CALQUENCE® Tablets

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 tablets?

CALQUENCE tablets contain the active ingredient acalabrutinib maleate monohydrate. CALQUENCE tablets are used to treat Mantle Cell Lymphoma (MCL) and Chronic Lymphocytic Leukaemia (CLL)/Small Lymphocytic Lymphoma (SLL).

For more information, see Section 1. Why am I using CALQUENCE tablets? in the full CMI.

2. What should I know before I use CALQUENCE tablets?

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 tablets? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CALQUENCE tablets 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 tablets?

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

More instructions can be found in Section 4. How do I use CALQUENCE tablets? 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 tablets. • You should be careful to protect yourself from the sun.
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.
Driving or using machines	• Be careful driving or operating machinery until you know how CALQUENCE tablets affects you.
Looking after your medicine	• Keep your tablets in a cool dry place where the temperature stays below 30°C.

	• Do not store CALQUENCE tablets or any other medicine in 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 tablets? 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® Tablets

Active ingredient(s): *acalabrutinib maleate monohydrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using CALQUENCE tablets. **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 tablets.**

Where to find information in this leaflet:

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

1. Why am I using CALQUENCE?

CALQUENCE tablets contain the active ingredient acalabrutinib maleate monohydrate.

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 tablets are used to treat:

Mantle Cell Lymphoma (MCL), a type of blood cancer that affects the lymph nodes (lymph glands). It is used in:

- patients who are not intending to have a stem cell transplant procedure and have not been previously treated.
- or in patients who have had at least one other treatment for their cancer.

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. It is used in:

- patients who have not had any previous treatment for their cancer, CALQUENCE can be used alone, or in combination with other anti-cancer medicines.
- patients who have had at least one previous treatment for their cancer.

If using CALQUENCE in combination, it is important that you also read the Consumer Medicine Information (CMI) for the specific anti-cancer medicines you may

be receiving. If you have any questions about these medicines, ask your doctor.

2. What should I know before I use CALQUENCE?

Do not use CALQUENCE tablets 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.

CALQUENCE tablets may harm your unborn baby.

You should not take CALQUENCE tablets if you are pregnant and you should not get pregnant while you are taking CALQUENCE tablets. Use effective contraception (such as condoms) during treatment with CALQUENCE tablets and for at least one week after your final dose of CALQUENCE tablets.

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

You should not breastfeed during treatment with CALQUENCE tablets.

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

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 tablets 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
- 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 (e.g. metformin)

CALQUENCE tablets 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 tablets.

4. How do I use CALQUENCE tablets?

Your doctor has prescribed CALQUENCE film-coated tablets for you. Please note CALQUENCE is also available as a 100 mg capsule and should not be interchanged with CALQUENCE film-coated tablets.

How much to take

- The usual dose is one 100 mg tablet twice a day.

Follow the instructions provided and use CALQUENCE tablets 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 tablets

- CALQUENCE tablets 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 tablet of CALQUENCE tablets 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
- take your medicine at a different time to CALQUENCE tablets
- Temporarily decrease your dose of CALQUENCE depending on which other medicine.

How to take / use CALQUENCE tablets

- Swallow the tablet whole with water. Do not chew, dissolve, divide, or crush the tablets.
- You can take CALQUENCE with or without food.

If you forget to use CALQUENCE tablets

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

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 tablets

If you think that you have used too much CALQUENCE tablets, 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 tablets?

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 tablets.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.
- 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 tablets.

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 tablets affects you.

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

Food and drink

You can take CALQUENCE tablets with or without food.

Looking after your medicine

Store it in a cool dry place where the temperature stays below 30°C. Keep CALQUENCE tablets 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
Bleeding • bruising, bleeding, including nose bleeds **Gastrointestinal** • diarrhoea, nausea, vomiting, stomach pain, constipation **Infections** • infection, signs include fever, chills, or flu-like symptoms **Musculoskeletal** • muscle, joint and bone pain **Skin** • rash **Nervous system** • headache, dizziness **Heart problems** • high blood pressure **General**	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
• feeling very tired (fatigue) • physical weakness or lack of energy (asthenia) The above list includes the less serious side effects of your medicine.	

Serious side effects

Serious side effects	What to do
Bleeding • signs or symptoms of serious bleeding, such as blood in your stools or urine or bleeding that lasts for a long time or that you cannot control **Infections** • signs or symptoms of an infection which may be fungal, viral or bacterial in nature, and can include conditions such as aspergillosis, pneumonia and COVID-19. Symptoms of an infection may	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
include fevers, chills, body aches, cold or flu symptoms, feeling tired or feeling short of breath **Heart problems** • 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 **Other cancers** • new cancers, including skin cancer **Liver problems** • 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.	

Serious side effects	What to do
The above list includes serious side effects that may require medical attention.	

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 tablets.

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).
- increased level of liver enzymes (aspartate aminotransferase and alanine aminotransferase).
- 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. 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 tablets contain

Active ingredient (main ingredient)	acalabrutinib maleate monohydrate
Other ingredients (inactive ingredients)	mannitol microcrystalline cellulose hyprolose sodium stearylfumarate hypromellose copovidone

	titanium dioxide macrogol 3350 medium chain triglycerides iron oxide yellow iron oxide red

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 film-coated tablet is an orange, 7.5 x 13 mm, oval, biconvex tablet, debossed with ‘ACA 100’ on one side and plain on the reverse (AUST R 377410).

CALQUENCE tablets is supplied in a carton containing:

- 7 blister strips, each containing 8 tablets (a total of 56 tablets in a carton)
- 6 blister strips, each containing 10 tablets (a total of 60 tablets in a carton)

Who distributes CALQUENCE tablets

AstraZeneca Pty Ltd
ABN 54 009 682 311
66 Talavera Road
MACQUARIE PARK NSW 2113

Telephone: 1800 805 342

This leaflet was prepared in July 2026.

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