

GEMPLAN™

Gemcitabine (as hydrochloride)

Consumer Medicine Information

What is in this leaflet

This leaflet is designed to provide you with the answers to some common questions about this medicine. It does not contain all the available information and does not take the place talking with your doctor. All medicines have risk 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 is GEMPLAN is used for

GEMPLAN is used to treat patients with:

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

GEMPLAN works by killing cancer cells and preventing cancer cells from growing and multiplying. GEMPLAN 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 GEMPLAN for another reason. Ask your doctor or health care professionals if you have any questions about why GEMPLAN has been prescribed for you.

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

Before you are given GEMPLAN

Tell your doctor or health care professionals if you have any of the following medical conditions or if you have experienced any of these conditions:

- liver problems
- kidney problems.

Tell your doctor if you have allergies to:

- any other medicines
- any other substances such as foods, preservative or dyes.

Tell your doctor if you are pregnant or intend to become pregnant. Like most medicines used to treat cancer, GEMPLAN is not recommended to be given during pregnancy. If there is a need to consider GEMPLAN 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 GEMPLAN, as it is not known whether GEMPLAN passes into breast milk.

Tell your doctor or health care professionals about these things before you are given GEMPLAN.

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

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

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

Taking other medicines

Tell your doctor or health care professionals if you are taking other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines may be affected by GEMPLAN or may affect how it works. Your doctor or health care professional may have more information on medicines to be careful with or avoid while being given GEMPLAN.

How GEMPLAN is given

GEMPLAN is given as an infusion (drip) into your veins over a 30 minute period. Your doctor or nurse will inject GEMPLAN for you. Never inject GEMPLAN yourself. Always let your doctor or nurse do this.

How much GEMPLAN 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 GEMPLAN be given:

For Lung Cancer

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

GEMPLAN 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

GEMPLAN 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

GEMPLAN 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 GEMPLAN 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 GEMPLAN, tell your doctor immediately.

While you are receiving GEMPLAN

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 your progress and detect any unwanted side effects.

Tell all doctors and health care professionals who are treating you that you are being given GEMPLAN.

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

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

Things to be careful of

Do not drive or operate machinery after receiving GEMPLAN until you know how GEMPLAN affects you. GEMPLAN 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 GEMPLAN. Like other medicines that treat cancer, GEMPLAN may have unwanted side effects, some of which may be serious. You may need medical treatment if you experience the side effects.

Ask your doctor or health care professional to answer 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
- 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 also 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 GEMPLAN may take some time to occur. Therefore, even after you have finished your GEMPLAN treatment, you should tell your doctor or health care professional immediately if you notice any of the side effects listed in this section.

Storage

GEMPLAN will be stored in the pharmacy or on the ward. The injection is kept in a cool dry place where temperature stays below 25°C.

Production Description

What it looks like

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

Ingredients

GEMPLAN is available in two strengths:

- GEMPLAN 200mg contains the active ingredient, gemcitabine hydrochloride, equivalent to 200 mg of gemcitabine.
- GEMPLAN 1g contains the active ingredient, gemcitabine hydrochloride, equivalent to 1g gemcitabine.

Both strengths of GEMPLAN also contain the active ingredients mannitol and sodium acetate.

Sponsor

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Australian Registration Numbers

- GEMPLAN 200 mg is AUST R 165619
- GEMPLAN 1000 mg is AUST R 165620

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