

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

^{Pr}**Gemcitabine Injection** solution for injection (ready-to-use)

Read this carefully before you start taking **GEMCITABINE INJECTION** and each time you receive an infusion. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **GEMCITABINE INJECTION**.

Serious Warnings and Precautions

- Gemcitabine Injection should only be prescribed by physicians experienced in giving chemotherapy.
- Gemcitabine Injection is for intravenous (IV) use only.
- Gemcitabine Injection infusions that last longer than 60 minutes or are given more often than once per week are known to cause more side effects.
- Gemcitabine Injection often causes a fall in blood counts. If this is severe you have a higher risk of infection and bleeding. If you had previous chemotherapy or radiation therapy, your blood counts may already be low.
- While you are receiving Gemcitabine Injection, your healthcare professional will do blood tests to monitor your blood counts and measure how your kidneys and liver are working.
- If your cancer has already spread to your liver or you have hepatitis, you drink alcohol heavily and frequently (alcoholism) or you have cirrhosis of the liver, Gemcitabine Injection may make your liver problems worse.
- Shortness of breath may develop or worsen with Gemcitabine Injection treatment. This may be the result of worsening lung cancer or due to the drug. If this happens to you, contact your healthcare professional right away.

What is Gemcitabine Injection used for?

Gemcitabine Injection is used to treat adults with:

- Non-small cell lung cancer (NSCLC) that has spread outside of the lung (locally advanced) or has spread into other parts of the body (metastatic). For these patients, Gemcitabine Injection is given alone or in combination with another medication.
- Pancreatic cancer that has spread outside the pancreas (locally advanced) or is metastatic;
- Bladder cancer that has spread outside the bladder (locally advanced) or is metastatic. For these patients, Gemcitabine Injection is given in combination with another medication.
- Breast cancer that:
 - cannot be removed by surgery, or
 - has come back after previous treatment, or
 - is metastatic.

For these patients, Gemcitabine Injection is given in combination with the medication, paclitaxel.

How does Gemcitabine Injection work?

Product Monograph

^{Pr} **GEMCITABINE INJECTION** (gemcitabine hydrochloride)

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Gemcitabine Injection is a type of chemotherapy. It acts on quickly dividing cells and interrupts their ability to divide or grow. Chemotherapies will affect both healthy cells and cancer cells. However, cancer cells are known to divide or grow more quickly than most healthy cells making chemotherapies such as Gemcitabine Injection effective in the treatment of various cancers.

What are the ingredients in Gemcitabine Injection?

Medicinal ingredients: Gemcitabine hydrochloride

Non-medicinal ingredients: Hydrochloric acid, Sodium Hydroxide, Water for Injection

Gemcitabine Injection comes in the following dosage forms:

Sterile solution for injection : 38 mg/mL gemcitabine (as gemcitabine hydrochloride) in vials containing 200 mg / 5.3 mL, 1 g / 26.3 mL and 2 g / 52.6 mL gemcitabine (as gemcitabine hydrochloride).

Do not use Gemcitabine Injection if:

- you have had an allergic or sensitivity reaction to this drug or any of its ingredients.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Gemcitabine Injection. Talk about any health conditions or problems you may have, including if you:

- are also being treated with radiation therapy
- have liver or kidney problems, or a bone marrow disorder

Other warnings you should know about:

Low blood counts: Gemcitabine Injection may temporarily affect your blood counts. This may be more common in patients older than 65 years and in women. Your healthcare professional will do blood work before each dose to monitor your blood counts. If your red blood cell counts become too low, you might need a blood transfusion. Avoid using acetylsalicylic acid while you are receiving Gemcitabine Injection. This is because acetylsalicylic acid can affect your platelets, which may make it easier for you to bleed.

Pregnancy and breastfeeding in women:

- If you are pregnant, plan on becoming pregnant or are breastfeeding, there are specific risks you should discuss with your healthcare professional.
- Avoid becoming pregnant while you are receiving Gemcitabine Injection. It may harm your unborn baby. Use effective birth control while you are receiving Gemcitabine Injection and for 6 months after your last dose.
- Avoid breastfeeding while you are receiving Gemcitabine Injection. It may pass into your breastmilk and may harm the baby.

Birth control and fertility in men:

- Avoid fathering a child while you are receiving Gemcitabine Injection. Use effective birth control during your treatment and for 3 months after your last dose.
- Gemcitabine may affect your fertility. This may make it difficult for you to father a child in the future.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Gemcitabine Injection:

- radiation therapy.

Be sure to check with your healthcare professional before taking any medications on your own.

How to take Gemcitabine Injection:

- Gemcitabine Injection will be given to you by a healthcare professional in a healthcare setting. It will be given through a tube placed into your vein. This is called an IV infusion. Gemcitabine Injection is given over a 30-minute period.
- You will have blood work done before each dose to check your blood counts and how your liver and kidneys are working. Your healthcare professional will also do regular physical exams.

Usual dose: 1000 mg/m² or 1250 mg/m²

- Your healthcare professional will decide how much and how often you will receive Gemcitabine Injection. This will depend on:
 - your height and weight,
 - the type of cancer you have, and
 - whether you are also receiving other medications.
- If you have certain side effects while receiving Gemcitabine Injection, your healthcare professional may reduce, temporarily stop or permanently stop your treatment.

Overdose:

Gemcitabine Injection will be given under the supervision of a qualified physician. If you receive too much Gemcitabine Injection, you may experience low blood counts or feel numbness, tingling, itching, burning or prickling ('pins and needles') under your skin.

If you think you, or a person you are caring for, have taken too much Gemcitabine Injection, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

Contact your healthcare professional right away if you miss an infusion of Gemcitabine Injection.

What are possible side effects from using Gemcitabine Injection?

These are not all the possible side effects you may have when taking Gemcitabine Injection. If you experience any side effects not listed here, tell your healthcare professional.

- Nausea
- Constipation
- Fever
- Rash
- Flu-like symptoms
- Tingling, burning, prickling or numbness ('pins and needles') under the skin
- Sleepiness or drowsiness
- Tremor, muscle jerks, twitches or spasms

- Hearing loss
- Changes in mood
- Headache
- Pain, muscle pain, joint pain
- Sore throat or mouth
- Hair loss
- Breathing difficulty (short of breath)
- swelling, pain, redness, or burning at the injection site

Gemcitabine Injection can cause abnormal blood test results. Your healthcare professional will do blood tests before each of your treatments. They will interpret the results.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Myelosuppression (low blood counts) including: <ul style="list-style-type: none"> • Leucopenia / Neutropenia (low white blood cells): fever, fatigue, infection, aches and pains, flu-like symptoms • Anemia (low red blood cells): tiredness, feeling faint, becoming easily breathless or pale skin • Thrombocytopenia (low platelets): bleeding from the gums, nose or mouth or any bleeding that would not stop, reddish or pinkish urine, unexpected bruising 		✓	
Diarrhea (loose/watery stools): three or more watery bowel movements per day, lasting more than 24 hours		✓	
Skin reactions (allergic reactions): Mild to moderate skin rash / itching, or fever		✓	
Edema (fluid retention): swelling of hands, feet or face		✓	
Vomiting	✓		
COMMON			
Febrile neutropenia (low white blood cells and fever): body		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
temperature over 38°C, shaking chills			
Stomatitis (inflamed and sore mouth): pain, redness, swelling or sores in the mouth	✓		
Fatigue : feeling overtired, low energy, a strong desire to sleep that interferes with normal daily activities	✓		
UNCOMMON			
Dyspnea (new or worsening shortness of breath): difficulty catching your breath, noisy breathing, very fast and shallow breaths, increased heart rate, wheezing, chest pain			✓
Arrhythmia (irregular heart rate): a fluttering, pounding, or racing feeling in the chest, fast heartbeat, slow heartbeat, chest pain, shortness of breath			✓
Hemolytic uremic syndrome (a condition that damages blood vessels in your kidney) or Thrombotic microangiopathy (clots in small blood vessels): extreme tiredness and weakness, red or purple spots under the skin, low or no urine output fever, chills			✓
Kidney failure (kidneys stop working properly): nausea, vomiting, fever, swelling of arms, legs, and face, fatigue, thirst, dark urine, changes in urine output, blood in urine, rash, weight gain, loss of appetite, drowsiness, confusion, coma			✓
Heart Failure (heart does not pump enough blood): shortness of breath with activity or when lying down, rapid or irregular heartbeat, swelling in the legs, ankles and			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
feet, cough that doesn't go away, fatigue and weakness			
Liver failure (liver stops working properly): yellowing of your skin and eyes (jaundice), right upper stomach area pain or swelling, nausea or vomiting, unusual dark urine, unusual tiredness, unexplained loss of appetite			✓
RARE			
Myocardial infarction (heart attack): chest pain or discomfort, shortness of breath, nausea, light-headedness			✓
Adult respiratory distress syndrome (severe lung inflammation causing respiratory failure): severe shortness of breath, labored and rapid breathing, cough, chest discomfort, fast heart rate, confusion and extreme tiredness			✓
Peripheral vasculitis (inflammation of the blood vessels): headache, fever, aches and pains, fatigue, weight loss, skin discoloration, unusual rashes and ulcers.		✓	
VERY RARE			
Posterior reversible encephalopathy syndrome (a rare neurological disorder): headache with confusion, seizures (fits), changes in vision, loss of speech, high blood pressure			✓
Capillary leak syndrome (fluid leakage from small blood vessels into the tissues): generalised swelling, shortness of breath or weight gain			✓
Stevens-Johnson syndrome and Toxic epidermal necrolysis (severe skin reaction): severe rash with			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
itching, blistering, or peeling of the skin			
Anaphylactic reaction (severe allergic reaction): severe skin rash including red itchy skin, swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing), wheezing, fast beating heart, feeling faint			✓
FREQUENCY UNKNOWN			
Acute generalised exanthematous pustulosis (severe skin reaction): red, scaly widespread rash with bumps under the swollen skin and blisters accompanied by fever			✓
Drug Reaction with Eosinophilia and Systemic Symptoms (severe reaction to a medication): widespread skin rash, fever, swollen lymph nodes			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Your healthcare professional will store Gemcitabine Injection. It will be stored at 2°C to 8°C and protected from freezing.

Before administering Gemcitabine Injection, the healthcare professional will check the solution for particles or changes in colour.

Gemcitabine Injection will be kept out of reach and sight of children.

If you want more information about Gemcitabine Injection:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website www.pfizer.ca, or by calling 1-800-463-6001.

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Last Revised: 03 JAN 2025