

PART III: CONSUMER INFORMATION

Pr Cytarabine Injection 100 mg/mL

This leaflet is part III of a three-part "Product Monograph" published when Cytarabine 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 Cytarabine Injection. Contact a member of your healthcare team if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

Cytarabine Injection (Cytarabine) is used to treat patients with cancer of the blood (leukemia) or cancer of the lymph nodes (lymphoma). It is used alone or in combination with other medicines.

What it does:

Cytarabine slows or stops the growth of cancer cells.

When it should not be used:

Do not take Cytarabine Injection (Cytarabine):

- If you/ the child in your care are allergic (hypersensitive) to cytarabine or any other ingredients in Cytarabine Injection (see "**What the nonmedicinal ingredients are**" section of this leaflet).

What the medicinal ingredient is:

Cytarabine.

What the nonmedicinal ingredients are:

Water for injection, may contain hydrochloric acid and/or sodium hydroxide to adjust the pH.

What dosage forms it comes in:

Cytarabine Injection is available in single-use vials of 100 mg/mL, 1 g / 10 mL and 2 g / 20 mL.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Cytarabine Injection should be prescribed and monitored only by doctors with experience with cancer medicines.

The following are serious side effects of Cytarabine Injection:

- **Serious Allergic Reaction:** Symptoms include sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body), hives.
- **Cytarabine Injection can cause damage to the heart.** Tell your doctor right away if you/the child in your care have chest pain, shortness of breath, swelling of the legs or irregular heartbeat.

- **Cytarabine Injection can cause changes to the lungs.** Tell your doctor right away if you/the child in your care develop wheezing, cough, fever or feeling of breathlessness, or if existing breathing problems get worse.
- **Cytarabine Injection can have harmful effects on the nervous system.** Tell your doctor right away if you/the child in your care feel drowsy or confused, dizzy or unsteady, get headaches or personality changes.
- **Cytarabine Injection can have harmful effects on the stomach and gut that can sometimes be fatal.** Tell your doctor right away if you/the child in your care feel sick or vomit, have diarrhea, a loss of appetite or abdominal pain.
- **Cytarabine Injection can cause a decrease in the number of white blood cells, red blood cells, and platelets** (low blood cell counts). This means that you/the child in your care may bruise or bleed more easily. Tell your doctor right away if you/the child in your care get infection, bleeding, fever, or chills with shivering, bruising or rash.

While you/the child in your care are being given Cytarabine Injection your doctor will monitor your blood counts (white blood cells, red blood cells, platelets) as well as your liver and kidney function by doing regular blood tests.

A preservative called **benzyl alcohol** should not be given to low birth weight or premature babies.

Cytarabine Injection may cause Tumour Lysis Syndrome (TLS). This happens when Cytarabine Injection makes the cancer cells break down very quickly. This releases uric acid (a waste product) into the blood. The kidneys usually get rid of uric acid but may not be able to cope with large amounts. This can cause serious imbalances in the blood that affect the kidneys and the heart. Tell your doctor immediately if you/ the child in your care have palpitations/irregular heartbeats; vomiting; fatigue/weakness; difficulty concentrating/trouble thinking; swelling, numbness or tingling in hands, face or feet; back pain; muscle cramps; fainting or trouble breathing.

Vaccination with a live vaccine should be avoided while being treated with Cytarabine Injection. Tell your doctor that you/the child in your care are on Cytarabine Injection before getting any vaccine.

Cases of sudden inflammation of the pancreas, and cases of paralysis, at times fatal in children, have been reported with the use of cytarabine in combination with other drugs.

Serious nervous system side effects that ranged from headache to paralysis, coma and stroke-like episodes have been reported mostly in children (under 18 years of age) given intravenous (injected into the vein) cytarabine in combination with intrathecal (injected into the spinal cord) methotrexate.

The safety of Cytarabine Injection in infants (under 1 year of age) is not known.

Before starting treatment with Cytarabine Injection, tell your doctor if you, or the child in your care, have any of the following:

- Liver or kidney problems;
- Heart problems;
- Lung problems;
- Stomach or gut problems;
- Low blood cell counts;
- Skin problems.

Pregnancy, Breastfeeding and Fertility:

Cytarabine Injection may harm your baby/ unborn baby.

Do not become pregnant while being treated with Cytarabine Injection. Women who may become pregnant must use effective birth control during treatment and for 3 months after treatment has finished.

If you are pregnant, think you might be pregnant or are planning to have a baby, ask your doctor for advice before starting treatment with Cytarabine Injection.

Tell your doctor immediately if you become pregnant.

Do not breastfeed while you are being treated with Cytarabine Injection. .

Male Fertility:

Do not father a child while being treated with Cytarabine Injection and for 3 months after stopping treatment. Use condoms and do not donate sperm during treatment and for 3 months after your treatment has finished. If you plan to father a child, talk to your doctor before starting treatment with Cytarabine Injection.

Driving and using machines

If you feel drowsy or dizzy, do not drive or use machinery.

INTERACTIONS WITH THIS MEDICATION

Serious Drug Interactions

If Cytarabine Injection is given to you/the child in your care with methotrexate (another drug used to treat cancer), you have more chances of having serious side effects on your nervous system such as headache, paralysis, coma and stroke-like episodes.

Tell your doctor or pharmacist about any medicines you or the child in your care are on or have taken (including the ones that you don't need a prescription for), especially the following:

- 5-Fluorocytosine (a medicine used to treat fungal infections);
- Digoxin (a heart medicine);
- Gentamicin (an antibiotic);
- Cyclophosphamide, vincristine and prednisone.

PROPER USE OF THIS MEDICATION

Cytarabine Injection will be given to you or the child in your care as an injection or an infusion. It can be given:

- Into the spinal cord

- Into a vein (through a “drip”)
- Under the skin

Chemotherapy is usually given during several cycles of treatment over a few months. The length of your/the child in your care’s treatment and the number of cycles you or the child in your care need will depend on the type of cancer you/they have. Your doctor will discuss your treatment plan with you.

Usual dose:

The dose of Cytarabine Injection you or the child in your care will be given will be calculated by your doctor based on your/the child’s weight and height.

Overdose

In case of drug overdose, contact a healthcare practitioner, hospital emergency department or regional poison control centre, even if there are no symptoms.

Missed dose:

Call your doctor for instructions if you/the child in your care miss an appointment for your Cytarabine Injection.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects of Cytarabine Injection may include:

- Viral, bacterial, or fungal infections: Infections can be serious and may lead to death. Contact your doctor if you or the child in your care have fever, chills, or any other signs or symptoms of a possible infection.
- Cytarabine Syndrome: Cytarabine Injection may cause a reaction called Cytarabine Syndrome 6 to 12 hours after it has been given. Contact your doctor if you or the child in your care develop fever, muscle pain, bone pain, chest pain, rash, eye problems (pain, itching, redness, discharge, blurred vision), or generally feel unwell.
- Feeling tired or weak.
- Headaches or feeling dizzy, fainting.
- Feeling of pins and needles.
- Nausea, vomiting, diarrhea, loss of appetite, abdominal pain.
- Eye infection, irritation, pain and blurred vision.
- Hair loss, skin rash or open sores, peeling of the skin, itching or increased freckles.
- Swelling of the throat, heartburn, sores and bleeding in the mouth, lips, or on the anus.
- Feeling hot and feverish.
- Sore throat.
- Muscle pain, bone pain.
- Fast heartbeat.
- Rash or blisters on the palms of the hands and soles of the feet.

If any of these affects you severely, tell your doctor, nurse or pharmacist.

During treatment, you or the child in your care will need to have regular blood tests. Your doctor will tell you how often this should be done. It is important that you do not miss any of these tests.

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Symptom / Effect		Talk with your doctor or pharmacist		Stop taking the drug and call your doctor or pharmacist
		Only if severe	In all cases	
Very common	Anemia: symptoms include fatigue, loss of energy, weakness, shortness of breath.		√	
	Decreased platelets: symptoms include bruising, bleeding, fatigue and weakness.		√	
	Decreased white blood cells: symptoms include infections, fever, chills with shivering, fatigue, aches pains and flu-like symptoms.		√	
	Infection of the blood: symptoms include feeling dizzy or faint, confusion or disorientation, diarrhea, nausea, vomiting, slurred speech, severe muscle pain.			√
	Megaloblastic anemia: symptoms include fatigue, weakness, loss of appetite, nausea, diarrhea, fast heartbeat, smooth or tender tongue, tingling or numbness in hands and feet.		√	
	Pneumonia: symptoms include cough with or without mucus, fever, chills, shortness of breath.		√	

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Symptom / Effect	Talk with your doctor or pharmacist		Stop taking the drug and call your doctor or pharmacist
	Only if severe	In all cases	
Serious stomach or gut problems: symptoms include severe vomiting, severe diarrhea (increased number of bowel movements, watery or bloody stool), stomach pain and/or cramps.		√	
Frequency not known			√
Serious allergic reaction: symptoms include rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing. It may lead to a heart attack.			√
Edema: symptoms include swelling of the stomach, legs, ankles or feet.		√	
Inflammation of the pancreas: symptoms include abdominal pain that lasts and gets worse when you lie down, fever, nausea, vomiting.		√	
Injection site reaction: symptoms include pain, redness, warmth, swelling at the injection site or along the vein.			√
Kidney disorder: symptoms include decreased urination, nausea, vomiting, swelling of extremities, fatigue, difficulty or pain when urinating, blood in the urine.		√	

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Symptom / Effect	Talk with your doctor or pharmacist		Stop taking the drug and call your doctor or pharmacist
	Only if severe	In all cases	
Liver disorder: symptoms include yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite.		√	
Serious bleeding problems: symptoms include blood in your stool or urine, bleeding that lasts for a long time or that you cannot control, coughing up blood or blood clots, increased bruising, feel dizzy or weak, confusion, change in your speech, or a headache that lasts a long time.			√
Serious eye problems: symptoms include sensitivity to light, blurry vision, eye pain, tearing, feeling like there is something stuck in your eye.		√	
Serious heart problems: symptoms include shortness of breath, swelling of the legs, irregular heartbeat, chest pain.			√
Serious nervous system problems: symptoms include headache, paralysis, coma, stroke-like episodes, drowsiness or confusion, dizziness or unsteadiness, personality changes, shaking and fits, speech problems, involuntary movements.			√

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Symptom / Effect	Talk with your doctor or pharmacist		Stop taking the drug and call your doctor or pharmacist
	Only if severe	In all cases	
Tumor Lysis Syndrome: symptoms include nausea, vomiting, decreased urination, irregular heartbeat, confusion, delirium, seizures.			√

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

HOW TO STORE IT

Keep out of reach and sight of children.

This drug will be given to you in a hospital or doctor's office. You will not store it at home.

Medicines should not be thrown down the drain or in the garbage. Ask your pharmacist how to dispose of medicines you no longer need. This will help to protect the environment.

REPORTING SUSPECTED 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) (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.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals, can be obtained by contacting the sponsor, Pfizer Canada ULC, at **1-800-463-6001**.

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Last revised: L3: March 13, 2020

Approval date: November 6, 2017