1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

LEUKERAN 2 mg film-coated tablets

Chlorambucil

Contains sugar: Lactose anhydrous 67,65 mg

Read all of this leaflet carefully before you start taking LEUKERAN 2 mg

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- LEUKERAN 2 mg has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What LEUKERAN 2 mg is and what it is used for

LEUKERAN 2 mg contains the active substance chlorambucil.

This belongs to a group of medicines called cytotoxics (also called chemotherapy).

LEUKERAN 2 mg is used for various types of blood cancers.

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

2. What you need to know before you take LEUKERAN 2 mg

Do not take LEUKERAN 2 mg:

- if you are hypersensitive (allergic) to chlorambucil or any of the other ingredients of LEUKERAN 2 mg (listed in section 6).
- if you have been vaccinated, or plan to be vaccinated with a live vaccine.
- if you are pregnant or breastfeeding your baby.

Warnings and precautions

Take special care with LEUKERAN 2 mg if:

- you are a potential candidate for bone marrow transplantation (autologous stem cell transplantation) as the long-term use of LEUKERAN 2 mg may reduce the amount of stem cells.
- you have had radiotherapy or chemotherapy, now or recently.
- you have a kidney problem (nephrotic syndrome) or had a high pulse dosing regimen.
- you 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 2 mg.
- you experience the following symptoms; tiredness, fever, infection and bruising which may be symptoms of a secondary blood cancer. It is possible that the use of LEUKERAN 2 mg, 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. Tell your doctor as soon as possible if you have any of these symptoms.

- you experience shortness of breath or lung disease which could be due to scarring and thickening in the lungs such as pulmonary fibrosis or interstitial pneumonia.
- you experience skin rash, skin peeling and sores on the mucous membranes as these symptoms have been reported to progress to serious conditions including Stevens-Johnson syndrome and toxic epidermal necrolysis.
- you have a liver problem.
- you are elderly.
- you are planning to have a baby as it may cause sterility (inability to have a baby) in men and women. You should speak to your healthcare provider before you start treatment with LEUKERAN 2 mg.

Children and adolescents

LEUKERAN 2 mg, may be used in accordance with the treatment management.

Other medicines and LEUKERAN 2 mg

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following:

- *Vaccines* which contain live organisms (such as oral polio vaccine, measles, mumps, rubella).
- *Fludarabine or cladribine*, which are other chemotherapy medicines that may be used for the treatment of haematological malignancies (types of cancer that affects blood, bone marrow and lymph nodes).

LEUKERAN 2 mg with food and drink

LEUKERAN 2 mg should be taken on an empty stomach.

Pregnancy, breastfeeding and fertility

You should not take LEUKERAN 2 mg if you are pregnant or breastfeeding your baby (see section 2).

You should use adequate contraceptives if either you or your partner is taking LEUKERAN 2 mg.

Mothers taking LEUKERAN 2 mg should not breastfeed their babies.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Fertility

LEUKERAN 2 mg 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) (see section 2).

Use a reliable form of contraception to avoid pregnancy if either you or your partner is taking LEUKERAN 2 mg. Ask your doctor for advice.

Ask your doctor for advice regarding storing your sperm before you start taking LEUKERAN 2 mg.

Driving and using machines

LEUKERAN 2 mg can have a moderate to major influence on the ability to drive and use machines.

Since adverse reactions such as convulsions (fits), abnormal and repetitive shaking movements of the body or twitching (without convulsion or fits) and conditions affecting nerves leading to impairment of sensation, movement and organ function (peripheral neuropathy) have been reported whilst using LEUKERAN 2 mg, you should not drive, use machinery or perform any tasks that require concentration, until you are certain that LEUKERAN 2 mg does not adversely affect your ability to do so (see section 4)

It is not always possible to predict to what extent LEUKERAN 2 mg may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which LEUKERAN 2 mg affects them (see section 4).

LEUKERAN 2 mg contains lactose anhydrous

LEUKERAN 2 mg contains lactose anhydrous which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Lactose is a source of glucose and galactose. If you have one of the rare genetic disorders galactosaemia, or glucose-galactose intolerance or congenital lactase deficiency, you must talk to your doctor or pharmacist before taking LEUKERAN 2 mg.

3. How to take LEUKERAN 2 mg

Do not share medicines prescribed for you with any other person.

Always take LEUKERAN 2 mg exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how long your treatment with LEUKERAN 2 mg will last. Do not stop treatment early. If you have the impression that the effect of LEUKERAN 2 mg is too strong or too weak, tell your doctor or pharmacist.

The dose of LEUKERAN 2 mg depends on the type of your blood problem or cancer. Your doctor may change your dose during your treatment depending on your needs.

When you take LEUKERAN 2 mg your doctor will take regular blood tests to check the number of cells in your blood and your medicine dose may be adjusted as a result.

LEUKERAN 2 mg is administrated 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 suitable for you will be determined by your doctor and may range from 0,1 mg/kg to 0,2 mg/kg every day.

If you take more LEUKERAN 2 mg than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take LEUKERAN 2 mg

Do not take a double dose to make up for forgotten individual doses.

If you stop taking LEUKERAN 2 mg

Do not stop taking LEUKERAN 2 mg early or without talking to your doctor. If you have any further questions on the use of LEUKERAN 2 mg, ask your doctor or pharmacist.

4. Possible side effects

LEUKERAN 2 mg can have side effects.

Not all side effects reported for LEUKERAN 2 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LEUKERAN 2 mg, please consult your healthcare provider for advice.

If any of the following happens, stop taking LEUKERAN 2 mg and tell your doctor immediately or go to the casualty department at your nearest hospital:

- rash,
- allergy symptoms such as skin lumps, hives (urticaria) or swelling of the tissues (oedema),
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS) and toxic epidermal necrolysis (TEN) which is a rare, life-threatening skin condition that is usually caused by a reaction to medicines. This disease causes the top layer of skin (the epidermis) to detach from the lower layers of the skin (the dermis), all over the body, leaving the body susceptible to severe infection,
- swelling of deeper skin tissues, just beneath the skin (subcutaneous tissue and mucosa), around the eyes, lips, tongue, hands and feet known as angioedema.

These are all very serious side effects. If you have them, you may have had a serious reaction to LEUKERAN 2 mg. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- any unexpected bruising or bleeding, as this could mean that too few blood cells of a particular type are being produced (bone marrow depression, leucopenia, neutropenia or thrombocytopenia),
- increased and repeated infections,
- if you are feeling extremely tired or weak (due to drop in red blood cells or anaemia),
- convulsions (fits),
- liver damage/problems (hepatotoxicity), including jaundice (signs include yellowing of your skin and eyes, sometimes with a fever, pale stools and dark urine),
- scarring and thickening in the lungs with shortness of breath, lung disease (pulmonary fibrosis, interstitial pneumonia).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- feeling sick (nausea), being sick (vomiting), diarrhoea or mouth ulcers (sores),
- an increased risk of developing a secondary blood cancer with the use of LEUKERAN 2 mg, particularly long-term use,

Less frequent side effects:

- any sudden changes to your eyesight (such as loss of vision or blurred vision),
- fever (pyrexia),
- abnormal and repetitive shaking movement of the body or twitching, without fits or convulsions (myclonus),
- inflammation of the bladder called cystitis,
- condition affecting nerves leading to impairment of sensation, movement and organ function (peripheral neuropathy),

Side effects with an unknown frequency:

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

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to:

SAHPRA: https://www.sahpra.org.za/health-products-vigilance/

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of LEUKERAN 2 mg.

5. How to store LEUKERAN 2 mg

Store all medicines out of reach of children.

Store between 2 °C to 8 °C.

Protect from light.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What LEUKERAN 2 mg contains

The active substance is 2 mg of chlorambucil.

The other ingredients are colloidal anhydrous silica, hypromellose, lactose anhydrous, microcrystalline cellulose, polyethylene glycol, stearic acid, synthetic red iron oxide (C.I. 77491), synthetic yellow iron oxide (C.I. 77492), titanium dioxide (C.I. 77891).

What LEUKERAN 2 mg looks like and contents of the pack

LEUKERAN 2 mg is a brown, round, biconvex, film-coated tablets, one side engraved with “L” and the other side engraved “GX EG3”.

LEUKERAN 2 mg 25 or 50 tablets are packed into a round, amber glass bottle with a child-resistant cap, composed of an inner polypropylene shell and an outer white high-density polypropylene shell. The bottle is placed in an outer cardboard carton.

Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration

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