PART III: CONSUMER INFORMATION

[Pr] Gemcitabine Injection
Concentrate Sterile Solution for Injection
Gemcitabine (as Gemcitabine Hydrochloride)
Solution: 40 mg of gemcitabine per mL

This leaflet is part III of a three-part "Product Monograph" published when Gemcitabine Injection was approved for sale in Canada and is designed specifically for consumers. This leaflet is a summary and will not tell you everything about Gemcitabine Injection. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
Gemcitabine Injection is an approved chemotherapy for treatment of:

- Non-small cell lung cancer (NSCLC), alone or in combination with another medication
- Pancreatic cancer
- Bladder cancer, in combination with another medication
- Breast cancer, in combination with another medication

What it does:
Gemcitabine Injection is a chemotherapy that works through disrupting the cells ability to divide or grow. Chemotherapies are active in both healthy and cancer cells. However, cancer cells are known to divide or grow at a faster rate than most healthy cells making chemotherapies such as Gemcitabine Injection effective in the treatment of various cancers. While the time it takes to see if Gemcitabine Injection shrinks your cancer varies from person to person, your doctor will ask you if you are feeling better and will perform regularly scheduled examinations and x-rays to determine if Gemcitabine Injection has been effective.

When it should not be used:
Do not take Gemcitabine Injection if you have had an allergic or sensitivity reaction to this drug or any of its ingredients (see **What the important nonmedicinal ingredients are** section of this leaflet).

What the medicinal ingredient is:
Gemcitabine hydrochloride

What the important nonmedicinal ingredients are:
Water for injection and hydrochloric acid may have been added for pH adjustment.

What dosage forms it comes in:
Gemcitabine Injection (40 mg/mL) concentrate sterile solution is available in the following formats: 200 mg/5 mL (5 mL vial), 1 g/25 mL (50 mL vial) and 2 g/50 mL (50 mL vial).

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- **Gemcitabine Injection should only be prescribed by physicians experienced with delivery of chemotherapy.**
- **Gemcitabine Injection is intended for intravenous use only.**
- **Gemcitabine Injection infusion times longer than 60 minutes and given more often than once per week are known to increase negative side effects.**
- **As with other chemotherapies, there is a risk of side effects, sometimes severe, with Gemcitabine Injection therapy.**
- **Gemcitabine Injection routinely leads to a fall in blood counts which, if severe can lead to an increased risk of infection and bleeding.**
- **Gemcitabine Hydrochloride has been associated with a type of pneumonia that can be quite severe in less than 1 in 1 000 patients and less severe in less than 1 in 100 patients.**

BEFORE you receive Gemcitabine Injection talk to your doctor if:

- You have had an allergic reaction to any chemotherapy or have been treated with any chemotherapy in the past.
- You are pregnant, plan on becoming pregnant, or are currently breast feeding.
- You have liver or kidney problems, or a bone marrow disorder.

INTERACTIONS WITH THIS MEDICATION

Gemcitabine Injection is known to increase your body's sensitivity to radiation therapy.

It is very important to tell your doctor about any medications you may be taking, including over the counter drugs, such as Aspirin® (acetylsalicylic acid), vitamins, and other pain relievers. Be sure to check with your doctor before taking any medications on your own.

PROPER USE OF THIS MEDICATION

Usual Dose:
Your doctor will develop a Gemcitabine Injection treatment plan based on your needs. You are encouraged to discuss your treatment plan with your doctor. There are many points your doctor will consider when selecting the appropriate treatment plan for you. Your doctor may recommend skipping a dose based upon your response to Gemcitabine Hydrochloride for Injection.

Overdose:
Gemcitabine Injection will be given under the supervision of a qualified physician. Any overdose should be managed by a qualified physician experienced in the use of anticancer agents.

In case of drug overdose, contact a health care practitioner, hospital emergency or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:
Contact your healthcare professional immediately for further instructions.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

In clinical studies of gemcitabine hydrochloride, side effects were generally manageable. Side effects significant enough to cause your treatment to be stopped occurred in about 10% of all patients. Less than 1% of patients stopped therapy due to any one side effect. Most side effects were reversible and can be managed by either a delay in your treatment, a reduction of the dose of chemotherapy or both. Therefore, it is important for you to know about common side effects and for you to communicate any suspected side effects to your doctor.

You should discuss possible side effects with your doctor before beginning Gemcitabine Injection therapy and at any time you think you may be experiencing a side effect. For a list of possible side effects see the **Call Your Doctor or Nurse If You Experience** section and **Serious Side Effects** table below.

In clinical studies of gemcitabine hydrochloride, the most common reason for dosage adjustments was low blood counts. About two thirds of patients had low blood counts. In about one fourth of patients, decreases in blood counts were severe. For more information speak with your doctor and see section below on **Low Blood Counts**.

Shortness of breath may develop or worsen during treatment due to disease progression or in rare cases, due to a direct effect of the drug. If this occurs, patients should inform their treating doctor immediately of the developing or worsening of shortness of breath.

Nausea and vomiting were the most common side effects in clinical studies of gemcitabine hydrochloride. About two thirds of patients experienced nausea and vomiting, which were usually mild to moderate. Other common side effects included fever, swelling, rash, and flu-like symptoms.

In rare cases, gemcitabine hydrochloride may affect your liver, especially if you have liver metastases (spreading of cancer) or medical history of hepatitis (inflammation of the liver), alcoholism or liver cirrhosis (liver disease). Follow your doctor's instructions on having periodic blood work to check your liver.

In rare cases, gemcitabine hydrochloride may affect your kidney, especially if your kidney function is not normal. Follow your doctor's instructions on having periodic blood work to check your kidneys.

Low Blood Counts:
Chemotherapy drugs often affect the blood cells, which means that temporary changes in their counts may occur. These effects may be more common in patients older than 65 and in women. Blood tests will be done before each dose of Gemcitabine Hydrochloride for Injection to monitor your blood counts.

If your doctor notices changes in your blood counts, follow their advice, which may include:

White Blood Count:
- if your white blood count becomes low, you may have trouble fighting infections.
- stay out of crowds and away from people with colds or other illnesses.
- call your doctor if you develop a temperature over 38°C.
- ensure regular mouth care to reduce chance of infection.

Red Blood Count:
- if your red blood count becomes low, you may feel tired or weak. If it becomes too low, your doctor may recommend a red blood cell transfusion.
- rest as much as you need to.
- try to eat a well-balanced diet.

Platelet Count:
- if your platelet count becomes low, your blood may not clot as fast as usual, and bleeding or bruising may occur. Sometimes a blood transfusion is given if platelet counts drop very low.
- try to avoid getting cuts, bumps, or bruises (for example avoid contact sport and using a razor).
- since acetylsalicylic acid can affect your platelets, you should avoid taking acetylsalicylic acid while you are receiving chemotherapy, unless your doctor advises otherwise.

Call Your Doctor or Nurse If You Experience:
- any unusual bruising or bleeding.
- any pain around an infusion site.
- a sore mouth or throat.
- prolonged or uncomfortable swelling.
- severe diarrhea, meaning three or more watery bowel movements per day, lasting more than 24 hours.
- severe constipation for three days that has not been relieved by laxatives.
- numbness or tingling in your hands or feet.
- vomiting for more than 24 hours after your treatment.
- any changes in your skin, especially rash or potential allergic skin reactions.
- headache with confusion, and/or seizures (fits), and/or changes in vision.
- see also **Serious Side Effects** table below.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/effect		Talk with your doctor or nurse	
		Only if severe	In all cases
Very Common	Diarrhea		✓
	Swelling		✓
	Vomiting	✓	
Common	Body temperature over 38°C or shaking chills		✓
	Fatigue	✓	
Uncommon	Shortness of breath		✓
Very rare	Skin reactions including blistering		✓
Very rare	Headache with confusion, and/or seizures (fits), and/or changes in vision		✓

This is not a complete list of side effects. For any unexpected effects while taking Gemcitabine Injection, contact your doctor or nurse.

HOW TO STORE IT

Gemcitabine Injection should be refrigerated between 2°C and 8°C. Do not freeze.

Dilutions prepared using 0.9% sodium chloride injection or 5% glucose injection should be used immediately or if not used immediately the solution should be used within 24 hours stored between 15 ºC and 30ºC. Any unused solution should be discarded.

Handling and storage of Gemcitabine Injection is restricted to qualified healthcare professionals. Keep out of reach of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

1. Report online at www.healthcanada.gc.ca/medeffect
2. Call toll-free at 1-866-234-2345
3. Complete a Canada Vigilance Reporting Form and:
   - Fax toll-free to 1-866-678-6789, or
   - Mail to: Canada Vigilance Program
     Health Canada
     Postal Locator 0701E
     Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document, plus the full product monograph prepared for health professionals, can be obtained by contacting the sponsor, Sandoz Canada Inc., at: 1-800-361-3062
or
by written request at:
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Boucherville, (QC), Canada
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or by e-mail at :
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