

GEMCITABINE EBewe

gemcitabine hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Gemcitabine Ebewe.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking gemcitabine against the benefits this medicine is expected to have for you.

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

Keep this leaflet

You may need to read it again.

It is important to remember that Gemcitabine Ebewe is a **PRESCRIPTION ONLY MEDICINE**.

Gemcitabine Ebewe will only be given to you by specially trained personnel in a hospital environment.

What Gemcitabine Ebewe is used for

Gemcitabine belongs to the group of medicines called antineoplastics or cytotoxic medicines. It is typically used to treat patients with lung cancer, cancer of the pancreas, bladder cancer, cancer of the breast or ovarian cancer. It works by killing cancer cells and preventing cancer cells from growing and multiplying. Gemcitabine may also be used to treat other conditions as

determined by your doctor.

Ask your doctor if you have any questions about why Gemcitabine Ebewe has been prescribed for you.

Gemcitabine Ebewe may also be used in combination with other cytotoxic medicines to treat cancer.

Before you are given Gemcitabine Ebewe

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 this medicine:

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

Symptoms of an allergic reaction may include rashes, itching and redness of the skin and swelling of the tongue or face.

You must not be given this medicine if the packaging is torn or shows signs of tampering.

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

Before you are given this medicine

Tell you 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, Gemcitabine Ebewe is not recommended to be given during pregnancy. If there is a need to consider this medicine 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 Gemcitabine Ebewe, as it is not known whether gemcitabine passes into breast milk.

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

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

Some medicines may be affected by Gemcitabine Ebewe 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 Gemcitabine Ebewe.

How Gemcitabine Ebewe is given

How it is given

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

Your doctor or nurse will inject the medicine for you. **Never inject this medicine yourself. Always let your doctor or nurse do this.**

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.

How often it will be given

For Lung Cancer

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

In Case of Overdose

As Gemcitabine Ebewe 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 Gemcitabine Ebewe, tell your doctor immediately.

While you are being given Gemcitabine Ebewe

Things you MUST do:

- **Be sure to keep all of your doctor's appointments so that 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 Ebewe.**
- **If you are about to be started on any new medicine, tell your doctor or health care professional that you are being given Gemcitabine Ebewe.**
- **Tell your doctor if you become pregnant while you are being given Gemcitabine Ebewe.**

Things to be careful of:

- **Do not drive or operate machinery after receiving this medicine until you know how it affects you.** Gemcitabine Ebewe 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 Gemcitabine Ebewe.

Like other medicines that treat cancer, Gemcitabine Ebewe 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..

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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 immediately if you notice any of the following:

- 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.

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.

Storage

Gemcitabine Ebewe will be stored appropriately at the pharmacy or on the ward. The

injection is kept in a cool dry place where the temperature stays below 25°C. It will not be refrigerated or frozen.

Product Description

What it looks like

Gemcitabine powder for injection is a white or almost white powder, supplied in a clear glass vial.

Ingredients

Gemcitabine Ebewe powder for injection:

Active Ingredients:

Gemcitabine Ebewe powder for injection contains the active ingredient gemcitabine hydrochloride 40mg/mL (when reconstituted)

Other ingredients:

Gemcitabine Ebewe powder for injection also contains mannitol, sodium acetate and sodium hydroxide.

Manufacturer

Gemcitabine Ebewe is made by:
EBEWE Pharma Ges.m.b.H.
Nfg. KG
A-4866 Unterach
Austria

Sponsor

Gemcitabine Ebewe is distributed in Australia by:
InterPharma Pty Ltd
Suite 3, 14 Sydney Road
Manly
NSW 2095

Gemcitabine Ebewe can be identified by an Australian Register Number, which is found on the packaging:

AUST R 151747
Gemcitabine Ebewe 200mg

powder for injection glass vial
(single vial and five vial pack)

AUST R 151748

Gemcitabine Ebewe 1000mg
powder for injection glass vial
(single vial)

This leaflet was prepared in

January 2009