
Consumer Medicine Information

GEMCITABINE ACTAVIS®

Gemcitabine (as hydrochloride)

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July 2009

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 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 or health care professional 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

Tell your doctor or health care professional if you have any of the following medical conditions or if you have ever 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, preservatives or dyes.

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 breast-feeding or plan to breast-feed. 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

When you must not be given GEMCITABINE ACTAVIS

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

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

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

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 GEMCITABINE ACTAVIS 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 ACTAVIS.

How GEMCITABINE ACTAVIS is 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 much 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 will GEMCITABINE ACTAVIS 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 health care professional as soon as possible if you do not feel well while you are being given GEMCITABINE ACTAVIS. Like other medicines that treat cancer, GEMCITABINE ACTAVIS 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 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 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 GEMCITABINE ACTAVIS may take some time to occur. Therefore, even after you have finished your GEMCITABINE ACTAVIS treatment, you should tell your doctor or health care professional immediately if you notice any of the side effects listed in this section.

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.

Ingredients

GEMCITABINE ACTAVIS is available in two strengths: GEMCITABINE ACTAVIS 200mg contains the active ingredient, gemcitabine hydrochloride, equivalent to 200 mg of gemcitabine.

GEMCITABINE ACTAVIS 1g contains the active ingredient, gemcitabine hydrochloride, equivalent to 1g of gemcitabine.

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

Sponsor

GEMCITABINE ACTAVIS is a product of Actavis Australia Pty Ltd
Upper Ground Floor
183 Melbourne Street
North Adelaide
South Australia 5006

Solely distributed in Australia by:
Generic Health Pty Ltd.,
Suite 1, 1175 Toorak Road,
Camberwell VIC 3124

Australian Registration Numbers

GEMCITABINE ACTAVIS 200 mg is AUST R 151702.

GEMCITABINE ACTAVIS 1000 mg is AUST R 151703