

## Leukeran® 2mg 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.
- The name of this medicine is Leukeran 2mg Tablets but will be referred to as Leukeran throughout the remainder of this leaflet.

### What is in this leaflet

1. What Leukeran is and what it is used for
2. What you need to know before you take Leukeran
3. How to take Leukeran
4. Possible side effects
5. How to store Leukeran
6. Contents of the pack and other information

### 1. What Leukeran is and what it is used for

Leukeran contains a medicine called chlorambucil. This belongs to a group of medicines called cytotoxics (also called chemotherapy). Leukeran is used to treat some types of cancer and certain blood problems. It works by reducing the number of abnormal cells your body makes.

Leukeran 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.

Ask your doctor if you would like more explanation about these diseases.

You must talk to a doctor if you do not feel better or if you feel worse.

### 2. What you need to know before you take Leukeran

#### Do not take Leukeran:

- If you are allergic (hypersensitive) to chlorambucil or any of the other ingredients of Leukeran tablets (see section 6).

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

#### Warnings and precautions

Before you take Leukeran, tell your doctor or nurse if:

- you have been recently vaccinated, or planning to be vaccinated with a live vaccine (see Other medicines and Leukeran). 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 or kidney problems.
- you have a kidney problem (nephrotic syndrome), had high pulse dosing regimen or ever had a fit or convulsion. If you had 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. 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, have recently taken or might take any other medicines, including medicines obtained without a prescription. This includes herbal medicines.

In particular, 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 haematological malignancies (types of cancer that affect blood, bone marrow and lymph nodes).

#### 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, ask your doctor for advice before taking this medicine.

Do 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 may cause permanent damage to a foetus. Your doctor will consider the risks and benefits to you and your baby of taking Leukeran.

Do not breast-feed while taking Leukeran. There have been reports indicating that Leukeran and its ingredients can be passed into breast-milk. Ask your doctor or midwife for advice.

##### Fertility

Leukeran can affect ovaries or sperm, which may cause infertility (inability to have a baby). In woman 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 Leukeran on the ability to drive and use machines is available.

##### Leukeran contains lactose

Leukeran tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before you take Leukeran tablets.

### 3. How to take Leukeran

Always take this medicine 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. The duration of the treatment will be decided by your doctor based on your disease.

- Leukeran is administered orally and should be taken daily on an empty stomach (at least one hour before meals or three hours after meals).
- 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 blood problem or cancer (see section 1).

- Your doctor may change your dose during your treatment depending on your needs. The 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.
- When you take Leukeran your doctor will 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 0.2mg per kilogram of your body weight each day for adults and children.

### Non-Hodgkin's Lymphoma

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

### Chronic Lymphocytic Leukaemia

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

### Waldenstrom's macroglobulinaemia

- The usual starting dose is 6 to 12mg each day. Some people have to take Leukeran long term. If you have to take it long term, the usual dose is 2 to 8mg each day. 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.

### 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

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 experiences them.

### If you experience any of the following, talk to your specialist doctor or go to hospital straight away:

- any signs of fever or infection (sore throat, sore mouth or urinary problems),
- 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),
- 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 tissues (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 stores 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,
- 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,
- lung disease,
- condition affecting nerves leading to impairment of sensation, movement and organ function (peripheral neuropathy).

### Not known: frequency cannot be estimated from the available data

- absence of menstruation (amenorrhoea),
- absence of sperm (azoospermia).

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

### 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 the Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Leukeran

### • Keep out of the sight and reach of children.

- Store in a dry place.
- Store in a refrigerator (2°C - 8°C).
- Do not use this medicine after the expiry date which is stated on the label and the carton after 'EXP'. The expiry date refers to the last day of that month
- If the tablets become discoloured or show any sign of deterioration, return them to your pharmacist.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. Contents of the pack and other information

### What Leukeran contains

Each film-coated tablet contains 2mg of the active ingredient chlorambucil.

The other ingredients are microcrystalline cellulose, lactose anhydrous, 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

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

Leukeran is available in packs containing a glass bottle of 25 tablets.

Manufactured by

Excella GmbH & Co. KG, Nürnberger Strasse 12, 90537 Feucht, Germany.

Procured from within the EU by the Product Licence Holder: MPT Pharma Ltd., Westgate Business Park, Unit 5-7 Tintagel Way, Aldridge, Walsall, WS9 8ER.

Repackaged by MPT Pharma Ltd.

PL 33532/0922

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Leaflet dated 19<sup>th</sup> August 2019

Leaflet coded XXXXXXXXXX

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## Chlorambucil 2mg Tablets

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### 2. What you need to know before you take Chlorambucil

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If you are not sure, talk to your doctor or nurse before taking Chlorambucil.

#### Warnings and precautions

Before you take Chlorambucil, tell your doctor or nurse if:

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- you have had radiotherapy or chemotherapy, now or recently.
- you have a liver or kidney problems.
- you have a kidney problem (nephrotic syndrome), had high pulse dosing regimen or ever had a fit or convulsion. If you had ever had fits or convulsions, you might be more at risk of having fits or convulsions when taking Chlorambucil.

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- Swallow your tablets whole with a glass of water.
- **Do not break, crush or chew the tablets.**

The dose of Chlorambucil depends on the type of your blood problem or cancer (see section 1).

- Your doctor may change your dose during your treatment depending on your needs. The 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.
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Tell your doctor immediately or go to a hospital straight away. Ensure to take the medicine pack with you.

#### If you forget to take Chlorambucil

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

#### If you stop taking Chlorambucil

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#### 4. Possible side effects

Like all medicines, Chlorambucil can cause side effects, although not everybody experiences them.

#### If you experience any of the following, talk to your specialist doctor or go to hospital straight away:

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- 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),
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#### 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),
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- 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,
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- 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,
- 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,
- lung disease,
- condition affecting nerves leading to impairment of sensation, movement and organ function (peripheral neuropathy).

#### Not known: frequency cannot be estimated from the available data

- absence of menstruation (amenorrhoea),
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If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

#### Reporting of side effects

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#### 5. How to store Chlorambucil

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##### What Chlorambucil contains

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