

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

PrLEUKERAN®
Chlorambucil tablets, USP
(klor-AM-byoo-sil)

Read this carefully before you start taking **LEUKERAN®** 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 **LEUKERAN®**.

Serious Warnings and Precautions

LEUKERAN® (Chlorambucil) is a potent drug and should be used only by doctors experienced with cancer, chemotherapeutic drugs.

LEUKERAN can cause severe side effects which include:

- **Myelosuppression** which is a temporary reduction in the amount of new blood cells and bone marrow cells produced by your body. This increases your risk of getting an infection.
- **Seizures** which are fits or convulsions.
- **Stevens-Johnson syndrome and toxic epidermal necrolysis** which are severe skin diseases causing rash, skin peeling and sores on mucous membranes.

What is LEUKERAN® used for?

LEUKERAN® is used to treat adult patients with cancers of the blood.

It is used:

- to treat certain forms of leukemias (cancers of the blood)
- alone or in combination with other cancer medicines to treat certain types of lymphomas (cancers of the lymph nodes which start in the white blood cells).

How does LEUKERAN® work?

LEUKERAN® belongs to a group of medicines called cytotoxics. It interferes with the growth of cancer cells which eventually are killed. Normal cells may also be affected which may lead to side effects.

What are the ingredients in LEUKERAN®?

Medicinal ingredient: chlorambucil

Non-medicinal ingredients: anhydrous lactose, colloidal silicon dioxide, hydroxypropyl methylcellulose, macrogol, microcrystalline cellulose, stearic acid, synthetic red iron oxide, synthetic yellow iron oxide and titanium dioxide.

LEUKERAN® comes in the following dosage form:

2 mg chlorambucil tablets

Do not use LEUKERAN® if you:

- had a severe allergic reaction to any medicine containing chlorambucil in the past
- are allergic to any of the other ingredients contained in LEUKERAN®.
- are currently receiving, or have recently had, radiotherapy or other chemotherapy.

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

- had a severe allergic reaction to any ingredient in LEUKERAN®
- have a history of seizures (fits or convulsions). You may have an increased risk of seizures when taking LEUKERAN®
- are pregnant or likely to become pregnant or father a child. Reliable birth control **MUST** be taken to avoid pregnancy while you or your partner is taking LEUKERAN®
- are breastfeeding a baby
- have been vaccinated, or are planning to be vaccinated with a live vaccine
- you have or have had kidney disease
- you have or have had liver problems
- will be having surgery

Other warnings you should know about:

Myelosuppression

LEUKERAN® decreases the production of blood cells which can lower your blood counts. Neutropenia (a decrease in the level of white blood cells) increases your risk of getting an infection. Anemia (a decrease in the level of red blood cells) may make you tired or take longer for a minor injury to stop bleeding. Your doctor will want you to have regular blood tests while taking LEUKERAN®. This is to check your blood cell count and to change your dose if necessary.

Pregnancy and breast-feeding

LEUKERAN[®] may harm an unborn baby. You must tell your healthcare professional if you are or think you may be pregnant. Ask your healthcare professional for advice if you are planning to have a baby or are breastfeeding.

Birth control in men and women

Women:

During your LEUKERAN[®] treatment, you should not become pregnant. Use an effective birth control method during this time. Talk to your healthcare professional for advice on effective methods of birth control.

Men:

You should not father a child during your LEUKERAN[®] treatment. Use condoms if you have sex while receiving LEUKERAN[®].

Cancer

LEUKERAN[®] may cause secondary cancers.

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 LEUKERAN[®]:

- other medicines used to treat cancer known as purine nucleoside analogues (such as fludarabine, pentostatin and cladribine)
- phenylbutazone
- live vaccines

How to take LEUKERAN[®]:

LEUKERAN[®] will be given to you by a healthcare professional with experience in the use of cancer chemotherapeutic medicines.

Your healthcare professional will decide how much LEUKERAN[®] you will receive based on your weight and the type of cancer you have. It is important to take your medicine at the right times. You must take it in the way your doctor has told you to.

Swallow your tablets whole with a glass of water on an empty stomach (at least one hour before meals or three hours after meals). Do not break, crush or chew the tablets.

Remember: This medicine is for you. Only a doctor can prescribe it for you. Never give it to someone else. It may harm them even if their symptoms are same as yours.

Overdose:

If you think you have taken too much LEUKERAN® or if someone else takes your medicine by mistake, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to take a dose, ask your doctor or pharmacist for advice. DO NOT double your next dose.

What are possible side effects from using LEUKERAN®?

These are not all the possible side effects you may feel when taking LEUKERAN®. If you experience any side effects not listed here, contact your healthcare professional.

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			
Bone Marrow Suppression (a drop in the number of blood cells)		X	
Neutropenia (decreased white blood cells): aches, feeling tired, fever, flu-like symptoms, infections.		X	
Thrombocytopenia (decreased platelets in the blood); bleeding, bruising, fatigue, weakness.		X	
COMMON			
Nausea		X	
Vomiting		X	
Diarrhea (loose or watery and frequent stools)		X	
Mouth Ulcers (sores in the mouth)		X	
Acute Secondary Haematologic Malignancies (secondary blood cancers)		X	
Seizures (convulsions or fits in children with a kidney problem known as nephrotic syndrome.)		X	
Anemia (decrease in number of red blood cells): dizziness, feeling tired and weak, loss of energy, shortness of breath.		X	
UNCOMMON			
Rash		X	

RARE			
Allergic reaction: swelling of the mouth and/or throat, difficulty breathing, rash, hives, increased heart rate			X
Stevens-Johnson syndrome and toxic epidermal necrolysis (serious skin disease): rash, skin peeling and sores on mucous membranes (body openings)		X	
Jaundice (yellowing of the whites of eyes or the skin)		X	
Fever (increase in body temperature)		X	
Seizures (fits or convulsions)		X	
Hepatotoxicity (liver damage)		X	
Progressively increasing shortness of breath		X	
VERY RARE			
Abnormal and repetitive shaking of the body or twitching, without fits or convulsions		X	
Cystitis (inflammation of the bladder): pain or burning sensation while peeing. Needing to pee often and urgently.		X	
Irreversible bone marrow failure: your body may stop producing blood cells		X	
Pulmonary fibrosis (scarring and thickening of the lungs): shortness of breath		X	
Pneumonia (infection of the lungs): cough, difficult or painful breathing, fever, shortness of breath, wheezing.		X	
Peripheral neuropathy (condition affecting nerves) loss of sensation, movement and organ function		X	
NOT KNOWN			
Amenorrhoea monthly periods stop		X	
Azoospermia sperm production stops		X	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to 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: Refrigerate LEUKERAN® at 2°C to 8°C (36°F to 46°F). Do not freeze. Keep out of reach and sight of children.

If you want more information about LEUKERAN®:

- 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 <http://hc-sc.gc.ca/index-eng.php>; the manufacturer's website www.aspenpharma.ca, or by calling 1-844-330-1213.

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