PACKAGE LEAFLET

Package Leaflet: Information for the user

Leukeran 2mg Film-coated Tablets
chlorambucil

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Leukeran is and what it is used for

Leukeran contains an active substance called chlorambucil which belongs to a group of medicines called cytotoxics (also called chemotherapy). This medicine is used to treat certain type of cancers affecting human blood and lymphatic system. Your doctor will be able to explain how Leukeran might help in your particular condition.

Leukeran is used in patients with:
- **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 blood cancer where the bone marrow produces a large number of abnormal white blood 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.

2. What you need to know before you take Leukeran

Do not take Leukeran if:
You are allergic to chlorambucil or any of the other ingredients of this medicine (listed in section 6).
Leukeran should not be used for the treatment of non-malignant cancer.

If you are not sure, talk to your doctor before taking Leukeran.

Warnings and precautions
Talk to your doctor or nurse before you take this medicine if:
- You have been recently vaccinated, or planning to be vaccinated with a live vaccine (see Other medicines and Leukeran) as Leukeran can make your body less able to fight infections.
- You are a potential candidate for bone marrow transplantation (autologous stem cell transplantation) as the long term use of Leukeran may reduce the amount of stem cells.
- You have had radiotherapy or chemotherapy, now or recently.
- You have a liver disease.

- You have a kidney disease (nephrotic syndrome), had high pulse dosing regimen or ever had a fit or convulsion. If you have ever had fits or convulsions, you might be more at risk of having fits or convulsions when taking Leukeran.

It is possible that the use of Leukeran, particularly long term use, may increase the risk of developing a secondary blood cancer called acute secondary haematological malignancy. In many cases, patients who develop this have also received another type of chemotherapy or some form of radiation therapy. Symptoms of a secondary blood cancer include tiredness, fever, infection and bruising. Tell your doctor as soon as possible if you have any of these symptoms (see section 4).

Other medicines and Leukeran
Please tell your doctor if you are taking or have recently taken any of the following:
- Vaccines which contain live organisms (such as oral polio vaccine, measles, mumps, rubella).
- Phenylbutazone (a medicine used to treat fever, pain, and inflammation in the body) - you may require a lower dose of Leukeran.
- Fludarabine, Pentostatin or Cladribine, which are other chemotherapy medicines that may be used for the treatment of certain blood cancers.

Please tell your doctor if you are taking or have recently taken or may take any other medicines, including medicines obtained without a prescription. This includes herbal medicines also.

Leukeran with food
Leukeran should be taken on an empty stomach. See section 3.

Pregnancy, breast-feeding and fertility

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, it is important to tell your doctor this before you are given Leukeran.
You should not take Leukeran if you are planning to have a baby. This applies to both men and women. Treatment with Leukeran is not recommended during pregnancy because it can be very damaging to your unborn baby.

You should not breast-feed while taking Leukeran.

Fertility
Leukeran can affect ovaries or sperm, which may cause infertility (inability to have a baby). In women menstruation can stop (amenorrhoea) and in men, a complete lack of sperm can be observed (azoospermia). Use a reliable form of contraception to avoid pregnancy if either you or your partner is taking Leukeran. Ask your doctor for advice.

Driving and using machines
No information on the effects of Chlorambucil on the ability to drive and use machines is available.

Leukeran tablets contain lactose
Leukeran tablets contain lactose, a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before you take this medicine.

3. How to take Leukeran

Always take Leukeran exactly as your doctor has told you. Check with your doctor if you are not sure.

Leukeran should only be given to you by a specialist doctor who is experienced in treating cancer. Your doctor will advise you of how much and how often you will need to take this medicine. Your dosage is calculated based on your body weight and your disease.

- Leukeran tablet is administered orally. Food is known to affect the absorption of Leukeran therefore it is advisable to take Leukeran on an empty stomach (one hour before a meal or 3 hours after a meal).
- Swallow your tablets whole with a glass of water.
- **Do not break, crush or chew the tablets.**

The dose of Leukeran depends on the type of your disease condition (see section 1).
- Your doctor may change the dose during treatment depending on your needs. The drug dose can sometimes be changed if you are an older person or have liver problems. Your kidney or liver functions may be monitored during treatment, if you are an elderly person.
- While on Leukeran therapy, your doctor may take regular blood tests to check the number of cells in your blood, and your drug dose may be adjusted as a result.

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 Leukeran long term. Follow your doctor's instructions carefully.

If you take more Leukeran than you should
Tell your doctor immediately or go to a hospital straight away. Ensure to take the medicine pack with you, even if there are no tablets left.

If you forget to take Leukeran
Tell your doctor. **Do not take a double dose to make up for a forgotten dose.**

If you stop taking Leukeran
Do not stop taking Leukeran without your doctor's advice.
If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

Like all medicines, Leukeran can cause side effects, although not everybody gets them.

If you experience any of the following, talk to your specialist doctor or go to hospital straight away:
- any signs of a high temperature or infection (sore throat, sore mouth or urinary problems). Treatment with Leukeran can cause a lowering of the white blood cell count. White blood cells fight infection, and when there are too few white blood cells, infections can occur.
- any **unexpected** bruising or bleeding, as this could mean that too few blood cells of a particular type are being produced
- if you **suddenly** feel unwell (even with a normal temperature)
- if you start feeling extremely tired
- if you notice numbness or weakness of your muscles
- if you experience skin rashes, blisters on the skin, sore mouth or eyes and have a high temperature.

Talk to your doctor if you have any of the following side effects, which may also happen with this medicine:

Very Common (affects more than 1 in 10 people)
- a drop in the number of blood cells, or bone marrow suppression.

Common (affects less than 1 in 10 people)
- feeling sick (nausea), being sick (vomiting), diarrhoea or mouth ulcers (sores),
- secondary blood cancers (acute secondary haematologic malignancies) especially after long term treatment,
- fits (convulsions) in children with a kidney problem known as nephrotic syndrome,
- a drop on red blood cells or anaemia which may make you feel tired or weak or breathless.

Uncommon (affects less than 1 in 100 people)
- rash.

Rare (affects less than 1 in 1,000 people)
- yellowing of the whites of the eyes or skin (jaundice),
- allergy symptoms such as skin lumps, hives (urticaria) or swelling of the face, eyelids, lips or throat (oedema),
- skin rash has been reported to progress to serious conditions including Stevens-Johnson syndrome and toxic epidermal necrolysis. These two forms of the same serious skin disease cause rash, skin peeling, and sores on the mucous membranes,
- fever,
- fit or convulsion,
- liver damage/injury (hepatotoxicity).

Very rare (affects less than 1 in 10,000 people)
- abnormal and repetitive shaking movement of the body or twitching, without fits or convulsions, condition affecting nerves leading to impairment of sensation, movement and organ function (peripheral neuropathy),
- inflammation of the bladder called cystitis,
- irreversible bone marrow failure - your body may stop producing blood cells transiently,
- scarring and thickening in the lungs with shortness of breath,
- a type of pneumonia that can cause scarring on the lungs,
- lung disease.

Not known (frequency cannot be estimated from the available data)
- absence of menstruation (amenorrhoea),
- absence of sperms in the semen (azoospermia).

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:
Ireland: HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; e-mail: medsafety@hpra.ie
Malta: http://www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Leukeran

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date, which is stated on the bottle label and the carton after ‘Exp’. This is printed as month; year and refers to the last date of the month.

- Store in the original container.
- Store in a refrigerator (2 and 8°C).
- If your doctor tells you to stop taking the tablets, it is important to return any which are left over to your pharmacist, who will destroy them according to disposal of dangerous substance guidelines. Only keep the tablets if your doctor tells you to.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Leukeran contains
The active substance is chlorambucil. Each Leukeran tablet contains 2 mg of chlorambucil.
The other ingredients are microcrystalline cellulose, anhydrous lactose, colloidal anhydrous silica, stearic acid, hypromellose, titanium dioxide (E171), synthetic yellow iron oxide (E172), synthetic red iron oxide (E172) and macrogol.

What Leukeran looks like and contents of the pack
Leukeran tablets are brown, film-coated, round, biconvex tablets engraved 'GX EG3' on one side and 'L' on the other. Your Leukeran tablets are in bottles of 25 and 50 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation holder:
Aspen Pharma Trading Limited
3016 Lake Drive,
Citywest Business Campus,
Dublin 24, Ireland

Manufacturer: EXCELLA GmbH & Co. KG, Nürnberger Strasse 12, 90537 Feucht, Germany

Medical Information Enquiries
For any Medical Information enquiries about this product, please contact:
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Tel: 00353 1 630 8400
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This leaflet was last revised in January 2017

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