

PART III: CONSUMER INFORMATION

PrCLOLAR®
(Clofarabine for injection)

This leaflet is part III of a three-part “Product Monograph” published when CLOLAR was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about CLOLAR. Read this information carefully before you or your child starts taking CLOLAR. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

CLOLAR is used to treat young patients (1 – 21 years of age) with acute lymphoblastic leukemia (ALL) when previous treatments have not worked or have stopped working. Approval is based on objective response rates. No survival advantage has been demonstrated and palliative benefit was not evaluated.

What it does:

CLOLAR damages rapidly proliferating (fast producing) cells and kills them.

When it should not be used:

- If you or your child have ever had an allergic reaction (for example, rash, or itchiness) to clofarabine or any ingredient in CLOLAR.
- If you or your child have leukemia cells in the fluid that surrounds the brain and spinal cord.
- If you or your child have had serious heart, liver, kidney or pancreas problems.
- If you or your child have severe liver or kidney disease that results in decreased function of these organs.

What the medicinal ingredient is:

CLOLAR Injection contains clofarabine.

What the nonmedicinal ingredients are:

Water for Injection and Sodium Chloride.

What dosage forms it comes in:

CLOLAR is available as a sterile solution for injection. CLOLAR is diluted (thinned) before being given as an intravenous infusion. Each mL contains 1 mg clofarabine.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

CLOLAR must be administered under the supervision of a physician qualified in the use of antineoplastic agents.

CLOLAR is associated with:

- Tumor Lysis Syndrome (TLS) due to rapid destruction of leukemia cells
- Systemic Inflammatory Response Syndrome (SIRS)/Capillary Leak Syndrome
- Inflammation of the intestines (enterocolitis)
- Bleeding (hemorrhage) (such as bleeding into the brain, stomach, intestines or lung)
- Severe skin reaction (such as Stevens-Johnson syndrome, toxic epidermal necrolysis)
- Liver injury
- Kidney failure, due to TLS or infections.

BEFORE using CLOLAR talk to your doctor or pharmacist if:

- You or your child have had liver and/or kidney problems
- You are pregnant or plan to become pregnant. CLOLAR may harm an unborn baby, effective birth control methods must be used while receiving CLOLAR. Talk to your doctor about your choices.
- You are breastfeeding. It is not known if CLOLAR passes through breast milk. Women should not breastfeed while taking CLOLAR.
- You or your child are allergic to clofarabine, or any ingredient in this medicine or the components of the container.
- You or your child are taking other medications or treatments, including any products you buy, such as over-the-counter medicines and herbal or home remedies.
- You or your child have low blood cell counts.

INTERACTIONS WITH THIS MEDICATION

Tell your or your child’s doctor or pharmacist about any medications or treatments you or your child are taking, including medicines prescribed by a doctor, any products you buy, such as over-the-counter medicines, vitamins, and herbal or home remedies.

PROPER USE OF THIS MEDICATION

Usual dose:

The recommended pediatric dose of CLOLAR is 52 mg/m² as an intravenous (IV) infusion over 2 hours each day for 5 days one after another.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, CLOLAR can have side effects.

Some possible side effects of CLOLAR are listed below:

The following side effects have been reported very commonly (reported in more than 10 out of every 100 people):

- Nausea, vomiting and diarrhea can result in dehydration
- Fatigue
- Loss of appetite
- Anxiety
- Itching
- Headache
- Rash
- Cough
- Flushing
- Constipation
- Inflammation of the mucus membranes with symptoms of mouth soreness, sore throat and inflamed gums
- Muscle aches

The following side effects have been reported commonly (reported in 1 to 10 out of every 100 people):

- Weakness, irritability, generally feeling unwell, feeling sleepy, depression
- Joint aches

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

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist		
	Only if severe	In all cases			
Very Common	Decreased production of blood cells (tiredness, weakness, easy bruising and bleeding, gum bleed, blood in urine)		✓		
	Infection (fever or chill)		✓		
	Feeling unwell		✓		
	Rapid heart rate (tachycardia)		✓		
	Shortness of breath or difficulty breathing		✓		
	Changes in blood pressure (drowsiness, dizziness, headache, light headedness or fainting spells)		✓		
	Pain in extremity (hand and foot)	✓			
	Inflammation of the mucus membranes with symptoms such as: mouth soreness, sore throat and inflamed gums	✓			
	Common	Hand and foot syndrome (redness, tenderness, blisters and possibly peeling of the skin on palms and soles with numbness or tingling)	✓		
		Muscle and joint pain, back pain, bone pain, rectal pain		✓	
Serious liver problems (yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite, rectal bleeding, vomiting blood, increase in weight, and build up of fluid in the abdomen)			✓		
Tumor lysis syndrome (rapid breathing, rapid heartbeat, and low blood pressure) which can lead to acute kidney failure (generalised swelling, decrease in urination)			✓		
Accumulation of fluid around the heart, with symptoms such as: chest pain, shortness of breath, difficulty breathing, shortness of breath when lying down, painful breathing or fainting.			✓		

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

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
	Irritability, feeling sleepy, depression	✓	
Uncommon	Stevens-Johnson syndrome or toxic epidermal necrolysis (severe skin reaction, blistering or red and flaky skin)		✓
	Allergic reaction (rash, itching, difficulty breathing)		✓
	Accumulation of water in the lung (shortness of breath, rapid breathing, chest pain)		✓
	Systemic Inflammatory Response Syndrome/Capillary Leak Syndrome (Rapid breathing, rapid heartbeat, low blood pressure, high or low temperature, swelling, mental confusion)		✓
Unknown frequency	Inflammation of the intestines (enterocolitis), with symptoms such as: abdominal pain, vomiting, diarrhea, fever		✓
	Kidney problems, with symptoms such as: decrease in urination, swelling of feet and ankles, fatigue, drowsiness, nausea, vomiting		✓

This is not a complete list of side effects. For any unexpected effects while taking CLOLAR, contact your or your child's doctor or pharmacist.

HOW TO STORE IT

Vials containing undiluted CLOLAR should be stored at 25°C (77°F); excursions permitted to 15 - 30°C (59 - 86°F).

Once diluted, use preparation immediately.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug, you may notify Canada Vigilance:

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

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

Postage paid labels, Canada Vigilance Report 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 the side effect, please contact your health care professional. The Canada Vigilance program does not provide medical advice.

MORE INFORMATION

This leaflet provides important information about CLOLAR. If you have questions or concerns, talk to your or your child's doctor or other healthcare provider.

This document plus the full product monograph, prepared for health professionals can be found at: www.sanofi.ca or by contacting the sponsor, sanofi-aventis Canada Inc., at: 1-800-265-7927

This leaflet was prepared by sanofi-aventis Canada Inc.

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