

**PART III: CONSUMER INFORMATION**

**PrLEUKERAN® Tablets  
Chlorambucil tablets, USP**

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

You may want to read this leaflet again. **Please Do Not Throw It Away** until you have finished your medicine.

**ABOUT THIS MEDICATION**

**What the medication is used for:**

LEUKERAN® is used to treat cancers of the blood:

- as a single agent to treat certain forms of leukemias
- alone or in combination with other agents to treat certain types of lymphomas.

**What it does:**

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

**When it should not be used:**

Do not use LEUKERAN® if:

- You have previously experienced an allergic reaction to chlorambucil or any of the other ingredients in LEUKERAN®.
- You are currently receiving, or have recently had, radiotherapy or other chemotherapy.

**What the medicinal ingredient is:**

The medicinal ingredient in LEUKERAN® is chlorambucil.

**What the important nonmedicinal ingredients are:**

Each LEUKERAN® Tablet contains anhydrous lactose, colloidal silicon dioxide, hydroxy propylmethylcellulose, macrogol, microcrystalline cellulose, stearic acid, synthetic red iron oxide, synthetic yellow iron oxide and titanium dioxide.

**What dosage forms it comes in:**

Tablets. Each tablet contains 2 mg chlorambucil.

**WARNINGS AND PRECAUTIONS**

LEUKERAN® should be prescribed by a doctor who is experienced in the use of medicines to treat cancers.

LEUKERAN® decreases the production of blood cells, which can lower your blood counts. Your blood counts should be measured regularly.

LEUKERAN® can cause an allergic reaction.

LEUKERAN® may harm an unborn fetus.

LEUKERAN® may cause secondary cancers.

LEUKERAN® can cause severe skin rash.

BEFORE you use LEUKERAN® talk to your doctor or pharmacist if:

- you have a history of hypersensitivity (an allergic reaction) to any ingredient in LEUKERAN®.
- you have a history of seizures. You may have an increased risk of seizures when taking LEUKERAN®.
- you are pregnant or likely to become pregnant or father a child. Reliable contraceptive precaution MUST be taken to avoid pregnancy whilst you or your partner is taking LEUKERAN®.
- you are breastfeeding a baby.
- you have been vaccinated, or planning to be vaccinated with a live vaccine.
- you have kidney disease.
- you have liver problems.

If you need surgery, tell the doctor/anaesthetist that you are taking LEUKERAN®.

**INTERACTIONS WITH THIS MEDICATION**

It is important that your doctor know about all your medication so that you get the best possible treatment. Tell your doctor about all the medicines you are taking including herbal products and those you have bought yourself.

Drugs may interact with LEUKERAN® include:

- phenylbutazone
- live organism vaccines

Ask your doctor before receiving any vaccination.

**PROPER USE OF THIS MEDICATION**

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. Do not break, crush or chew the tablets.

From time to time while you are taking LEUKERAN<sup>®</sup>, your doctor will want you to have a blood test. This is to check your blood cell count and to change your dose if necessary.

**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 take too much LEUKERAN<sup>®</sup> or if someone else takes your medicine by mistake, do not delay; ask your doctor what to do immediately, or contact your nearest hospital emergency department, or poison control centre.

**Missed Dose:**

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

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Like all medicines, LEUKERAN<sup>®</sup> can have side effects. The most common side effects with LEUKERAN<sup>®</sup> are:

- A temporary reduction in the amount of new blood cells and bone marrow cells produced by your body. In particular, a type of white blood cell which is important for your body to prevent and fight-off an infection.
- You may become temporarily anemic and tired or take longer for a minor injury to stop bleeding.

In addition, LEUKERAN<sup>®</sup> may cause the following side-effects:

- Diarrhea
- Nausea
- Vomiting
- Mouth ulcers
- In women, periods may stop. In men, sperm production may be reduced or stopped.
- Allergic reactions such as difficulty breathing, swelling of eyelids and mouth (refer to SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM)

Tell your doctor if any of the following happen to you while you are taking LEUKERAN<sup>®</sup>:

- if you feel sick, vomit or develop diarrhea or mouth ulcers
- if you notice any signs of jaundice (yellowing of the whites of the eyes or the skin)
- if you start feeling more tired than usual, or if you notice any signs of a rash, a fever or an infection such as cystitis
- if you have any unexpected bruising or bleeding
- if you have a convulsion
- if you develop a persistent cough or breathlessness
- if you notice numbness or weakness of your muscles

- if you experience jerking movements

Tell your pharmacist or doctor if you notice any other symptoms that you do not understand which are not mentioned here.

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

Frequency	Side Effect/ Symptom	Talk with your Doctor or Pharmacist	Stop taking drug and call your doctor or pharmacist immediately
Rare	Immediate allergic reaction and symptoms such as swelling of the mouth, throat, difficulty in breathing, rash, hives, increased heart rate		X
	Jaundice (yellowing of the whites of eyes or the skin)	X	
	Progressively increasing shortness of breath	X	

*This is not a complete list of side effects. For any unexpected effects while taking LEUKERAN<sup>®</sup>, contact your doctor or pharmacist.*

**HOW TO STORE IT**

- Keep your LEUKERAN<sup>®</sup> tablets in a safe place, between 2°C and 8°C
- Keep out of the reach of children.

### **REPORTING SUSPECTED SIDE EFFECTS**

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

By toll-free telephone: 866-234-2345

By toll-free fax: 866-678-6789

Online: [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)

By email: [CanadaVigilance@hc-sc.gc.ca](mailto:CanadaVigilance@hc-sc.gc.ca)

By regular mail:

Canada Vigilance National Office  
Marketed Health Products Safety and Effectiveness  
Information Bureau  
Marketed Health Products Directorate  
Health Products and Food Branch  
Health Canada  
Tunney's Pasture, AL 0701C  
Ottawa ON K1A 0K9

*NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying Canada Vigilance. The Canada Vigilance Program does not provide medical advice.*

### **MORE INFORMATION**

This document plus the full product monograph, prepared for health professionals can be found at:  
<http://www.tritonpharma.ca> or by contacting the sponsor,

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