

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**  
**PATIENT MEDICATION INFORMATION**

 **CALQUENCE®**

**acalabrutinib capsules**

Read this carefully before you start taking **CALQUENCE** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **CALQUENCE**.

**Serious Warnings and Precautions**

- Take CALQUENCE only under the care of a doctor who knows how to use anti-cancer drugs.
- **Haemorrhage (serious bleeding problems)** may occur when you take CALQUENCE. This can be bleeding a lot, or bleeding that is difficult to stop.

**What is CALQUENCE used for?**

CALQUENCE is used to treat patients with a kind of cancer called mantle cell lymphoma (MCL). It is only used in patients who received at least one other MCL therapy before using CALQUENCE.

**How does CALQUENCE work?**

CALQUENCE blocks a specific protein in the body that helps cancer cells live and grow. This protein is called “Bruton's Tyrosine Kinase.” By blocking this protein, CALQUENCE may help kill and reduce the number of cancer cells and slow the spread of the cancer.

**What are the ingredients in CALQUENCE?**

Medicinal ingredient: acalabrutinib

Non-medicinal ingredients: ammonium hydroxide, black iron oxide, colloidal silicon dioxide, FD&C Blue 2 (Indigotine/Indigo carmine), gelatine, magnesium stearate, microcrystalline cellulose, partially pregelatinized starch (maize), propylene glycol, shellac, sodium starch glycolate (Type A), titanium dioxide, and yellow iron oxide.

**CALQUENCE comes in the following dosage forms:**

Capsules: 100 mg

**Do not use CALQUENCE if:**

- You are allergic to acalabrutinib or any other ingredients in CALQUENCE.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take CALQUENCE. Talk about any health conditions or problems you may have, including if you:**

- have had recent surgery or plan to have surgery. Your healthcare provider may stop CALQUENCE for any planned medical, surgical, or dental procedure.

- have bleeding problems.
- have or had heart rhythm problems.
- have an infection.
- have or had hepatitis B virus (HBV) infection.
- Have severe liver or kidney disease or are on dialysis.
- are pregnant or plan to become pregnant. CALQUENCE may harm your unborn baby. Avoid getting pregnant while on CALQUENCE.
- are breastfeeding or plan to breastfeed. It is not known if CALQUENCE passes into your breast milk. Do not breastfeed during treatment with CALQUENCE and for 2 weeks after your final dose of CALQUENCE.

New cancers have happened in people during treatment with CALQUENCE, including cancers of the skin. Use sun protection when you are outside in sunlight.

**Other warnings you should know about:**

CALQUENCE is not for use in patients under the age of 18.

**Driving and Using Machines:** Before you do tasks which may require special attention, wait until you know how you respond to CALQUENCE. If you have blurred vision, feel tired or dizzy, do not drive or use tools or machines.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**Serious Drug Interactions**

Before you start any new medication, tell your doctor who prescribed CALQUENCE for you. You must not take CALQUENCE with certain medications. The combination can increase the amount of CALQUENCE in your blood. Your doctor can decide and tell you if it is safe to take the new medication while you are taking CALQUENCE.

**The following may interact with CALQUENCE:**

- Antibiotics used to treat bacterial infections (clarithromycin, erythromycin, rifampin).
- Medicines for fungal infections (fluconazole, ketoconazole, itraconazole, posaconazole, voriconazole).
- Medicines for HIV infection (indinavir, ritonavir).
- Medicines to treat low blood sodium levels (conivaptan).
- Medicines to treat hepatitis C (telaprevir).
- Medicines used to prevent seizures or to treat epilepsy or medicines used to treat a painful condition of the face called trigeminal neuralgia (carbamazepine, phenytoin).
- Medicines to treat acid reflux and stomach ulcers (omeprazole).
- Medicines to lower stomach acid (calcium carbonate, famotidine, ranitidine).
- Medicines used to treat cancer, rheumatoid arthritis and psoriasis (methotrexate).
- Medicines used to treat heart conditions or high blood pressure (diltiazem, verapamil).
- Medicines that may increase your risk of bleeding, including:
  - aspirin and anti-inflammatories such as ibuprofen or naproxen.
  - blood thinners such as warfarin, heparin or other medicines for blood clots such as dabigatran, rivaroxaban, apixaban.
  - supplements such as fish oil, vitamin E and flaxseed.

- An herbal medicine used for depression (St. John's Wort).

**How to take CALQUENCE:**

- Take it exactly as your healthcare provider tells you.
- If you are on 2 doses a day, take them about 12 hours apart.
- Take at about the same time each day.
- Take with or without food.
- Swallow whole with a glass of water. Do NOT chew, dissolve or open the capsules.

**Usual Adult Dose:** One capsule twice a day. Do not decrease, stop or change your dose on your own.

If you need to take other medications or develop certain side effects the doctor may tell you to reduce or stop your dose. Sometimes the stop is temporary.

If you need to take:

- **Antacid medicine (for example calcium carbonate):** take it either 2 hours before or 2 hours after you take CALQUENCE.
- **Certain other medicines called acid reducers (for example famotidine or ranitidine),** take CALQUENCE 2 hours before the acid reducer medicine.

**Overdose:**

If you think you have taken too much CALQUENCE, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

If you miss a dose of CALQUENCE, take it as soon as you remember. If it is more than 3 hours past your usual dosing time, skip the missed dose and take your next dose of CALQUENCE at your regularly scheduled time. Do not take an extra dose to make up for a missed dose.

**What are possible side effects from using CALQUENCE?**

These are not all the possible side effects you may feel when taking CALQUENCE. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- tiny red or purple spots on the skin, bruising
- watery eyes
- rash or redness of the skin
- constipation
- decreased appetite
- headache
- dizziness
- tiredness
- falls
- abdominal pain, muscle pain/aches, pain in the arms and legs, back pain
- tingling, pain, or numbness in hands, feet, legs
- sores in mouth
- trouble with falling asleep or staying asleep

- memory loss

CALQUENCE can cause abnormal blood test results. Your doctor may do blood tests before you start CALQUENCE and while you take it. Your doctor will decide when to perform blood tests and will interpret the results.

<b>Serious side effects and what to do about them</b>			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>VERY COMMON</b>			
<b>Infections (from bacteria, a virus or fungus):</b> cough, infection in your nose (sinus infection), sore throat, fatigue, loss of appetite, fever, chills and flu-like symptoms.		√	
<b>Anemia (low red blood cells):</b> Being short of breath. Feeling very tired. Having pale skin. Fast heartbeat. Loss of energy, or weakness.		√	
<b>Neutropenia (low white blood cells, neutrophils):</b> Fever or infection. Fatigue. Aches and pains. Flu-like symptoms.		√	
<b>Nausea and Vomiting:</b> Severe, feeling sick. Severe, being sick or throwing up.	√		
<b>Diarrhea:</b> Increased number of bowel movements. Watery stool. Stomach pain and/or cramps.	√		
<b>New cancers</b> of skin and other types of cancer.		√	
<b>COMMON</b>			
<b>Haemorrhage (serious bleeding problems):</b> Blood in your stool or urine. Long-lasting headache. Feeling dizzy or confused. Nose bleeds. Coughing up blood. Increased bruising.		√	
<b>Pneumonia, Bronchitis (infection in the lungs):</b> Cough with or without mucus. Fever, chills. Shortness of breath that may only occur when you climb stairs. Difficult and painful breathing.		√	
<b>Thrombocytopenia (low blood platelets):</b> Bruising or bleeding for longer than usual if you hurt yourself. Fatigue and weakness.		√	
<b>Arrhythmia (heart rhythm problems):</b> Racing or uncomfortable or irregular heartbeat. Flip-flop feeling in your chest. Feeling dizzy or confused.		√	
<b>Hypotension (low blood pressure):</b> Dizziness, fainting, lightheadedness		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

## Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

## Storage:

Store at room temperature between 15 to 30°C in original bottle.

Keep out of reach and sight of children.

## If you want more information about CALQUENCE:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website ([www.canada.ca/en/health-canada.html](http://www.canada.ca/en/health-canada.html)); the manufacturer's website ([www.astrazeneca.ca](http://www.astrazeneca.ca)), or by calling 1-800-668-6000.
- This Patient Medication Information is current at the time of printing. The most up-to-date version can be found at [www.astrazeneca.ca](http://www.astrazeneca.ca).

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