

# TO YOU WHO RECEIVED CALQUENCE® (ACALABRUTINIB) TABLETS PRESCRIBED BY YOUR DOCTOR

CALQUENCE is a medicine used to treat adults  
with chronic lymphocytic leukemia (CLL).

For full details, please read the package leaflet.



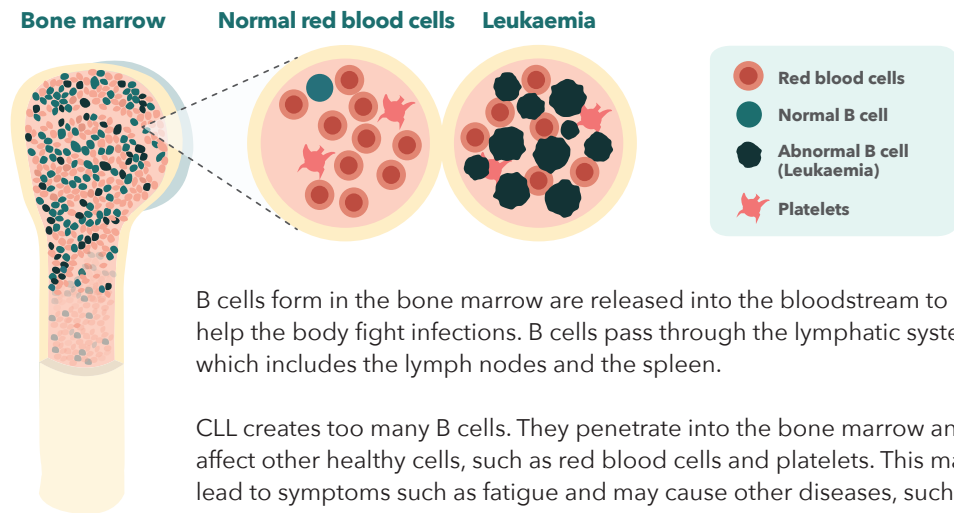
# IMPORTANT CONSIDERATIONS BEFORE STARTING TREATMENT

Starting your first treatment for CLL- chronic lymphocytic leukaemia - changing or restarting treatment, may be overwhelming. Therefore, in addition to managing your symptoms, it is important that you keep track of your meetings with the health care service etc. and try to take care of yourself in the best possible way.

This leaflet is designed to help you start your treatment with CALQUENCE® (akalabrutinib). Here, you will find out how the treatment works and important considerations, as well as tips and advice. It is essential that you consult your doctor and/or contact nurse if you have questions or concerns about Calquence and your medication. This brochure does not replace their advice but complements it.

## What is CLL

**CLL is a cancer that starts in B cells – a type of white blood cell that is formed in the bone marrow.**



B cells form in the bone marrow are released into the bloodstream to help the body fight infections. B cells pass through the lymphatic system, which includes the lymph nodes and the spleen.

CLL creates too many B cells. They penetrate into the bone marrow and affect other healthy cells, such as red blood cells and platelets. This may lead to symptoms such as fatigue and may cause other diseases, such as infections.

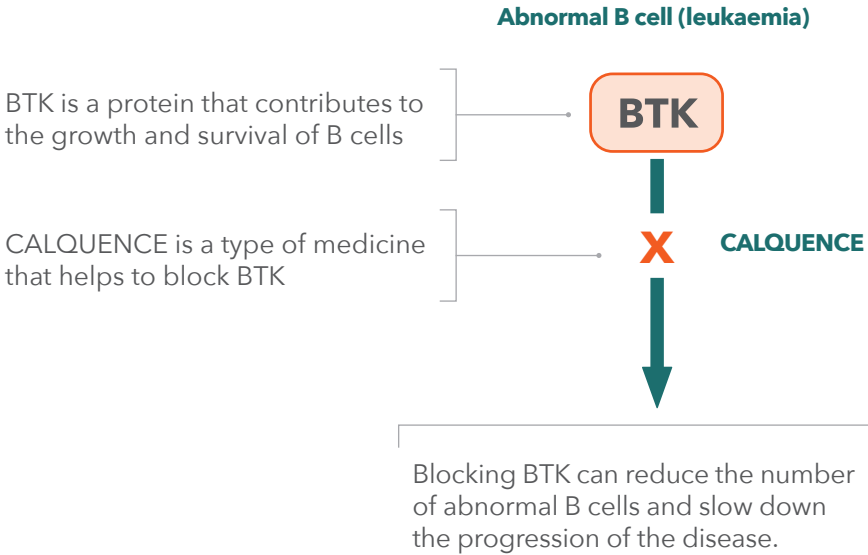
In CLL, there are too many abnormal B cells in the blood, and the objective of treatment is to reduce the number of these cells.

# WHAT IS CALQUENCE?

CALQUENCE is a medicine that targets the abnormal B cells (cancer cells) found in CLL.

CALQUENCE is a so-called tyrosine kinase inhibitor. Kinases are part of the chemical pathways in the cells, some of which are used to start the growth of new cells.

CALQUENCE works by blocking (inhibiting) such a pathway through a protein called Bruton's tyrosine kinase, BTK, in B cells. BTK inhibitors help to stop growth signals and thus reduce the number of abnormal B cells.



# BEFORE YOU TAKE CALQUENCE

It is important that you work with your doctor to create a treatment plan that works for you.

## **Tell your doctor and/or nurse before taking CALQUENCE if you:**

- Have ever had unusual bruising/bleeding or are taking medicines or food supplements that increase the risk of bleeding
- Have an infection
- Have liver problems or have had hepatitis B
- Have or have had an irregular heart rhythm, heart rate problems.
- Are breast-feeding, pregnant or think you may be pregnant, or you are planning to have children
- Your doctor may pause your treatment with CALQUENCE for any planned medical, surgical, or dental procedures.

Your doctor should do blood tests to check your blood counts regularly during treatment.

**Tell your doctor or pharmacist if you are taking, have recently taken or might take other medicines.**

**Full information on possible interactions between CALQUENCE with other medicines can be found in the package leaflet.**



**CALQUENCE may cause you to bleed more easily.** This means that you should tell your doctor if you are taking other medicines that increase your risk of bleeding.

This includes:

- Antiplatelet drugs (prevents blood clots) e.g. aspirin and clopidogrel
- Anticoagulants (blood thinners) e.g. warfarin or enoxaparin

Do **not** take CALQUENCE if you are allergic to acalabrutinib or any of the other ingredients of this medicine as listed in the package leaflet.

# HOW TO TAKE CALQUENCE

Remember that you and your doctor have a treatment goal, so it is important that you take **CALQUENCE as prescribed by your doctor.**



The usual dose is one 100 mg tablet twice a day, **a total of 200 mg/day**



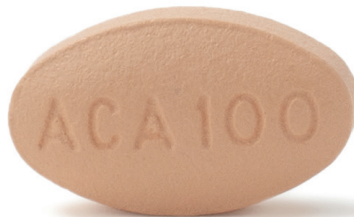
Take the tablets **approximately 12 hours apart**  
e.g. at 8:00 and 20:00



Swallow the tablet **whole** with a glass of water. Do not chew, crush, dissolve or split the tablets



You can take the tablet with or without food



Not actual size.



### Tips to avoid missing a dose!

- Set an alarm to take the medicine on time
- Take your medicine with e. g. breakfast and evening meals, approximately 12 hours apart
- Keep your medicine in a place where you can easily see it every day but out of the reach of children
- If you are away from home, pack 2 tablets for each day

You can check when you last took a tablet of CALQUENCE by looking on the blister pack. Pictures of the blister will help you take your dose at the right time - the sun for the morning dose and the moon for the evening dose.

- If you miss a dose by less than 3 hours, take the missed dose immediately. Take your next dose at your usual time
- If it is more than 3 hours from your usual dosing time, skip the missed dose and take the next dose at the usual time
- Never take a double dose to make up for the missed dose
- Do not stop taking CALQUENCE unless instructed to do so by your doctor
- If you have taken more CALQUENCE than you should, contact your doctor, nurse or head to the hospital straight away. Take the remaining tablets and package leaflet with you



## TIPS FOR FOLLOWING YOUR TREATMENT

To take CALQUENCE exactly as prescribed, you may need to change your usual routine. It can be hard to make changes and stick to them. Here are some tips to help you create good habits during your treatment.

### **Be informed**

Read all of the information about your medicine and why it is important for your treatment for CLL. Consider what you can do to help yourself.



## Make a plan

Involve friends and loved ones who can help you manage your treatment and your everyday life.

- If you live with other people, ask them to remind you to take CALQUENCE as prescribed, or put a reminder in a visible place, for example on the refrigerator.
- Plan for any problems that may occur, such as what to do if you miss a dose or how to manage feelings and thought patterns that may affect your treatment and quality of life.
- Plan ahead, do I have enough medicine at home? Do I have enough to travel? What issues do I want to raise during my next visit?

## Keep a journal

To follow your treatment plan more easily and keep your questions and thoughts in order, please use the last pages of this leaflet as a diary.

- Record each dose on a calendar to keep track, and also to see that your treatment is progressing.
- Write down any side effects or if you have any questions. Bring your journal notes to your next visit.

## Reward yourself

Remember to praise yourself - it can help you keep motivated. Don't be discouraged if you begin to waver, focus on what's going well instead!

- What makes you feel good? Maybe it's talking to a particular person, taking a long walk, enjoying a nice cup of tea or reading a good book. When you have the opportunity, prioritise yourself and your goal!

# WHAT YOU NEED TO KNOW ABOUT SIDE EFFECTS

Like all medicines, CALQUENCE may cause side effects in some people.

It is important to tell us about possible side effects at an early stage! Both your doctor and your contact nurse have extensive knowledge of how to reduce any side effects that may arise, thereby avoiding situations that might otherwise prevent you from following your treatment as planned.

**Stop taking CALQUENCE and contact a doctor or go to your nearest emergency room immediately if you experience any of the following side effects.**

**Bleeding.** Symptoms may include black stools or blood in the stool, pink or brown urine, nose bleeds, bruising, unexpected bleeding, vomiting or coughing up blood, dizziness, weakness, confusion.

**Infections.** Signs may include fever, chills, feeling weak or confused, cough, shortness of breath [pneumonia, a very common side effect (may affect more than 1 in 10 people) or aspergillus infection, an uncommon side effect (may affect up to 1 in 100 people)].

Some of the most common side effects of CALQUENCE are headache, diarrhea, nausea, fatigue, muscle and joint pain. For a list of side effects, see the package leaflet. It is important that you contact your doctor or nurse as soon as you think you are experiencing any side effects.

Common serious side effects (may affect up to 1 in 10 people): fast or irregular heartbeat, weak or irregular pulse, dizziness, feeling faint, chest discomfort or shortness of breath (signs of problems with heart rhythm called atrial fibrillation and atrial flutter).



**Always read the package leaflet that comes with the medicine.**

### **Reporting of adverse reactions**

If you get any side effects, talk to your doctor, contact the nurse or pharmacist. This also applies to any side effects not listed in this leaflet.

You can also report the side effects directly to the Medical Products Agency.  
[www.lakemedelsverket.se](http://www.lakemedelsverket.se).

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

# HOW TO DEAL WITH SIDE EFFECTS?

It is important to pay attention to the early symptoms of side effects and several side effects can be alleviated by prevention.



## INFECTION

Infection occurs when your body is not able to fight off invading microbes quick enough. Signs of infection may include fever (38° C or higher), chills, feeling weak or confused, coughing and shortness of breath.

- **Stop taking CALQUENCE if you notice any signs of infection and contact your doctor or go to the nearest emergency room immediately**
- To prevent infection, wash your hands frequently or use a hand disinfectant. Avoid crowds and physical contact with people who are ill



## DIARRHEA

Diarrhea is characterised by loose and sometimes watery faeces and you have to go to the toilet more often than usual. Although mild diarrhea may be uncomfortable, it does not usually cause serious problems, however, it can cause conditions like dehydration if you do not take it seriously.

- For mild diarrhea, avoid caffeine, dairy products and spicy food
- Eat more frequently, but in smaller portions, and food that is easy to digest (low in fiber), such as banana, rice, pasta, apple sauce, toasted white bread, cooked rather than raw vegetables. However, it is good to reintroduce fiber-rich food after the diarrhea has passed
- Avoid fatty food
- Remember to drink plenty of fluids, preferably clear liquids such as water, sports drink, tea and preferably decaffeinated coffee
- If your diarrhea is severe or does not improve despite these measures, contact your doctor or nurse immediately



## NAUSEA AND VOMITING

Mild nausea and vomiting do not usually harm your health, but general nausea may lower your quality of life and vomiting, if frequent, may cause health problems such as dehydration.

- Eat often but smaller meals. Do not skip a meal, as an empty stomach can cause nausea in itself
- Avoid strong food and beverages
- Drink water or other mild beverages at a time, but often. If you have suffered from vomiting, it is especially important to replace lost fluids



## MUSCLE AND JOINT PAIN

Joint pain, also known as arthralgia, may occur as a sensation of pain, stiffness or tenderness both during movement and at rest. It may be isolated or affect all your joints, and it may also cause swelling.

- Ask your doctor or nurse for advice on using over-the-counter painkillers
- Applying heat or cold therapy to affected areas may relieve the symptoms
- Perform gentle stretches



## BRUISES

Contact your doctor or nurse immediately if you notice any bruising, even if your blood count has been checked without any significant abnormalities.



## HEADACHE

Headache symptoms can vary from person to person. It can be a dull pain throughout the head or a more sharp and only felt in certain parts of the head.

- Talk to your doctor or nurse for advice on treatment with over-the-counter painkillers
- Make sure to get enough sleep, fluids and try to reduce your stress levels. Sometimes a little fresh air, a walk or a cup of coffee can help stop the headache in the early stage



## FATIGUE

Fatigue is a common symptom of CLL and can be caused by many factors. Tell your doctor or nurse if you feel tired even though you have had a good night's sleep.

- Physical activity can reduce fatigue, so plan light exercises
- Try not to rush - it might be a good idea to plan your days so they also include rest
- Ask family and friends for help



## RASHES

A rash is an inflammation of the skin that can lead to red, dry and/or itchy skin.

- If your skin is dry or itchy, regular application of fragrance-free moisturising lotion may help
- In case of more severe problems, consult your doctor or nurse to see if you need a prescribed treatment
- Use soft clothes and cotton sheets
- Avoid products that irritate the skin e.g scented soap and detergents
- Contact your doctor if you notice a change in your skin that isn't normal for you
- Use sunscreen and perform regular skin examination

# ADDITIONAL SUPPORT AND INFORMATION

Being affected by leukaemia can have a major impact on your life. In addition to the support of your family, friends, doctor and nurse, you can also reach out to the Blood Cancer Association if you have any questions. In some parts of the country, there may be a local CLL support team, where you can meet people in the same situation and where you and your family can receive support.

Name and contact information of your doctor:

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Name and telephone number of your contact nurse:

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▼ **This medicinal product is subject to additional monitoring. You can help by reporting any side effects you may get.**

**Calquence (acalabrutinib):** 100 mg film-coated tablets. Calquence is a medicine used to treat adults with chronic lymphocytic leukaemia (CLL). CLL is a cancer of the white blood cells, called B lymphocytes (or B cells). These cells are part of the immune system (the body's defence).

**Do not take Calquence** if you are allergic to acalabrutinib or any of the other ingredients of this medicine.

**Special warnings and precautions for use:** Talk to your doctor, pharmacist or contact nurse before taking Calquence if you have ever had unusual bruising or bleeding, or are taking any medicines that increase the risk of bleeding, have an infection, have recently had or are about to have surgery, have ever had hepatitis B (an infection of the liver), have or have had irregular heart rhythm. Talk to your doctor if you develop a new skin change or see any change in the appearance of your skin, as you are at an increased risk of developing skin cancer. Use sunscreen and regularly inspect your skin.

**Read the package leaflet carefully before you start taking this medicine. It contains important information for you.**

Last review of the product information 2023-04-06.  
For additional information: [www.fass.se](http://www.fass.se)

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