

LEUKERAN TABLETS

Chlorambucil (2mg)

What is in the leaflet

1. What LEUKERAN Tablet is used for
2. How LEUKERAN Tablet works
3. Before you use LEUKERAN Tablet
4. How to use LEUKERAN Tablet
5. While you are using it
6. Side effects
7. Storage and Disposal of LEUKERAN Tablet
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision
11. Serial Number

What LEUKERAN Tablet is used for

LEUKERAN Tablet is used to treat some types of cancer and certain blood disorders.

Chlorambucil is used for:

- Hodgkin's disease and Non Hodgkin's Lymphoma. Together, these form a group of diseases called lymphomas. They are cancers formed from cells of the lymphatic system.
- Chronic lymphocytic leukaemia. A type of white blood cell cancer where the bone marrow produces a large number of abnormal white cells.
- Waldenstrom's macroglobulinaemia A rare lymphoma associated with an uncontrolled increase of B-cells, a type of white blood cell, resulting in the release of an abnormal protein into the blood.

How LEUKERAN Tablet works

LEUKERAN Tablet contains a medicine called Chlorambucil. This belongs to a group of medicines called cytotoxics (also known as chemotherapy). It works by reducing the number of abnormal cells in the body.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed it for another reason.

Before you use LEUKERAN Tablet

- When you must not take it

Do not take this medicine if you have an allergy to:

- Chlorambucil, the active ingredient
- any of the other ingredients (refer to section Product Description)

Do not take LEUKERAN Tablet if you are planning to become pregnant or father a child unless you and your doctor have discussed the risks and benefits involved.

LEUKERAN Tablet may harm eggs and sperm. Reliable contraceptive methods must be taken to avoid pregnancy whilst you or your partner is taking this medicine.

Do not take LEUKERAN Tablet if you are pregnant or breastfeeding unless you and your doctor have discussed the risks and benefits involved.

Do not take this medicine after the expiry date printed on the

pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged,

return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

- Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following conditions:

- you have recently received or are receiving radiotherapy or chemotherapy
- you have recently been vaccinated or are planning to be vaccinated
- kidney or liver disease
- you are a potential candidate for bone marrow transplantation (autologous stem cell transplantation) as the long term use of Chlorambucil may reduce the amount of stem cells.

It is possible that the use of Chlorambucil, particularly long term use, may increase the risk of developing a secondary blood cancer. Your doctor will weigh the potential benefit of this medicine against the risk.

If you have not told your doctor any of the above, talk to he/she before taking LEUKERAN Tablet.

- Taking other medicines

Tell your doctor or pharmacist if you are taking any other

medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and LEUKERAN Tablet may interfere with each other.

These include:

- Phenylbutazone (used to treat fever, pain and inflammation in the body)
- vaccinations with 'live' organism vaccines.
- Purine nucleoside analogues (such as fludarabine, pentostatin and cladribine)

These medicines may be affected by LEUKERAN Tablet or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

If you not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to use LEUKERAN Tablet

Follow all directions given to you by your doctor and pharmacist carefully.

These directions may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

- How much to use

LEUKERAN Tablet should only be given to you by a specialist doctor who is experienced in treating cancer.

Hodgkin's Disease

- The usual dose is 0.2 mg per kilogram of your body weight each day for adults and children.

Non-Hodgkin's Lymphoma

- The usual dose is 0.1 to 0.2 mg per kilogram of your body weight each day for adults and children.

Chronic Lymphocytic Leukaemia

- The usual starting dose is 0.15 mg per kilogram of your body weight each day.

Waldenstrom's macroglobulinaemia

- The usual starting dose is 6 to 12 mg each day. Some people have to take Chlorambucil long term. If you have to take it long term, the usual dose is 2 to 8 mg each day. Follow your doctor's instructions carefully.

Always take LEUKERAN Tablet exactly as your doctor has told you.

Your doctor will decide what dose and for how long you will be taking LEUKERAN Tablet. This depends on factors such as your weight and your response to the treatment. Your doctor may change the dose and frequency of your medicine as your condition changes.

Your doctor may order regular blood tests while you are taking LEUKERAN in order to monitor your blood cell count and to change your dose if necessary.

- When to use it

Take each dose of LEUKERAN Tablet at about the same time each day.

Chlorambucil is administered orally and should be taken daily on an empty stomach (at least one hour before meals or three hours after meals).

Taking each dose of LEUKERAN Tablet at the same time each day will have the best effect. It will also help you to remember when to take the medicine.

- How long to use it

Continue taking LEUKERAN Tablet for as long as your doctor recommends.

- If you forget to use it

Tell your doctor if you forget to take a dose.

Do not take a double dose to make up for the dose that you missed.

- If you use too much (overdose)

Immediately telephone your doctor for advice or go to Accident and Emergency (Casualty) at your nearest hospital if you think that you or anyone else may have taken too much LEUKERAN Tablet.

Do this even if there are no signs of discomfort or poisoning.

Overdose symptoms may include decrease in production of blood cells and platelets, agitated behaviour, loss of control of body movement and fits.

You may need urgent medical attention.

While you are using it

- Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking LEUKERAN Tablet.

Tell your doctor if you are pregnant, plan to become pregnant, breast-feeding or trying to father a child.

If you are about to start taking any new medicine tell your doctor and pharmacist that you are taking LEUKERAN Tablet.

- Things you must not do

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Do not take LEUKERAN Tablet to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

- Things to be careful of

Be careful driving or operating machinery until you know how LEUKERAN Tablet affects you.

Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

Ask for the advice of your doctor or pharmacist if you have any concerns about the effects of taking this medicine.

Do not be alarmed by the following lists of side effects.

You may or may not experience any of them.

Tell your doctor if you notice any of the following side effects:

- A drop in number of blood cells
- Fits
- Nausea and vomiting
- Diarrhea
- Mouth ulcer
- Secondary blood cancers
- Serious allergic reactions
- Movement disorder
- Absence of menstruation or absence of sperms in semen

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of LEUKERAN Tablet

- Storage

Keep your medicine in its original packaging until it is time to take them.

If you take the tablets out of the pack, they may not keep well.

Keep your medicine in a place where the temperature will stay between 2 to 8°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink.

Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

- Disposal

If your doctor or pharmacist tells you to stop taking this medicine or it has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

Product Description

- What it looks like

Brown film-coated, round, biconvex tablets engraved 'GX EG3' on one side and 'L' on the other.

- Ingredients

Active ingredient:

- Chlorambucil

Inactive ingredients:

- Lactose anhydrous
- Silica colloidal anhydrous
- Stearic acid
- Opadry brown
- Microcrystalline cellulose

- MAL number

MAL04125474ACZ

Manufacturer

Excella GmbH, Nürnberger Strasse 12, D- 90537 Feucht, Germany.

Product Registration Holder

Aspen Medical Products Malaysia Sdn Bhd (1004761-W)
Unit 1302A, Level 13A, Uptown 1, 1 Jalan SS21/58, Damansara Uptown, 47400

Petaling Jaya, Selangor,
Malaysia.

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