

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

^{PR}**CALQUENCE®**

acalabrutinib tablets

This Patient Medication Information is written for the person who will be taking **CALQUENCE**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **CALQUENCE**, talk to a healthcare professional.

Serious warnings and precautions box

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

What CALQUENCE is used for:

CALQUENCE is used in adults to treat:

- **Chronic Lymphocytic Leukemia (CLL)**
 - patients with a kind of cancer called chronic lymphocytic leukemia (CLL) who have not had any previous treatment for their disease. For these patients, CALQUENCE is used:
 - alone or;
 - in combination with obinutuzumab or;
 - in combination with venetoclax
 - patients with CLL who have had at least one previous treatment for their disease.
- **Mantle Cell Lymphoma (MCL):**
 - patients with a kind of cancer called mantle cell lymphoma (MCL) who have not had any previous treatment for their disease and who are not able to have an autologous stem cell transplant. For these patients, CALQUENCE is used with the medications, bendamustine and rituximab.
 - patients with MCL who received at least one other MCL therapy before using CALQUENCE.

How CALQUENCE works:

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.

The ingredients in CALQUENCE are:

Medicinal ingredient: acalabrutinib (as acalabrutinib maleate)

Non-medicinal ingredients: copovidone, hypromellose, iron oxide red (E172), iron oxide yellow (E172), low-substituted hydroxypropyl cellulose, macrogol 3350, mannitol, microcrystalline cellulose, purified water, sodium stearyl fumarate, titanium dioxide, triglycerides (mediumchain).

CALQUENCE comes in the following dosage forms:

Tablets; 100 mg

Please note: CALQUENCE is also available as a 100 mg capsule which should NOT be interchanged with CALQUENCE tablets.

Do not use CALQUENCE if:

- You are allergic to acalabrutinib, any other ingredients in CALQUENCE or the container it is provided in.

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 professional 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 liver problems, including 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.

Other warnings you should know about:

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

New Cancers:

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

Liver Problems:

CALQUENCE may cause liver problems. These side effects can be severe, life-threatening and potentially fatal. Your healthcare professional will monitor your liver function throughout your treatment with CALQUENCE.

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.

Check-ups and Testing:

CALQUENCE can cause abnormal blood test results (i.e. increased levels of liver enzyme). Your healthcare professional may do blood tests before you start CALQUENCE and while you

take it. Your healthcare professional will decide when to perform blood tests and will interpret the results.

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 healthcare professional 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 healthcare professional can decide and tell you if it is safe to take the new medication while you are taking CALQUENCE.

The following may also 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 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 to treat or prevent 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 professional tells you.
- If you are taking two CALQUENCE tablets 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, crush, dissolve or divide the tablets.
- You may be treated with CALQUENCE in combination with other medicines. Speak to your healthcare professional on how to take CALQUENCE with those other medicines.

Usual Adult Dose:

One tablet twice a day. Do not change your dose or stop taking CALQUENCE unless your healthcare care professional tells you to.

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

Overdose:

If you think you, or a person you are caring for, have taken too much CALQUENCE, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or 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.

Possible side effects from using CALQUENCE:

These are not all the possible side effects you may have 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
- rash or redness of the skin
- watery eyes
- blurry vision
- constipation
- decreased appetite
- headache
- dizziness
- tiredness
- weakness or lack of energy
- falls
- abdominal pain, joint pain, muscle pain/aches, pain in the arms and legs, back pain
- tingling, pain, or numbness in hands, feet, legs
- swelling
- sores in mouth
- trouble with falling asleep
- memory loss

Serious side effects and what to do about them

Frequency / Side Effect / Symptom	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Very common			
Infections (from bacteria, a virus or fungus): Cough, rash or blisters on the skin (herpes zoster), infection in your nose (sinus infection), sore throat, fatigue, loss of appetite, fever, chills and flu-like symptoms.		✓	

Frequency / Side Effect / Symptom	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Anemia (low red blood cells): Being short of breath. Feeling very tired. Having pale skin. Fast heartbeat. Loss of energy, or weakness.		✓	
Neutropenia (low white blood cells, neutrophils): Fever or infection. Fatigue. Aches and pains. Flu-like symptoms.		✓	
Thrombocytopenia (low blood platelets): Bruising or bleeding for longer than usual if you hurt yourself. Fatigue and weakness.		✓	
Nausea and Vomiting: Severe, feeling sick. Severe, being sick or throwing up.	✓		
Diarrhea: Increased number of bowel movements. Watery stool. Stomach pain and/or cramps.	✓		
Urinary tract infection: Pain or burning when urinating, bloody or cloudy urine, foul smelling urine.		✓	
New cancers of skin and other types of cancer.		✓	
Common			
Hemorrhage (serious bleeding problems): Bleeding a lot or uncontrollably. Blood in your stool or urine. Long-lasting headache. Feeling dizzy or confused. Nose bleeds. Coughing up blood. Increased bruising.		✓	
Pneumonia, Bronchitis (infection in the lungs): Cough with or without mucus. Fever, chills. Shortness of breath that may only occur when you climb stairs. Difficult and painful breathing.		✓	
Arrhythmia (heart rhythm problems): Racing or uncomfortable or irregular heartbeat. Flip-flop feeling, or pain in your chest. Feeling dizzy or confused.		✓	
Hypotension (low blood pressure): Dizziness, fainting, light-headedness.		✓	
Tumour Lysis Syndrome (sudden, rapid death of cancer cells due to treatment): Nausea, vomiting, decreased urination, irregular heartbeat, confusion, delirium, seizures.		✓	

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 (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare 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 the Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website (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.

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