

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr**CLOLAR**®

Clofarabine for injection

Read this carefully before you start taking **CLOLAR** and each time you get a refill. 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 **CLOLAR**.

Serious Warnings and Precautions

CLOLAR will be given to you / your child under the supervision of a healthcare professional experienced in the use of anti-cancer medicines.

CLOLAR is associated with the following serious side effects, some of which can be fatal:

- **Tumor Lysis Syndrome (TLS):** caused by the sudden and rapid death of cancer cells due to treatment
- **Systemic Inflammatory Response Syndrome (SIRS)/Capillary Leak Syndrome:** inflammation throughout the body, with loss of fluid, causing a severe drop in blood pressure
- **Enterocolitis:** inflammation of the intestines
- **Hemorrhage:** bleeding into the brain, stomach, intestines or lung
- **Severe skin reactions:** Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN)
- **Severe liver problems:** liver injury causing swelling of your liver (hepatotoxicity) and veno-occlusive live disease
- **Kidney failure:** can be caused by TLS or infections
- **Myelosuppression:** a large decrease in the production of blood cells by the bone marrow
- **Infections:** this includes severe sepsis, an infection of the blood

See the **Serious side effects and what to do about them** table, below, for more information on these and other serious side effects.

Pregnancy: CLOLAR is not to be used if you are pregnant. It can harm your unborn baby.

What is CLOLAR used for?

CLOLAR is used to treat young patients (1 – 21 years of age) with a type of blood cancer called acute lymphoblastic leukemia (ALL) when previous treatments have not worked or have stopped working.

How does CLOLAR work?

CLOLAR is a chemotherapy drug. It is used to kill fast dividing cells, such as cancer cells.

What are the ingredients in CLOLAR?

Medicinal ingredients: clofarabine

Non-medicinal ingredients: sodium chloride, water for injection

CLOLAR comes in the following dosage forms:

sterile solution for infusion: 1 mg / mL

Do not use CLOLAR if:

- you or your child have ever had an allergic reaction to clofarabine or any of the other ingredients in CLOLAR (see **What are the ingredients in CLOLAR?**)
- you or your child have leukemia cells in the fluid that surrounds the brain and spinal cord
- you or your child have had serious heart, liver, kidney or pancreas problems
- you or your child have severe liver or kidney disease that results in decreased function of these organs

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

- you or your child have had liver and/or kidney problems
- you or your child have low blood cell counts
- you or your child are taking medicines that affect your blood pressure or heart function

Other warnings you should know about:

Pregnancy, Breastfeeding and Fertility – female patients:

- If you are pregnant, able to get pregnant, or think you are pregnant, there are specific risks you should discuss with your healthcare professional.
- You should not take CLOLAR if you are pregnant. It can harm your unborn baby.
- If you are able to get pregnant:
 - Avoid becoming pregnant while you are being treated with CLOLAR. Use effective birth control during treatment and for at least 6 months after your last dose.
 - Tell your healthcare professional right away if you become pregnant, or think you may be pregnant, during your treatment.
- It is not known if CLOLAR passes into breastmilk. You should not breastfeed during your treatment and for two weeks after your last dose.
- CLOLAR can affect your fertility. This means that it may be difficult for you to have a child. Talk to your healthcare professional if you have questions about this.

Pregnancy and Fertility – male patients:

- Avoid fathering a child while you are being treated with CLOLAR.
- During your treatment, use effective birth control each time you have sex with a woman who is pregnant, may be pregnant, or can get pregnant. Continue to use this birth control until 3 months after your last dose.
- If, during your treatment with CLOLAR, your sexual partner becomes pregnant, or thinks she may be pregnant, tell your healthcare professional right away.
- CLOLAR can affect your fertility. It is recommended that you talk to your healthcare professional about conservation of sperm before you start treatment with CLOLAR.

Dehydration: As with other chemotherapy drugs you may experience vomiting and diarrhea while you are being treated with CLOLAR. This can cause you to become dehydrated which can lead to low blood pressure. If you think you are dehydrated or if you experience dizziness, light-headedness, fainting or decreased urine output talk to your healthcare professional right away.

Check-ups and tests: You will have blood tests done regularly. The results of these tests will tell your healthcare professional how CLOLAR is affecting your blood, liver and kidneys. Your bone

marrow will be tested before you start each treatment cycle. Your lung function, blood pressure, blood electrolyte levels and weight will also be monitored during treatment.

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

How to take CLOLAR:

- You or your child will be given CLOLAR by a healthcare professional. It will be given through a vein in your arm (IV).
- It usually takes about 2 hours to receive CLOLAR. However, you might get other medicines before or after CLOLAR, so your entire treatment may last longer than 2 hours.
- CLOLAR will be given to you or your child in treatment cycles that include rest periods between treatments. These rest periods give your body a chance to build healthy new cells and regain strength before your next treatment. CLOLAR is usually given once a day for 5 days, followed by a rest period of 2 to 6 weeks. Your healthcare professional will tell you the schedule for your treatments.
- Your healthcare professional will decide how long you will need CLOLAR. It will depend on your medical condition, the other medicines you receive, and how your body responds to these medicines.

Usual dose:

Your healthcare professional will decide on the dose of CLOLAR that you or your child will receive. It will be different for each patient and will depend on your height, weight, age, and medical condition.

Overdose:

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

What are possible side effects from using CLOLAR?

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

Side effects may include:

- nausea, vomiting and diarrhea, can result in dehydration
- constipation
- headache
- rash
- itching
- fatigue, feeling sleepy
- loss of appetite
- abdominal pain
- anxiety, depression, irritability
- cough
- flushing
- muscle and joint aches, back pain, bone pain, rectal pain
- pain in the extremities (hands or feet)

- weakness, generally feeling unwell

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 (a large decrease in the production of blood cells and platelets by the bone marrow): tiredness, weakness, easy bruising and bleeding, gum bleeding, blood in urine, fatigue, chills, fever, shortness of breath or other signs of infection		✓	
Infections (including severe sepsis): fever or chills, nausea, vomiting, diarrhea, generally feeling unwell, dizziness, high or very low body temperature, little or no urine, low blood pressure, palpitations, rapid breathing, rapid heartbeat		✓	
Tachycardia (abnormally fast heartbeat): dizziness, light-headedness, shortness of breath, racing heart		✓	
Dyspnea: shortness of breath or difficulty breathing		✓	
Hypotension (low blood pressure): drowsiness, dizziness, headache, light-headedness, fainting, blurred vision (may occur when you go from lying or sitting to standing up)		✓	
Mucositis (inflammation and ulceration of the mucus membranes lining the digestive tract): painful, red, shiny or swollen gums, tongue, mouth or throat sores, blood in the mouth, difficult or painful swallowing or talking, dry mouth, mild burning or pain when eating food		✓	
COMMON			
Hemorrhage (bleeding into the		✓	

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	
brain, stomach, intestines or lung): <u>Brain</u> : sudden, severe headache, confusion, nausea, vomiting, seizure, loss of consciousness <u>Stomach or Intestines</u> : vomiting blood, black tarry stool, blood in the stool <u>Lung</u> : fever, cough, coughing up blood, shortness of breath			
Palmar-Plantar Erythrodysaesthesia Syndrome (also called Hand and Foot syndrome): red or swollen palms and soles, thick calluses and blisters on the hands and soles, numbness or tingling, burning, tightness of the skin	✓		
Serious liver problems (including hepatotoxicity and veno-occlusive disease): jaundice (yellowing of the skin or whites of the eyes), dark urine, light-coloured stool, abdominal pain, nausea, vomiting, loss of appetite, rectal bleeding, vomiting blood, increase in weight, build up of fluid in the abdomen		✓	
Tumor lysis syndrome (sudden, rapid death of cancer cells due to treatment): rapid breathing, shortness of breath, rapid or irregular heartbeat, low blood pressure, muscle spasms or twitching, severe muscle weakness, joint pain, tiredness, seizures, can lead to acute kidney failure (generalised swelling, decrease or lack of urination, clouding of urine)		✓	
Pericardial effusion (accumulation of fluid around the heart): sharp, piercing chest pain over the center or left side of the chest which is more intense when breathing in,		✓	

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	
shortness of breath, difficulty breathing, fainting, palpitations, fever, fatigue, weakness or feeling sick, cough, swelling in the abdomen or legs			
UNCOMMON			
Stevens-Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN) (severe skin reactions): redness, blistering and/or peeling of the skin and/or inside of the lips, eyes, mouth, nasal passages or genitals, accompanied by fever, chills, headache, cough, body aches or swollen glands		✓	
Allergic reaction: hives or rash, itching, difficulty swallowing or breathing, wheezing, drop in blood pressure, feeling sick to your stomach and throwing up, swelling of the face, lips, tongue or throat		✓	
Pulmonary edema (excess fluid in the lungs): difficulty breathing that worsens with activity or when lying down, extreme shortness of breath, rapid breathing, chest pain, wheezing or gasping for breath, cold clammy skin, irregular heartbeat, cough that produces frothy sputum, blue-tinged lips		✓	
Systemic Inflammatory Response Syndrome/Capillary Leak Syndrome: rapid breathing, rapid heartbeat, fatigue, nausea, abdominal pain, increased thirst, very low blood pressure, high or low temperature, swelling, sudden increase in body weight, mental confusion		✓	
UNKNOWN FREQUENCY			
Enterocolitis (inflammation of the intestines):abdominal pain, nausea, vomiting, diarrhea, fever		✓	

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	
Kidney failure (severe kidney problems): decrease or lack of urination, swelling of feet and ankles, puffiness in the face and hands, fatigue, drowsiness, nausea, vomiting, confusion, itchiness or rashes		✓	

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.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 CLOLAR between 15 - 30°C. They will use the solution immediately once it has been prepared.

Keep out of reach and sight of children.

If you want more information about CLOLAR:

- 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.sanofi.ca, or by calling 1-800-265-7927.

This leaflet was prepared by sanofi-aventis Canada Inc.

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