

Gemcitabine Hcl Cas No. : 122111-03-9

Gemcitabine is used alone or with other treatments/medications to treat certain types of cancer (e.g., breast, lung, pancreas). It is a chemotherapy drug that works by slowing or stopping the growth of cancer cells. This drug may also be used to treat certain other cancers, such as bladder and ovarian cancer.

Active Pharmaceuticals Ingredients Manufacturers



Taj Pharma PDF

Taj Pharmaceuticals Ltd.

Gemcitabine Hcl

CAS No. : 122111-03-9



Molecular Weight 207.70

Systematic (IUPAC) name

2-[1-(aminomethyl)cyclohexyl]acetic acid

Identifiers

CAS number 60142-96-3

ATC code N03AX12

PubChem 3446

DrugBank APRD00015

Chemical dataFormula C₉H₁₇NO₂

Mol. mass 171.237 g/mol

Pharmacokinetic data

Bioavailability Rapid, in part by saturable carrier-mediated L-amino acid transport system

60% for 0.9 g daily to 27% for 4.8 g daily dose

Food increases absorption by 14%

Protein binding Less than 3%

Metabolism Not appreciably metabolized

Half life 5 to 7 hours

Excretion Renal

DOSAGE

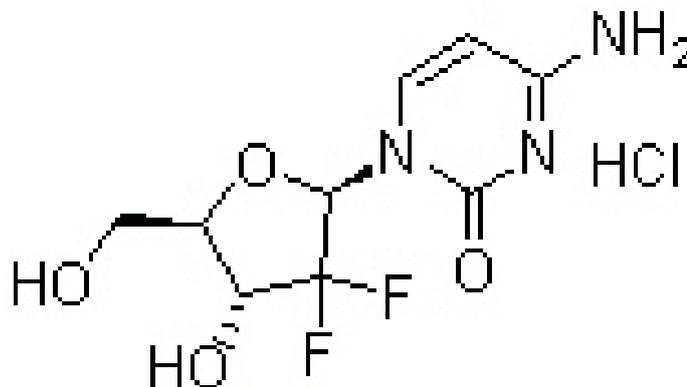
Gemcitabine may be given:

- * as a drip (infusion) through a fine tube (cannula) inserted into a vein, over a short period of time
- * through a central line, which is inserted under the skin into a vein near the collarbone, or a PICC line inserted into a vein in the crook of your arm.

The infusion usually takes about 30 minutes.

Chemotherapy is usually given as a course of several sessions (or cycles) of treatment over a few months. The length of your treatment and the number of cycles you have will depend on the type of cancer for which you are being treated.

This injection is given by vein (IV), usually over 30 minutes. The dose depends on your health condition and response to therapy. The recommended dose should not be exceeded. All mixing and dilution with correct IV fluids should be done properly, following all safety precautions.





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SIDE EFFECTS

Some side effects are normal while taking Gemcitabine, such as nausea, vomiting, or pain/redness at the injection site, hair loss etc. However, if any of these effects worsen, contact your doctor promptly. Certain serious side effects also occur which require immediate medical attention, like

- * Diarrhea
- * Mouth sores
- * Constipation
- * Chills
- * Fever
- * Cough
- * Unusual bleeding or bruising
- * Loss of appetite
- * Blood in the urine
- * Yellowing eyes or skin
- * Irregular heartbeat
- * Change in the amount of urine
- * Dark urine etc.

Each person's reaction to chemotherapy is different. Some people have very few side effects, while others may experience more. The side effects described in this information will not affect everyone who is given gemcitabine, and may be different if you are having more than one chemotherapy drug.

We have outlined the most common side effects and some of the less common ones, so that you can be aware of them if they occur. However, we have not included those that are very rare and therefore extremely unlikely to affect you. If you notice any effects which you think may be due to the drug, but which are not listed in this information, please discuss them with your doctor or chemotherapy nurse.

Lowered resistance to infection Gemcitabine can reduce the production of white blood cells by the bone marrow, making you more prone to infection. This effect can begin seven days after treatment has been given, and your resistance to infection usually reaches its lowest point 10–14 days after chemotherapy. Your blood cells will then increase steadily, and will usually have returned to normal levels before your next course of chemotherapy is due.

PRECAUTIONS

Before taking this medication, tell your doctor if you have any other medical conditions, especially kidney, liver, or heart disease. Also discuss any medicines that you take, including over-the-counter preparations. Gemcitabine is in the FDA pregnancy category C. This means that it is not known whether this medication will be harmful to an unborn baby. Do not take this medication without first talking to your doctor if you are pregnant or could become pregnant during treatment. Gemcitabine passes into breast milk. Do not take gemcitabine without first talking to your doctor if you are breast-feeding a baby.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: kidney disease.

This drug may make you dizzy or drowsy; use caution engaging in activities requiring alertness such as driving or using machinery. Limit alcoholic beverages as they may worsen these effects.

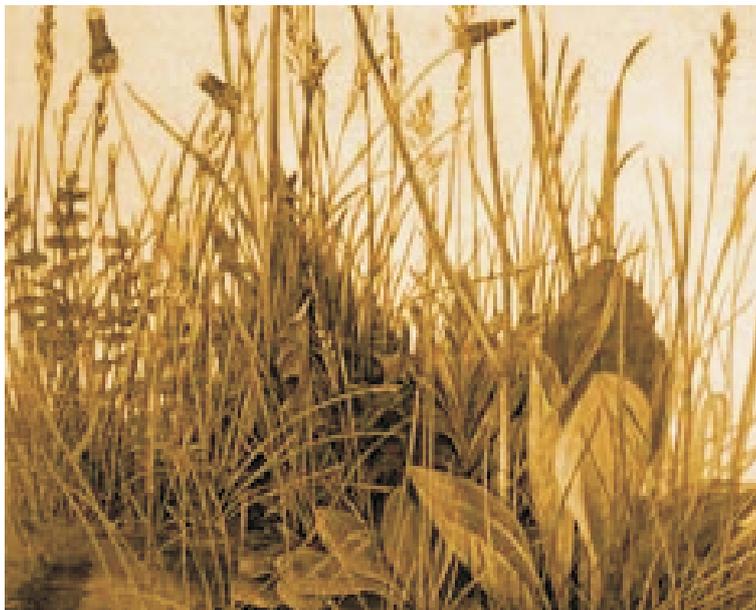


Caution is advised when using this drug in the elderly because they may be more sensitive to its effects, especially swollen arms/legs or loss of coordination.

Caution is advised when using this drug in children because they may be more sensitive to its effects, especially the mental/mood changes (e.g., hostility).

DRUG DESCRIPTION

Gemcitabine is a chemotherapy drug that is given as a treatment for some types of cancer. It is most commonly used to treat non-small cell lung cancer, pancreatic, bladder and breast cancer. This information describes gemcitabine, how it is given and some of its possible side effects. It should ideally be read with our general information about chemotherapy and about your type of cancer



Gemcitabine HCl is a white to off-white solid. It is soluble in water, slightly soluble in methanol, and practically insoluble in ethanol and polar organic solvents.

Gemcitabine is used to treat cancer of the pancreas and non-small cell lung cancer. It is also now used to treat breast cancer that has spread in combination with another drug called paclitaxel (Taxol). Gemcitabine is also used in combination with cisplatin to treat bladder cancer. This drug is one of a group of chemotherapy drugs called anti-metabolites. Anti-metabolites are similar to normal body molecules but they are slightly different in structure. These differences mean that anti-metabolites stop cells working properly.

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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at:

<http://www.tajapi.com>

or by contacting the sponsor, Taj Pharmaceuticals Limited., at:
91 022 30601000.

This leaflet was prepared by
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