

B. PACKAGE LEAFLET

Package Leaflet: Information for the User

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

1. What Chlorambucil is and what it is used for

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

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.

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 Chlorambucil

Do not take Chlorambucil :

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

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:

- you have been recently vaccinated, or planning to be vaccinated with a live vaccine (see Other medicines and Chlorambucil). Chlorambucil 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 Chlorambucil 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 Chlorambucil.

It is possible that the use of Chlorambucil, 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 Chlorambucil

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 Chlorambucil.
- 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).

Chlorambucil with food

Chlorambucil 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 Chlorambucil if you are planning to have a baby. This applies to both men and women. Treatment with Chlorambucil 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 Chlorambucil.

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

Fertility

Chlorambucil 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 Chlorambucil. 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.

Chlorambucil contains lactose

Chlorambucil 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 Chlorambucil tablets.

3. How to take Chlorambucil

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

Chlorambucil 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.

- Chlorambucil 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 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.
- When you take Chlorambucil 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 0.2 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.

If you take more Chlorambucil 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 Chlorambucil

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

If you stop taking Chlorambucil

If you have any further questions on the use of this medicine, ask your doctor or nurse.

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:

- 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 national reporting system: the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Chlorambucil

- 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 pack after 'Exp'.
- 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 Chlorambucil contains

- The active substance is chlorambucil. Each Chlorambucil 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 Chlorambucil looks like and contents of the pack

Chlorambucil tablets are brown, round, biconvex, film-coated tablets, one side engraved with 'L' on the other side engraved "GX EG3". Your Chlorambucil tablets are in bottles of 25 tablets.

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: 24 Hour Helpline +441748 823 391 (free phone UK only 0800 0087 392)

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: **0800 198 5000 (UK only).**

Please be ready to give the following information:

Product name	Chlorambucil Tablets 2 mg
Reference number	PL 39699/ 0041

This is a service provided by the Royal National Institute of Blind People.

This leaflet was last revised in January 2017