicine does not contain lactose, sucrose, gluten, tartrazine or any azo dyes.

Sponsor

DBL™ Gemcitabine for Injection is supplied by:

Australian Sponsor:

Hospira Australia Pty Ltd
ABN 58 097 064 330
Level 3
500 Collins Street
Melbourne VIC 3000
Australia

New Zealand Sponsor:

Hospira NZ Limited
58 Richard Pearse Drive
Airport Oaks, Mangere 2022
Auckland
New Zealand

DBL™ Gemcitabine for Injection is available in the following strengths:

- 200 mg/vial AUST R 147440
- 1 g/vial AUST R 147588
- 2 g/vial AUST R 147589

This leaflet was updated in December 2015.