

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS'
REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed with a doctor's prescription only

Calquence® Tablets

Film-coated tablets

Composition:

Each film-coated tablet contains:

Acalabrutinib (as maleate) 100 mg

For inactive and allergenic ingredients, please refer to section 2 "Important information about some of the ingredients in this medicine" and section 6 - "Further Information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Calquence tablets is indicated for the treatment of adults:

- with MCL (mantle cell lymphoma) in combination with bendamustine and rituximab who have not received prior treatment for MCL and are ineligible for autologous hematopoietic stem cell transplantation.
- with MCL (mantle cell lymphoma) who have received at least one prior therapy.
- with Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL).

Therapeutic group

BTK (Bruton tyrosine kinase) inhibitors.

2. BEFORE USING THE MEDICINE

Do not use this medicine if:

You are sensitive (allergic) to the active ingredient or to any of the other ingredients contained in the medicine (please refer to section 6 - "Further Information").

Special warnings regarding the use of Calquence tablets:

Before treatment with Calquence tablets tell your doctor if you:

- recently had surgery or plan to have surgery. Your doctor may stop treatment with Calquence tablets for any planned surgical, medical, or dental procedure.
- have bleeding problems.
- have or had heart rhythm problems.
- have an infection.
- have or had liver problems, including hepatitis B virus (HBV) infection.
- are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed.

Children and adolescents

There is no data regarding safety and efficacy of use of this medicine in children and adolescents.

Tests and follow up

In order to monitor your blood count, your doctor will refer you to do blood count test regularly during treatment with Calquence tablets.

Your doctor will check you for skin cancers during treatment with Calquence tablets.

If you are of childbearing age, your doctor may do a pregnancy test before you start treatment with the medicine.

Drug interactions

If you are taking, or if you recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Taking Calquence tablets with certain other medications may affect how Calquence tablets work and may cause side effects. Especially tell your doctor if you are taking:

- a blood thinner medicine.

Use of the medicine and food

This medicine can be taken with or without food.

Pregnancy, breast-feeding and fertility:

Pregnancy

If you are pregnant, think you may be pregnant or planning to get pregnant, inform your doctor before taking this medicine. Calquence tablets may hurt your fetus and cause problems during childbirth (dystocia). The doctor may ask you to do a pregnancy test before you start treatment with Calquence tablets. If you are of childbearing age, you should use effective birth control (contraception) during treatment with Calquence tablets and for at least 1 week after your final dose.

Breast-feeding

It is not known if Calquence tablets passes into your breast milk. Do not breastfeed during treatment with Calquence tablets and for at least 2 weeks after your final dose.

Driving and using machines

Calquence tablets has no or negligible effect on your ability to drive or use machines. However, if you feel dizziness, weakness, or tiredness during treatment with Calquence tablets, do not drive or use machines.

Important information about some of the ingredients in this medicine

This medicine contains less than 1 mmol sodium (23 mg) per dose, i.e., it is essentially 'sodium-free'.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use this medication exactly as directed by your doctor. If you are unsure about the dosage or how to use this medication, consult your doctor or pharmacist

- The dosage and treatment regimen will be determined by the doctor only.
- The usual dosage is generally: one Calquence tablet twice daily (about 12 hours apart).
- Do not change your dose or stop taking the medicine unless your doctor tells you to.
- Your doctor may instruct you to decrease your dose, temporarily stop or completely stop taking the medicine if you develop certain side effects.
- Do not switch (interchange) your Calquence tablets with Calquence capsules.
- **Do not exceed the recommended dose.**

Method of administration

- Can be taken with or without food.
- Swallow the tablet whole with a glass of water. Do not chew, crush, dissolve or cut the tablet.

If you accidentally taken a higher dose, or if a child has accidentally swallowed the medicine, immediately contact a doctor or go to a hospital emergency room, and bring the package of the medicine with you.

If you have forgotten to take the medicine:

If you have forgotten to take the medicine at its scheduled time, take it as soon as you remembered. If it is more than 3 hours past your usual dosing time, skip the missed dose and take your next dose at your regularly scheduled time and consult the doctor. Do not take a double dose to make up for the forgotten dose.

Adhere to the treatment regimen as recommended by your doctor.

Do not take medicines in the dark! Check the label and the dose every time you take a medicine. Wear glasses if you need them.

If you have any further questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Calquence tablets may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

Effects that require special attention:

Refer to the doctor or hospital emergency room immediately if you experience any of the following serious side effects:

- **Serious infections** have happened in people treated with Calquence tablets and may lead to death. Your doctor may prescribe certain medicines if you have an increased risk of getting infections. Tell your doctor immediately if you have any signs or symptoms of an infection, including fever, chills, or flu-like symptoms.

- **Bleeding problems** have happened in people treated with Calquence tablets. Bleeding problems can be serious and may lead to death. Your risk of bleeding may increase if you are also taking a blood thinner medicine. Inform your doctor if you have any signs or symptoms of bleeding, including:
 - blood in your stools or black stools (looks like tar)
 - pink or brown urine

- unexpected bleeding, severe bleeding or bleeding you cannot control
 - vomit blood or vomit that looks like coffee grounds
 - cough up blood or blood clots
 - dizziness
 - weakness
 - confusion
 - changes in your speech
 - headache that lasts a long time
 - bruising or red or purple skin marks
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- **Decrease in blood cell counts** (decreased number of white blood cells, platelets, and red blood cells). Decrease in blood cell counts are common during treatment with Calquence tablets, but can be severe. Your doctor should do blood tests to check your blood counts regularly during treatment with Calquence tablets.
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- **Second primary cancers.** New cancers have happened in patients during treatment with Calquence tablets, including cancers of the skin or other organs. Your doctor will check you for skin cancers during treatment with Calquence tablets. Use sunscreen when you are exposed to the sunlight.
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- **Heart rhythm problems** have happened to patients treated with Calquence tablets, which may be serious or lead to death. Tell your doctor if you have any of the following signs or symptoms:
 - your heartbeat is fast or irregular
 - dizziness
 - feeling faint
 - shortness of breath
 - chest discomfort
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- **Liver problems** have happened in people treated with Calquence tablets, and can be severe or life-threatening, or lead to death. Contact your doctor if you experience stomach pain or discomfort, urine of dark color or yellowing of your skin. Your doctor will instruct to perform tests to monitor your liver function during treatment with Calquence tablets.

Very common side effects – side effects occurring in more than one of ten users:

- diarrhea
- muscle and joint pain
- upper respiratory infection
- lower respiratory infection
- headache
- tiredness

If a side effect occurs, if any of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

5. HOW SHOULD CALQUENCE TABLETS BE STORED?

- Avoid poisoning! This medicine, and any other medicine, must be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor!
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Do not store above 30°C.

6. FURTHER INFORMATION

In addition to the active ingredients, Calquence tablets also contains:

Tablet:

mannitol, microcrystalline cellulose, low-substituted hydroxypropyl cellulose and sodium stearyl fumarate.

Tablet coating:

hypromellose, copovidone, titanium dioxide, macrogol 3350, medium-chain triglycerides, iron oxide yellow, iron oxide red.

What does the medicine look like and what are the contents of the package

The pack contains 60 tablets in blister pack.

A tablet of Calquence tablets 100mg is film-coated, orange, oval, biconvex, debossed with 'ACA 100mg' on one side and plain on the other.

Registration number of the medicine in the National Drug Registry of the

Ministry of Health: 176-50-37586-99

Manufacturer: AstraZeneca AB, Södertälje, Sweden.

License holder and Importer: AstraZeneca (Israel) Ltd., 1 Atirei Yeda St., Kfar Saba 4464301.

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