

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

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

This brochure is intended for English-speaking patients who
are treated by the health care system in Sweden

Not for use in children and adolescents under 18 years of age.
For full details, please read the package leaflet.

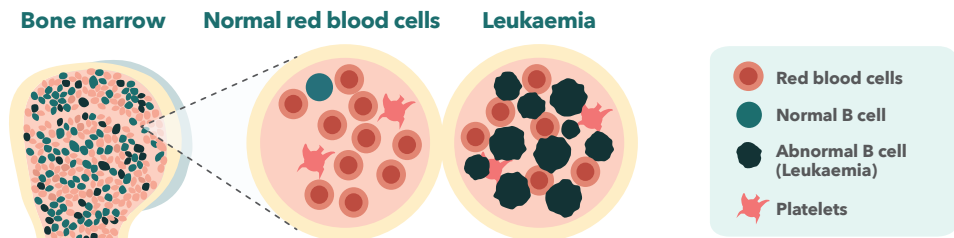
IMPORTANT CONSIDERATIONS BEFORE STARTING TREATMENT

Starting your first treatment for CLL- chronic lymphocytic leukaemia - or 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.



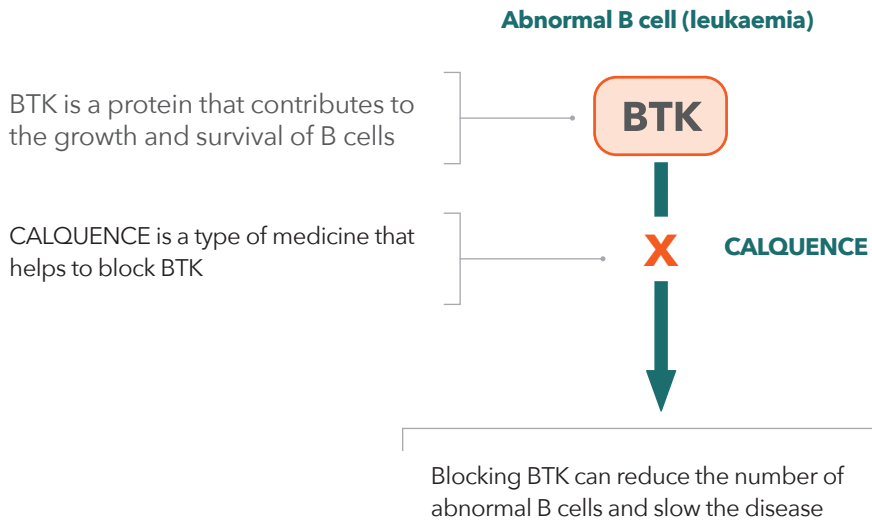
B cells form in the bone marrow and are released into the bloodstream to help the body fight infections. B cells pass through the lymphatic system, which includes the lymph nodes and the spleen. CLL creates too many B cells. They penetrate into the bone marrow and affect other healthy cells, such as red blood cells and platelets. This may lead to symptoms such as tiredness and may cause other disease, such as infections. With 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/treatment that is directed against the abnormal B cells of 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 path through a protein called Bruton's tyrosine kinase, BTK, in B cells. BTK inhibitors thus 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 contact nurse before taking CALQUENCE if you:

- Have recently undergone an operation or have an operation planned for the near future
- 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 a low blood count
- Have or have had an irregular heart rhythm, heart rate problems, or if you feel any of the following: rapid or abnormal heart rhythm, dizziness, fainting, chest discomfort or shortness of breath
- Are breast-feeding, pregnant or think you may be pregnant, or you are planning to have children

Some medicines may be affected by or may affect the levels of CALQUENCE in your body. Please tell your doctor, contact nurse or pharmacist if you are taking or have recently taken any other medicines, including herbal medicines, food supplements or the following:

- Antibiotics used to treat bacterial infections
- Medicines used to treat fungal infections such as ketoconazole
- Medicines to treat seizures or epilepsy
- St John's wort

For a more complete list, please consult 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:

- Acetylsalicylic acid and non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen
- Medicines used to prevent blood clots or blood-thinning medicines

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.

CALQUENCE IS EASY TO TAKE

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.



You can take the tablet with or without food





Tips to avoid missing a dose!

- Set an alarm for the times when you plan to take your medicine
- 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

Always take CALQUENCE exactly as your doctor has prescribed.

- 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, contact nurse or 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 here 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, but 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're wavering, but focus on what's going well!

- 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. If you experience side effects, talk to your doctor, contact nurse or pharmacist. This also includes any side effects not mentioned in the package leaflet.

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

However, some side effects may cause your doctor to advise you to reduce your dosage, stop or stop taking CALQUENCE temporarily or permanently. Some of the most common side effects of CALQUENCE are infection, headaches, diarrhoea, nausea, fatigue, muscle and joint pain and bruising. For a list of side effects, see the package leaflet. It is important that you contact your doctor or contact nurse as soon as you suspect you are experiencing any side effects.

Always read the package leaflet provided with the medicine.

REPORTING ADVERSE REACTIONS:

Not everyone will experience side effects from CALQUENCE (acalabrutinib), but if you do, talk to your doctor.

This also applies to side effects not mentioned in the package leaflet. By reporting possible side effects, you will help to provide more information on the safety of our medicines. This is an important part of the development of prescribing information, which improves the ability of healthcare workers to take appropriate prescription decisions.

Please use the following link to report side effects:

<https://aereporting.astrazeneca.com>

HOW TO ADDRESS 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 release foreign substances quickly enough. Signs of infection may include fever (38° C or higher), chills or sweating. Symptoms such as sore throat, cough, shortness of breath, pain or tenderness and sometimes swelling of the abdomen may also be symptoms of infection.

- If you notice any signs of infection, contact your doctor or contact nurse immediately
- To prevent infection, wash your hands frequently or use a hand disinfectant. Avoid physical contact with people who are ill or larger crowds



DIARRHOEA

Diarrhoea is characterised by loose and sometimes watery faeces, and you have to go to the toilet more often than you usually do. Although mild diarrhoea may be uncomfortable, it does not usually cause serious problems, but it may cause problems in terms of dehydration if you do not take it seriously.

- For mild diarrhoea, avoid caffeine, dairy products and spicy food
- Eat more frequently, but in smaller portions, and food that is easy to digest (low in fibre), such as bananas, rice, pasta, apple sauce, toasted white bread, cooked rather than raw vegetables. However, it is good to reintroduce higher fibre food after the diarrhoea has passed
- Avoid fatty food
- Remember to drink plenty of fluids, preferably clear fluids such as water, sports drink, tea and preferably decaffeinated coffee
- If your diarrhoea is severe or does not improve despite these measures, contact your doctor or contact 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 suffering 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 contact nurse for advice on the possible use of non-prescription painkillers
- Applying heat or cooling to affected areas may relieve the symptoms
- Perform gentle stretching exercises



BRUISES

Bruising occurs when damage causes blood to leak into surrounding tissues in the body. If you experience bruising, the pain can be relieved by applying ice to the bruise for a while. Tell your doctor or contact nurse if you have bruises.



HEADACHE

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

- Talk to your doctor or contact nurse for advice about treatment with non-prescription painkillers
- Be careful 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 headaches at an early stage



FATIGUE

Fatigue is a common symptom of CLL and causes may be many. Tell your doctor or contact nurse if you feel tired even though you have had what should be enough sleep.

- Physical activity can reduce fatigue, so plan lighter exercise activities
- 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, regularly applying a moisturising skin cream may help
- In case of more severe problems, consult your doctor or contact nurse to see if you need a prescription treatment
- Use soft clothes and cotton sheets
- Avoid products that irritate the skin, e.g. perfumed soap and detergents

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 contact 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:

Name and telephone number of your contact nurse:

NOTES:

NOTES:



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 2023-08-16. For additional information: www.fass.se

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