

▼ 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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

CALQUENCE®

Acalabrutinib

This medicine has provisional registration in Australia for (CALQUENCE is indicated for the treatment of patients with mantle cell lymphoma who have received at least one prior therapy.). The decision to provisionally register this new use of the medicine has been made on the basis of promising results from preliminary studies. More evidence is required to be submitted when available to substantiate the benefit of the medicine for this use.

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about CALQUENCE. It does not contain all the available information. It does not take the place of talking to your doctor, nurse or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking CALQUENCE against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor, nurse or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What CALQUENCE is used for

CALQUENCE is an anticancer medicine used in adults to treat:

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

CALQUENCE contains the active ingredient acalabrutinib which 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.

Ask your doctor, nurse or pharmacist if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

It is available only with a doctor's prescription.

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

Before you take CALQUENCE

When you must not take it

Do not take CALQUENCE if you have an allergy to any medicine containing acalabrutinib or other 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

Tell your doctor if you are pregnant or plan to become pregnant. You should not take CALQUENCE if you are pregnant and you should not get pregnant while you are taking CALQUENCE.

CALQUENCE may harm your unborn baby.

Tell your doctor if you are breastfeeding or planning to breastfeed. You should not breastfeed during treatment with CALQUENCE.

It is not known if CALQUENCE passes into your breast milk. Do not breast-feed during treatment with

CALQUENCE and for at least 2 weeks after your final dose of CALQUENCE.

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.

If you are not sure whether you should start taking this medicine, talk to your doctor, nurse or pharmacist.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- 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

Tell 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.

If you have not told your doctor, nurse or pharmacist about any of the above, tell them before you start taking CALQUENCE.

Taking other medicines

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

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. 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)

In addition, some medicines and CALQUENCE may interfere with each other. These include:

- 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)

These medicines may be affected by CALQUENCE or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor, nurse and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take CALQUENCE

Follow all directions given to you by your doctor, nurse or pharmacist carefully. Check with your doctor, nurse or pharmacist if you are not sure

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

How much to take

The usual dose is one 100 mg capsule twice a day. Doses should be taken about 12 hours apart.

How to take it

Swallow the capsule whole with water. Do not chew, dissolve, or open the capsules.

When to take it

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.

You can take CALQUENCE with or without food.

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 including other medicines which reduce your stomach acid.
- Temporarily increase or decrease your dose of CALQUENCE depending on which other medicine.

How long to take it

Continue taking your medicine for as long as your doctor tells you. Do not change your dose or stop taking it.

If you forget to take it

If you have 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 missed dose. Take the next dose at your usual time

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

If you are not sure what to do, ask your doctor, nurse or pharmacist.

If you have trouble remembering to take your medicine, ask your nurse or pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much CALQUENCE. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using CALQUENCE

Things you must do

If you are about to be started on any new medicine, remind your doctor, nurse and pharmacist that you are taking CALQUENCE.

Tell any other doctors, dentists, nurses and pharmacists who treat you that you are taking this medicine.

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 become pregnant while taking this medicine, tell your doctor immediately.

You should be careful to protect yourself from the sun.

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

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.

Things to be careful of

Be careful driving or operating machinery until you know how CALQUENCE affects you.

CALQUENCE is unlikely to affect the ability to drive and use machines. However, if you feel dizzy, weak or tired while taking CALQUENCE, take special care when driving or using machines.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are taking CALQUENCE.

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.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you:

- Infection, signs include fever, chills, or flu-like symptoms
- headache
- nausea, vomiting
- dizziness
- stomach pain
- diarrhoea
- constipation
- rash
- bruising
- bleeding, including nose bleeds
- feeling very tired (fatigue)
- muscle and bone pain
- joint pain
- new cancers, including skin cancer

The above list includes the more common side effects of your medicine.

Tell your doctor, nurse or pharmacists as soon as possible if you notice any of the following:

- 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.
- 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.
- Signs and symptoms of heart problems (eg atrial fibrillation) such as chest discomfort, shortness of breath or heart palpitations/change in rhythm (racing, pounding or fluttering).

The above list includes serious side effects that may require medical attention.

Tell your doctor, nurse or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

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

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.

After using CALQUENCE

Storage

Keep your capsules in a cool dry place where the temperature stays below 30°C.

Do not store CALQUENCE or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

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

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

Ingredients

CALQUENCE contains 100 mg of acalabrutinib as the active ingredient.

Other ingredients:

- 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)

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes (include any that are appropriate).

Supplier

CALQUENCE is supplied in Australia by:

AstraZeneca Pty Ltd

ABN 54 009 682 311

66 Talavera Road

MACQUARIE PARK NSW 2113

Telephone: 1800 805 342

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