

# CALQUENCE® Capsules

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using CALQUENCE capsules?

CALQUENCE capsules contain the active ingredient acalabrutinib. CALQUENCE capsules are used to treat Chronic Lymphocytic Leukaemia (CLL)/Small Lymphocytic Lymphoma (SLL).

For more information, see Section [1. Why am I using CALQUENCE capsules?](#) in the full CMI.

### 2. What should I know before I use CALQUENCE capsules?

Do not use if you have ever had an allergic reaction to CALQUENCE or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use CALQUENCE capsules?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with CALQUENCE capsules and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### **4. How do I use CALQUENCE capsules?**

- The usual dose is one 100 mg capsule twice a day. Doses should be taken about 12 hours apart.
- Swallow the capsule whole with water. Do not chew, dissolve, or open the capsules.

More instructions can be found in Section [4. How do I use CALQUENCE capsules?](#) in the full CMI.

### **5. What should I know while using CALQUENCE?**

#### **Things you should do**

- Remind any doctor, dentist, nurse, surgeon or pharmacist you visit that you are using CALQUENCE capsules.

	<ul style="list-style-type: none"> <li>• You should be careful to protect yourself from the sun.</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• Do not stop using this medicine or change the dose without checking with your doctor.</li> <li>• Do not give this medicine to anyone else, even if they have the same condition as you.</li> <li>• Do not take it after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Be careful driving or operating machinery until you know how CALQUENCE capsules affects you.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Keep your capsules in a cool dry place where the temperature stays below 30°C.</li> <li>• Do not store CALQUENCE capsules or any other medicine in</li> </ul>

the bathroom or near a sink. Do not leave it on a windowsill or in the car.

For more information, see Section [5. What should I know while using CALQUENCE capsules?](#) in the full CMI.

## 6. Are there any side effects?

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects. **Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you:** fever, chills, headache, nausea, vomiting, dizziness, stomach pain, diarrhoea, constipation, rash, bruising, bleeding, fatigue, muscle and bone pain, joint pain, new cancers. **Tell your doctor, nurse or pharmacist as soon as possible if you notice any of the following:** signs or symptoms of serious bleeding, infection or heart problems.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# CALQUENCE® Capsules

Active ingredient(s): *acalabrutinib*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using CALQUENCE capsules. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using CALQUENCE capsules.**

**Where to find information in this leaflet:**

- [1. Why am I using CALQUENCE capsules?](#)
- [2. What should I know before I use CALQUENCE capsules?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use CALQUENCE capsules?](#)
- [5. What should I know while using CALQUENCE capsules?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using CALQUENCE?

**CALQUENCE capsules contain the active ingredient acalabrutinib.**

CALQUENCE belongs to a group of anti-cancer medicines called Bruton tyrosine kinase (BTK) inhibitors. BTK is a protein in the body that helps cancer cells to grow.

CALQUENCE works by blocking BTK which may help to reduce the number of cancer cells and may slow the spread of the cancer.

**CALQUENCE capsules are used to treat:**

Chronic Lymphocytic Leukaemia (CLL)/Small Lymphocytic Lymphoma (SLL), a type of blood cancer that affects lymphocytes (a certain type of white blood cell) and the lymph nodes.

## **2. What should I know before I use CALQUENCE?**

**Do not use CALQUENCE capsules if:**

- you are pregnant or intend to become pregnant
- you are breastfeeding
- you are allergic to acalabrutinib, or any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

## Check with your doctor if you:

- have recently undergone surgery or are planning any surgery or medical or dental procedures. Your doctor may ask you to stop taking CALQUENCE for up to 7 days before or after a medical, surgical or dental procedure as it may increase your risk of bleeding.
- take any medicines for any other condition
- have allergies to any other medicines, foods, preservatives or dyes
- have any other medical conditions such as:
  - any unusual bruising or bleeding, or you have any bleeding disorders
  - infections (bacterial, viral and/or fungal)
  - any liver problems
  - a liver infection (Hepatitis B), so that your doctor can look out for signs of reactivation of this infection, such as fever, chills, weakness, confusion, vomiting and jaundice (yellowing of the skin or eyeballs)
  - have or have had heart rhythm problems (such as atrial fibrillation)
  - any other medical conditions

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

**CALQUENCE is not for use in patients under the age of 18.** There is not enough information to recommend the use of this medicine for children or adolescents under the age of 18 years.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant.

You should not take CALQUENCE capsules if you are pregnant and you should not get pregnant while you are taking CALQUENCE capsules.

CALQUENCE capsules may harm your unborn baby.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

You should not breastfeed during treatment with CALQUENCE capsules.

It is not known if CALQUENCE capsules pass into your breast milk. Do not breast-feed during treatment with CALQUENCE capsules and for at least 2 weeks after your final dose of CALQUENCE capsules.

### 3. What if I am taking other medicines?

Tell your doctor, nurse or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

#### **Some medicines may interfere with CALQUENCE capsules and affect how it works.**

- Medicines used to control heart rhythm disturbances (e.g. amiodarone, diltiazem, verapamil)
- Antibiotics used to treat bacterial infections (e.g. clarithromycin, erythromycin, telithromycin, ciprofloxacin, rifampin)
- Medicines to treat fungal infections (e.g. fluconazole, posaconazole, ketoconazole, itraconazole, voriconazole)
- Medicines used to treat HIV infection (e.g. ritonavir, cobicistat, indinavir, nelfinavir, saquinavir, amprenavir, atazanavir, darunavir/ritonavir or fosamprenavir)
- Medicines used to treat hepatitis C infection (e.g. telaprevir)
- Medicines used to prevent seizures or to treat epilepsy (e.g. carbamazepine, phenytoin)
- St. John's wort - a herbal medicine used to treat depression
- Medicines used to reduce stomach acid, such as antacids (e.g. calcium carbonate), histamine-2 receptor blockers (e.g. ranitidine or famotidine) or certain medicines used to treat severe acid

indigestion, such as proton pump inhibitors (e.g. omeprazole, esomeprazole)

- Methotrexate, a medicine used to treat other cancers or to treat immune disorders such as rheumatoid arthritis or psoriasis.
- Medicines used to control blood sugar in patients with diabetes (eg. metformin)

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

- Medicines used to treat pain and inflammatory conditions (e.g. aspirin and non-steroidal anti-inflammatory [NSAIDS] such as ibuprofen)
- Medicines used to prevent blood clots, such as antiplatelet therapy or blood thinners (e.g. aspirin, warfarin)

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect CALQUENCE capsules.**

## **4. How do I use CALQUENCE capsules?**

### **How much to take**

- The usual dose is one 100 mg capsule twice a day. Follow the instructions provided and use CALQUENCE capsules until your doctor tells you to stop. Check with your doctor, nurse or pharmacist if you are not sure.

The instructions may differ from the information contained in this leaflet.

## **When to take CALQUENCE capsules**

- CALQUENCE capsules should be taken about 12 hours apart
- Take your medicine at about the same time each day

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

You can check when you last took a capsule of CALQUENCE by looking at the sun and moon symbols on the blister pack. There is a sun (for the morning) and a moon (for the evening). This will tell you whether you have taken the dose.

It is important that you tell your doctor that you are taking any of the medicines mentioned in the 'Taking other medicines section', as you may need to:

- avoid taking certain medicines including certain medicines used to treat fungal infections, or reduce stomach acid (proton pump inhibitors)
- take your medicine at a different time to CALQUENCE capsules including other medicines which reduce your stomach acid
- temporarily decrease your dose of CALQUENCE depending on which other medicine

## **How to take / use CALQUENCE capsules**

- swallow the tablet whole with water. Do not chew, dissolve, or open the capsules

- you can take CALQUENCE with or without food

## **If you forget to use CALQUENCE capsules**

CALQUENCE capsules should be used regularly at the same time each day.

**If you missed a dose by less than 3 hours, take the missed dose right away. Take the next dose at your usual time.**

**If you miss a dose by more than 3 hours, skip the dose you missed and take your next dose when you are meant to.**

**Do not take a double dose to make up for the dose you missed.**

## **If you take too much CALQUENCE capsules**

If you think that you have used too much CALQUENCE capsules, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while using CALQUENCE capsules?**

### **Things you should do**

- You should be careful to protect yourself from the sun
- If you are about to be started on any new medicine, remind your doctor, nurse and pharmacist that you are taking CALQUENCE capsules
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery
- If you are about to have any blood tests, tell your doctor and nurse that you are taking this medicine
- Keep all of your doctor's appointments so that your progress can be checked

### **Call your doctor straight away if you:**

- become pregnant while taking this medicine

Remind any doctor, nurse, dentist or pharmacist you visit that you are using CALQUENCE capsules.

### **Things you should not do**

- Do not stop using this medicine or change the dose without checking with your doctor
- Do not give this medicine to anyone else, even if they have the same condition as you

- Do not take it after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how CALQUENCE capsules affects you.**

CALQUENCE may cause dizziness, weakness or tiredness in some people.

## **Food and drink**

You can take CALQUENCE capsules with or without food.

## **Looking after your medicine**

Store it in a cool dry place where the temperature stays below 30°C. Keep CALQUENCE capsules away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

**Keep it where young children cannot reach it.**

## **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<p><b>Bleeding</b></p> <ul style="list-style-type: none"><li>• bruising, bleeding, including nose bleeds</li></ul> <p><b>Gastrointestinal</b></p> <ul style="list-style-type: none"><li>• diarrhoea, nausea, vomiting, stomach pain, constipation</li></ul> <p><b>Infections</b></p> <ul style="list-style-type: none"><li>• Infection, signs include fever, chills, or flu-like symptoms</li></ul> <p><b>Musculoskeletal</b></p>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• muscle and bone pain, joint pain</li> </ul> <p><b>Skin</b></p> <ul style="list-style-type: none"> <li>• rash</li> </ul> <p><b>Nervous system</b></p> <ul style="list-style-type: none"> <li>• headache, dizziness</li> </ul> <p><b>Heart problems</b></p> <ul style="list-style-type: none"> <li>• high blood pressure</li> </ul> <p><b>General</b></p> <ul style="list-style-type: none"> <li>• feeling very tired (fatigue)</li> <li>• physical weakness or lack of energy (asthenia)</li> </ul> <p>The above list includes the less serious side effects of your medicine.</p>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Bleeding</b></p> <ul style="list-style-type: none"> <li>• signs or symptoms of serious bleeding, such as blood in your stools or urine or bleeding that</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p>lasts for a long time or that you cannot control.</p> <p><b>Infection</b></p> <ul style="list-style-type: none"> <li>• signs or symptoms of an infection (fungal, viral or bacterial - eg pneumonia and aspergillosis) such as fevers, chills, body aches, cold or flu symptoms, feel tired or feel short of breath.</li> </ul> <p><b>Heart problems</b></p> <ul style="list-style-type: none"> <li>• signs and symptoms of heart rhythm problems (cardiac arrhythmias including atrial fibrillation) may include: fast, racing, pounding, fluttering or irregular heartbeat; chest discomfort or pain, shortness of breath; dizziness, light-headed or fainting</li> </ul> <p><b>Other cancers</b></p> <ul style="list-style-type: none"> <li>• new cancers, including skin cancer</li> </ul> <p><b>Liver problems</b></p>	<p><b>notice any of these serious side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● signs and symptoms of yellowing of your skin or the whites of your eyes (a sign called jaundice), dark urine, or pain in the upper right side of your stomach.</li> </ul> <p>The above list includes serious side effects that may require medical attention.</p>	

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

Like other cancer medicines, new cancers such as skin cancers have been known to occur in patients taking CALQUENCE capsules.

Some side effects can also be found when your doctor or nurse does regular blood tests. These include:

- decreased number of white blood cells (neutropenia)
- decreased number of red blood cells (anaemia)
- decreased number of platelets which are cells that help your blood to clot (thrombocytopenia)
- condition called tumour lysis syndrome (TLS), when there are unusual levels of chemicals in the blood caused by the fast breakdown of cancer cells have

happened during treatment of cancer and sometimes even without treatment. Signs of TLS are changes in kidney function, abnormal heartbeat, or seizures

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What CALQUENCE capsules contain

<b>Active ingredient (main ingredient)</b>	acalabrutinib
<b>Other ingredients (inactive ingredients)</b>	silicified microcrystalline cellulose pregelatinised starch

magnesium stearate  
(E572)

sodium starch glycollate  
Type A

The capsule consists of gelatin, titanium dioxide (E171), iron oxide yellow (E172) and indigo carmine aluminium lake (E132) with black ink (shellac, iron oxide black (E172) and polypropylene glycol)

**Do not take this medicine if you are allergic to any of these ingredients.**

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

## **What CALQUENCE looks like**

The CALQUENCE 100 mg capsule is a size 1 hard gelatin capsule with a yellow body and blue cap, marked in black ink with 'ACA 100 mg' (AUST R 321419).

CALQUENCE is supplied in a carton containing 7 blister strips, each containing 8 capsules (a total of 56 capsules in a carton).

## **Who distributes CALQUENCE capsules**

AstraZeneca Pty Ltd  
ABN 54 009 682 311

66 Talavera Road  
MACQUARIE PARK NSW 2113

Telephone: 1800 805 342

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