

GEMCITABINE ACTAVIS

contains the active ingredient gemcitabine (as hydrochloride)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about GEMCITABINE ACTAVIS.

It does not contain all of 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 being given GEMCITABINE ACTAVIS against the benefits they expect it will have for you.

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

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

What GEMCITABINE ACTAVIS is used for

GEMCITABINE ACTAVIS is used to treat patients with:

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

GEMCITABINE ACTAVIS works by killing cancer cells and preventing cancer cells from growing and multiplying. GEMCITABINE ACTAVIS 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 GEMCITABINE ACTAVIS for another reason. Ask your doctor if you have any questions about why GEMCITABINE ACTAVIS has been prescribed for you.

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

Before you are given GEMCITABINE ACTAVIS

When you must not take it

You must not be given GEMCITABINE ACTAVIS if you are allergic to medicines containing gemcitabine or any of the ingredients listed at the end of this leaflet.

You must not be given GEMCITABINE ACTAVIS if you have:

- liver problems
- kidney problems.

You must not be given GEMCITABINE ACTAVIS if the expiry date (Exp.) printed on the pack has passed.

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

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

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

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

Tell your doctor if you are breastfeeding or plan to breastfeed.

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

Tell your doctor or health care professional about these things before you are given GEMCITABINE ACTAVIS

Taking other medicines

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking GEMCITABINE ACTAVIS.

How GEMCITABINE ACTAVIS is given

How GEMCITABINE ACTAVIS will be given

GEMCITABINE ACTAVIS is given as an infusion (drip) into your veins over a 30 minute period. Your doctor or nurse will inject GEMCITABINE ACTAVIS for you.

Never inject GEMCITABINE ACTAVIS yourself.

Always let your doctor or nurse do this.

How GEMCITABINE ACTAVIS 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 GEMCITABINE ACTAVIS will be given

For Lung Cancer

GEMCITABINE ACTAVIS 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 ACTAVIS is given once a week for up to seven weeks followed by a week without treatment. Subsequent cycles of GEMCITABINE ACTAVIS 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 ACTAVIS 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 ACTAVIS 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 ACTAVIS 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 GEMCITABINE ACTAVIS 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 ACTAVIS, tell your doctor immediately.

While you are receiving GEMCITABINE ACTAVIS

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 GEMCITABINE ACTAVIS.

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

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

Things to be careful of

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

GEMCITABINE ACTAVIS may cause sleepiness in some people.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking GEMCITABINE ACTAVIS.

Like other medicines that treat cancer, GEMCITABINE ACTAVIS may have unwanted side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

You may not experience any of them.

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

Tell your doctor if you notice any of the following and they worry you:

- include common and mild side effects
- 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 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.

These may be serious side effects. You may need medical attention.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- 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 if you notice anything that is making you feel unwell.

After using GEMCITABINE ACTAVIS

Storage

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

Product description

What it looks like

GEMCITABINE ACTAVIS is a white to off white powder and is available in a glass vial container with a rubber stopper, available in 3 strengths:

- GEMCITABINE ACTAVIS 200
- GEMCITABINE ACTAVIS 1000
- GEMCITABINE ACTAVIS 2000.

Ingredients

The active ingredient in GEMCITABINE ACTAVIS is gemcitabine (as hydrochloride):

- each vial of GEMCITABINE ACTAVIS 200 contains 200 mg of gemcitabine
- each vial of GEMCITABINE ACTAVIS 1000 contains 1000 mg of gemcitabine
- each vial of GEMCITABINE ACTAVIS 2000 contains 2000 mg of gemcitabine

The vials also contain:

- mannitol
- sodium acetate.

Supplier

Actavis Australia Pty Ltd
 Upper Ground Floor
 183 Melbourne Street
 North Adelaide SA 5006
 Australia
 Tel: 1300 881 893



Australian registration numbers:

GEMCITABINE ACTAVIS 200 - AUST R 151702
 GEMCITABINE ACTAVIS 1000 - AUST R 151703
 GEMCITABINE ACTAVIS 2000 - AUST R 190605

Date of preparation: March 2013