

GEMCITE®

Powder for Injection

contains the active ingredient gemcitabine hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet is designed to provide you with answers to some common questions about this medicine. It does not contain all the available information and does not take the place of talking with your doctor. All medicines have risks and benefits. Your doctor has more information about this medicine than is contained in this leaflet. Also, your doctor has had the benefit of taking a full and detailed history from you and is in the best position to make an expert judgement to meet your individual needs.

If you have any concerns about being given this medicine, talk to your doctor or health care professional.

Keep this leaflet with this medicine. You may need to read it again.

What GEMCITE is used for

GEMCITE is used to treat patients with:

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

GEMCITE works by killing cancer cells and preventing cancer cells from growing and multiplying. GEMCITE belongs to a group of medicines called antineoplastic or cytotoxic medicines. You may also hear of these being called chemotherapy medicines.

Your doctor may have prescribed GEMCITE for another reason. Ask your doctor or health care professional if you have any questions about why GEMCITE has been prescribed for you.

GEMCITE may be used in combination with other cytotoxic medicines to treat cancer.

Before you are given GEMCITE

Tell your doctor or health care professional if you have any of the following conditions or if you have ever experienced any of these conditions.

When you must not be given GEMCITE

You must not be given GEMCITE if you have had an allergic reaction to GEMCITE or to any of the ingredients listed at the end of this leaflet (see 'Product Description').

You must not be given GEMCITE if the packaging is torn or show signs of tampering.

You must not be given GEMCITE after the expiry date printed on the pack.

Before you are given GEMCITE

Tell your doctor if you have allergies to:

- any other medicines
- any other substances such as foods, preservatives or dyes

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

- liver problems
- kidney problems

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

Like most medicines used to treat cancer, GEMCITE is not recommended to be given during pregnancy. If there is a need to consider GEMCITE during your pregnancy, your doctor will discuss with you the benefits and risks involved.

Tell your doctor if you are breast-feeding or plan to breast-feed.

It is recommended that you do not breast-feed while you are receiving GEMCITE, as it is not known whether GEMCITE passes into breast milk.

Tell your doctor or health care professional about these things before you are given GEMCITE.

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 GEMCITE or may affect how it works. Your doctor and health care professional may have more information on medicines to be careful with or avoid while being given GEMCITE.

How GEMCITE is given

GEMCITE is given as an infusion (drip) into your veins over a 30 minute period.

Your doctor or nurse will inject GEMCITE for you.

Never inject GEMCITE yourself. Always let your doctor or nurse do this.

How much GEMCITE 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 GEMCITE be given

For Lung Cancer

GEMCITE 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, GEMCITE is given once a week for up to seven weeks followed by a week without treatment. Subsequent cycles of GEMCITE 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

GEMCITE 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

GEMCITE 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

GEMCITE 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.

Overdose

As GEMCITE 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 side effects after being given GEMCITE, tell your doctor immediately.

While you are receiving GEMCITE

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 GEMCITE.

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

Tell your doctor if you become pregnant while you are being given GEMCITE.

Things to be careful of

Do not drive or operate machinery after receiving GEMCITE until you know how GEMCITE affects you.

GEMCITE may cause sleepiness in some people.

Side effects

Tell your doctor or health care professional as soon as possible if you do not feel well while you are being given GEMCITE.

Like other medicines that treat cancer, GEMCITE 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:

- 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 about may occur in some patients. Tell your doctor or health care professional if you notice anything that is making you feel unwell.

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

You may not experience any of them.

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

Storage

GEMCITE will be stored in the pharmacy or in the ward. The injection is kept in a cool dry place where the temperature stays below 30°C.

Product Description

What it looks like

GEMCITE is a white to off white powder and is available in a glass vial container with a rubber stopper.

Ingredients

GEMCITE is available in two strengths.

1. GEMCITE 200 mg contains the active ingredient, gemcitabine hydrochloride, equivalent to 200 mg of gemcitabine.
2. GEMCITE 1000 mg contains the active ingredient, gemcitabine hydrochloride, equivalent to 1000 mg of gemcitabine.

Both strengths of GEMCITE also contain the inactive ingredients mannitol and sodium acetate.

Sponsor

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Australian Registration Numbers:

- GEMCITE 200 mg: AUST R 147414
- GEMCITE 1000 mg: AUST R 147413

This leaflet was prepared in April 2009.

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