

Welcome to **CALQUENCE**

and what you need to know
about your treatment



Not for use in children and adolescents under 18 years old.

This brochure is intended for patients who have been prescribed CALQUENCE® (acalabrutinib), which is used for the treatment of adults with chronic lymphocytic leukaemia (CLL). It does not replace the Patient Information Leaflet, which you can find in the carton containing your medicine and which you should read alongside this information. If you have any questions about your treatment, talk to your healthcare team or refer to the Patient Information Leaflet.

REPORTING OF SIDE EFFECTS: If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via 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.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See www.mhra.gov.uk/yellowcard for how to report side effects.



CALQUENCE IS *here to help*

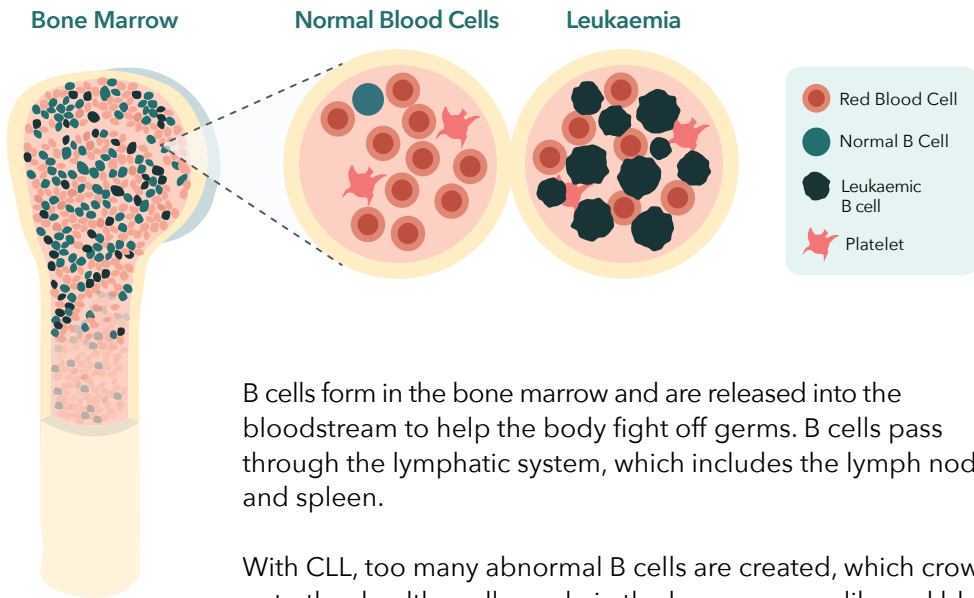
When you are adjusting to life with chronic lymphocytic leukaemia (CLL) you are dealing with a lot, managing your symptoms, scheduling appointments with different doctors, and keeping up with everything else in your life. Starting your first treatment for CLL, or changing treatment, can feel overwhelming. That is why it's important to stay informed.

This booklet is designed to introduce you to some of the important things you'll want to know about your treatment—like how CALQUENCE® (acalabrutinib) is designed to treat your cancer, what you can expect from treatment, and what's important to talk about with your doctor.

Let's talk about the basics

What is CLL?

CLL is a cancer that starts in B cells, a type of white blood cell that forms in the bone marrow.



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

With CLL, too many abnormal B cells are created, which crowd out other healthy cells made in the bone marrow, like red blood cells and platelets. This is what can lead to symptoms like feeling tired or picking up infections more often.

The aim of treatment is to reduce the number of abnormal B cells and manage the disease.



CALQUENCE WORKS DIFFERENTLY FROM *traditional chemotherapy*

CALQUENCE is a targeted treatment that helps fight CLL cancer cells, and it offers an alternative to traditional chemotherapy.

CALQUENCE is a Bruton Tyrosine Kinase inhibitor (BTKi) that affects the growth of CLL cancer cells. Kinases are part of the chemical pathways within cells, some of which can start the growth of new cells. This medicine works by blocking a protein called Bruton tyrosine kinase (BTK) in B cells.

BTK inhibitors help stop growth signals and reduce the number of new cancer cells being made.



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Abnormal B Cell (Leukaemia)

BTK is a protein that contributes to the growth and survival of B cells

CALQUENCE is a type of medicine that targets and helps block BTK

BTK



CALQUENCE



Blocking BTK can reduce the number of cancer cells and may slow the progression of the disease

Simplified representation of mechanism of action.


CALQUENCE ▼
acalabrutinib 100 mg tablets



HERE'S WHAT YOUR DOCTOR *needs to know*^{1,2}

It's important that you partner with your doctor to create a treatment plan that works for you.

Talk to your doctor, pharmacist, or nurse before taking CALQUENCE if you:

- have recently had an operation or are about to have one. Your doctor may temporarily stop treatment with CALQUENCE before and after a medical, surgical or dental procedure
- have ever had unusual bruising or bleeding or are on any medicines or supplements that increase your risk of bleeding
- have an infection
- have ever had hepatitis B (a liver infection)
- have any change in the appearance of an area on the skin
- have or ever had irregular heart beat
- are pregnant, think you may be pregnant, or are planning on having a baby
- are breast-feeding or planning to breast-feed

If any of the above apply to you (or you are not sure), talk to your doctor or a member of your healthcare team before taking this medicine.

Use sun protection and examine skin regularly due to increased risk of developing skin cancer.

CALQUENCE is unlikely to affect the ability to drive and use machines. However, if you feel dizzy, weak or tired while taking CALQUENCE, you must not drive or use machines.

Calquence can affect the levels of other medicines you take or can be affected by them. Tell your doctor, nurse or pharmacist if you have taken, are currently taking or are thinking about taking any other medicines, whether prescribed or not, including herbal medicines or supplements. It is especially important for the following medicines:

- antibiotics for bacterial infections
– such as clarithromycin
- medicines used to treat fungal infections, such as ketoconazole and posaconazole
- medicine for high blood sugars
– metformin
- methotrexate – a medicine for diseases such as rheumatoid arthritis, psoriasis and ulcerative colitis, which are caused by the immune system working incorrectly
- St. John's wort

These are not all the possible medicines that may affect or be affected by CALQUENCE. Please see the Patient Information Leaflet or talk to your doctor for more information.



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CALQUENCE may make you bleed more easily. This means you should tell your doctor if you take other medicines that increase your risk of bleeding. This includes:

- Antiplatelet drugs (act against blood clotting) such as acetylsalicylic acid and clopidogrel
- Anticoagulants (blood thinners) such as 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 Patient Information Leaflet. If you are unsure, talk to your doctor, pharmacist, or nurse before taking this medicine

HOW TO TAKE CALQUENCE TABLETS^{1,2}



tablet is not actual size.

Before we discuss how to take CALQUENCE, remember that your doctor knows you and your treatment goals, so **always take CALQUENCE exactly as your doctor has told you. Check with your doctor, pharmacist, or nurse if you are not sure.**



The usual dose is a 100 mg tablet taken **twice a day**



Take one tablet approximately every 12 hours at the same time, each day



Swallow each tablet **whole** with a glass of water. Do not chew, dissolve, or divide the medication as this may change how quickly the medicine gets into the body



Take with or without food

Here are some tips to help you remember to take your medicine as prescribed (and avoid accidentally missing a dose):

- Set alarms for the times when you're supposed to take this medicine. Remember to take it around the same time each day
- Keep your medicine somewhere that helps you to remember to take it. Keep this medicine out of the reach and sight of children
- If you're travelling, take your medicine with you. Double check that you packed the right number of doses: 2 tablets for each day you'll be away



Always take your medicine as your doctor recommends. And, of course, please talk with your doctor before doing or changing anything.

- If you miss a dose by less than 3 hours, take the missed dose right away. Take the next dose at your usual time
- If it's more than 3 hours after your usual dosing time, skip the missed dose and take your next dose at your usual time
- Do not take a double dose to make up for missing one
- **Do not stop taking CALQUENCE unless your doctor tells you.** If you have any questions about CLL or your treatment, please talk to your healthcare team. You can also refer to the CALQUENCE Patient Information Leaflet
- **If you have taken more CALQUENCE than you should, see a doctor or go to the nearest hospital straight away. Take the oral medication and the Patient Information Leaflet with you**

Your doctor may decide to prescribe CALQUENCE in combination with obinutuzumab^{1,2,11}



Obinutuzumab is administered intravenously (into your bloodstream) by your doctor. Combining these two treatments may not be right for everyone, so talk to your doctor about your treatment plan. If prescribed obinutuzumab, discuss with your doctor how it will fit into your treatment routine with CALQUENCE. Always read the Patient Information Leaflet that comes with each individual medicine.



STAYING ON TRACK *with your treatment*

Taking CALQUENCE as prescribed may require a change in your daily routine. Making any changes can be hard to stick with. Here are some tips to help you create good habits during your treatment with CALQUENCE.

Learn

First, learn about what you can do to help yourself. Read about your medicine and why it is important in your fight against cancer.



Make a plan

Identify the specific actions you'll need to take. Get loved ones and friends involved to help you stay on track.

- If you live with other people, have them help by reminding you to take your medicine as prescribed
- Plan for obstacles throughout your treatment, from what to do if you miss a dose to handling potential emotions and thought patterns that may impact your treatment progress. Identify solutions that will help you overcome these obstacles and write them down
- Plan to have enough medicine with you when you are travelling and away from home

Keep a record

Tracking your progress closely can help you stick to your plan.

- Tick off every dose on a calendar. Over time, you may get satisfaction from seeing all the tick marks
- Put your calendar or daily planner in a place where you will see it everyday.

Reward yourself

Take the time to reward yourself at every opportunity. Rewards can help you stay motivated. Don't get discouraged if you falter. Instead, try to understand what didn't go well. Be patient with yourself.

- While on treatment, congratulate yourself regularly by doing something that makes you feel good. It doesn't have to be expensive or time-consuming. You can get a new book, call a friend, or give yourself time to enjoy your favourite hobby



WHAT YOU NEED TO KNOW

about side effects^{1,2}

Like all medicines, CALQUENCE can have side effects, although not everybody gets them. If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in the Patient Information Leaflet.

Reporting side effects to your healthcare team early, with appropriate management, may help you stay on treatment, so be sure to keep your healthcare team updated.

Side effects of CALQUENCE include:

Very common

(may affect more than 1 in 10 people)

- muscle or joint pain
- headache
- rash
- feeling tired (fatigue), weakness or lack of energy
- feeling sick to your stomach (nausea), vomiting, stomach pain, constipation (infrequent or hard to pass stool), diarrhoea (frequent or loose stools)
- decreased number of red blood cells, decreased number of neutrophils (a type of white blood cells) or decreased number of cells that help blood clot (platelets).
- dizziness
- headache, pressure in the eyes, nose or cheek area (sinusitis)
- sore throat and runny nose (nasopharyngitis)
- upper respiratory tract infection
- urinary tract infection (pain or burning feeling when passing urine).
- new cancers, including cancers of the skin
- high blood pressure

Common

(may affect up to 1 in 10 people)

- bronchitis (does not require immediate action)
- herpes

Uncommon side effects

(may affect up to 1 in 100 people)

- memory loss, trouble thinking, difficulty walking or sight loss – these may be signs of a serious brain infection (Progressive Multifocal Leukoencephalopathy or PML)
- fever, chills, weakness, confusion, being sick and yellowing of the skin or eyeballs (jaundice) –these may be signs of hepatitis B (a liver infection) becoming active again.
- lymphocytosis (a higher than normal amount of lymphocytes, a type of white blood cells, in the blood)

These are not all of the possible side effects of CALQUENCE.

Please refer to the patient information leaflet for further information.



Serious side effects of CALQUENCE

Stop taking Calquence and contact a doctor or go to your nearest emergency department immediately if you experience any of the following symptoms:

- Bleeding. Symptoms may be black stools or stools with blood, pink or brown urine, nosebleeds, 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 infections, an uncommon side effect (may affect up to 1 in 100 people)].

Common serious side effects (may affect up to 1 in 10 people)

- fast heart rate, missed heart beats, weak or uneven pulse, dizziness, feeling faint, chest discomfort or shortness of breath (signs of heart rhythm problems known as atrial fibrillation and atrial flutter).

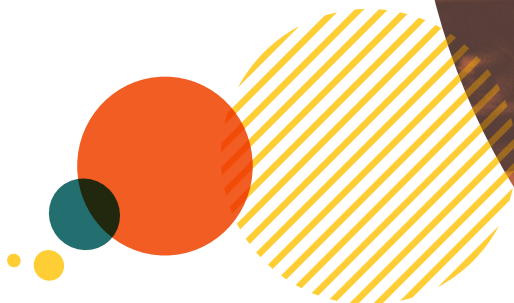
Uncommon serious side effects (may affect up to 1 in 100 people)

- fever, chills, nausea, vomiting, confusion, shortness of breath, seizures, irregular heartbeat, dark or cloudy urine, unusual tiredness, or muscle or joint pain. These can be symptoms of tumor lysis syndrome (TLS) – a condition caused by the fast breakdown of cancer cells.

Always read the Patient Information Leaflet that comes with your medicine.

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▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See www.mhra.gov.uk/yellowcard for how to report side effects.



Managing

SIDE EFFECTS

Here are things to consider about some of the common side effects of CALQUENCE. If you are concerned about these or any other side effect please discuss them with your healthcare team.



DIARRHOEA^{6,7}

- **Things to eat:**

- Small, frequent meals made from light foods, e.g. white bread, pasta or rice, white fish, poultry, and well-cooked eggs

- **Drink plenty of fluids**

- It is very important to stay hydrated. As well as water, you could try clear soups, fruit juices or caffeine-free herbal teas

- **Things to avoid:**

- Alcohol, live yoghurt, greasy or spicy foods, caffeine and raw fruits or vegetables.

- If your symptoms persist for more than 12 hours, despite following the advice you have been given, you should contact your healthcare team



INFECTION³

- Maintain good personal hygiene by washing your hands with soap and hot water after visiting the toilet and before preparing and eating food
- Avoid contact with others who have infections and avoid crowded places or public transport
- Avoid places where mould or fungus is likely to grow
- Maintain good oral hygiene and check for redness, swelling, ulcers, white patches or bleeding in your mouth on a regular basis
- Drink plenty of fluids and ensure you consume, store and heat food as instructed
- Any signs of infection must be reported to your healthcare team immediately



NAUSEA AND VOMITING^{4,5}

Nausea is a feeling of illness in the stomach that makes you think you are going to vomit.

- Eat smaller meals more frequently.
- **Eat plain foods, with a balance of:** Protein (e.g. plain yoghurt or plain chicken), fruits and vegetables (e.g. bananas, tinned fruit), and carbohydrates (e.g. crackers, pasta, plain white rice, boiled potatoes, white toast)
- Take ginger (e.g. as a tea)
- Avoid fried foods
- Drink water to keep hydrated, or try drinking a clear broth or fruit juices such as cranberry juice
- Try not to drink too many fluids before you eat. If your symptoms persist, contact your healthcare team
- In some cases, nausea may be caused by anxiety or be in anticipation of an event. You may benefit from self-help measures and avoidance of triggers such as food smells





MUSCLE OR JOINT PAIN⁸

Joint pain, also called arthralgia, may occur as a feeling of pain, stiffness, or tenderness (whether when moving or at rest) where two bones in your body connect, and may also involve swelling.

- Refer to your healthcare team for effective ways of pain management
- Physical therapies such as physiotherapy and exercise may help to relieve pain when done under the correct guidance



UNUSUAL LEVELS OF TIREDNESS (FATIGUE)⁹

Spread activities throughout the week

- Plan important activities for times when you have the most energy
- Prioritise what you need to do on a given day, and space out active periods with more restful ones
- Short naps and rests can help, but try to balance them with some activity or exercise
- Ask others for help with everyday tasks such as shopping, cooking or cleaning
- Eat a balanced diet and drink plenty of water
- Take light exercise, such as a short walk
- Do not drive or operate machinery while fatigued. If your symptoms persist, contact your healthcare team



HEADACHE¹¹

Symptoms vary from patient to patient, ranging from a dull ache to a piercing feeling somewhere on the head.

- Whilst common, headaches with CALQUENCE therapy generally cease within the first 2 months and can usually be managed with over-the-counter treatments



BRUISING^{1,2,12}

CALQUENCE can increase the risk of bleeding and bruising

- Brush your teeth gently with a soft brush
- Wear shoes indoors to protect your feet
- Take extra care when around sharp objects



COUGH^{1,2,13}

CALQUENCE can cause cough.

- Where possible avoid smoking and secondhand smoking
- Activities like a hot, steamy shower will help to loosen mucus
- Light exercise may help to open up your airways



REMINDERS



Next appointment
Next appointment
Next appointment
Next appointment
Next appointment
Next appointment
Next appointment
Next appointment



Order repeat prescription on
Order repeat prescription on
Order repeat prescription on
Order repeat prescription on
Order repeat prescription on
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THERE ARE MANY MORE RESOURCES



than just this booklet

There are lots of organisations and support groups to help you and your loved ones cope with and better understand your disease. Here are some support groups and resources that you may find helpful:

CLL Support

A charity run by volunteers, all of whom have been personally affected by CLL or Small Lymphocytic Lymphoma (SLL). They offer free support and membership including an online forum (healthunlocked.com), helpline (0800 977 4396), an Under 60 Club, webinars, conferences and newsletters.

For more information, please visit: cllsupport.org.uk

Leukaemia Care

A charity that provides free information, advice and support to patients, families and carers affected by blood cancer. They offer a nurse-led helpline (0808 801 0444), nationwide support groups, as well as emotional and financial support services. A range of information booklets are free to order or download from their website – with focused topics including CLL, living well, and watch and wait.

For more information, please visit: leukaemiacare.org.uk

Blood Cancer UK

A charity dedicated to beating blood cancer by funding research and supporting those affected. They offer free and confidential support by phone or email, free information about blood cancer, and an online forum where you can talk to others affected by blood cancer. Their booklet 'Chronic Lymphocytic Leukaemia (CLL)' is free to order or download from their website.

- bloodcancer.org.uk
- forum.bloodcancer.org.uk
- 0808 2080 888 (Mon-Fri: 10am–7pm, Sat-Sun: 10am–1pm)
- support@bloodcancer.org.uk



Lymphoma Action

An information and support charity for people affected by lymphoma (including CLL). Their services include detailed information, video and online content, peer-support through support groups and Facebook, and education and self-management workshops. Their freephone helpline (0808 808 5555) and Live Chat service via their website is available. For more information, please visit: lymphoma-action.org.uk

Macmillan Cancer Support

A group that wants to reach and improve the lives of everyone living with cancer and to inspire millions of others to do the same. They provide detailed information, resources and support for those whose lives are affected by cancer. The booklet, 'Understanding Chronic Lymphocytic Leukaemia (CLL)' is free to download from their website. For more information, please visit: macmillan.org.uk

Cancer Research UK

A charity that provides information and practical advice for people affected by all types of cancer, including CLL. For more information, please visit: cancerresearchuk.org or call Cancer Research UK's nurse helpline on 0808 800 4040

NHS website

The National Health Service (NHS) website provides clinically validated information and advice about CLL.

For more information, please visit: www.nhs.uk


CALQUENCE ▼
acalabrutinib 100 mg tablets





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