

PATIENT INFORMATION LEAFLET

Scheduling Status: **S4**

CALQUENCE Tablets 100 mg Film-coated Tablets

Acalabrutinib

Sugar free

Read all of this leaflet carefully before you start taking CALQUENCE Tablets

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- CALQUENCE Tablets has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What CALQUENCE Tablets is and what it is used for
2. What you need to know before you take CALQUENCE Tablets
3. How to take CALQUENCE Tablets
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1. What CALQUENCE Tablets is and what it is used for

CALQUENCE Tablets is a medicine used to treat cancer. CALQUENCE tablets contain acalabrutinib, an active substance belongs to the Bruton tyrosine kinase (BTK) inhibitor class of anti-cancer medicines.

CALQUENCE Tablets is used for the treatment of adults with:

- mantle cell lymphoma (MCL), who have received at least one prior treatment for their cancer
- chronic lymphocytic leukaemia (CLL)/small lymphocytic lymphoma (SLL)

CALQUENCE Tablets blocks BTK and can reduce the number of cancer cells and slow the progression of the disease.

CALQUENCE Tablets will only be prescribed to you by a doctor with experience in the use of medicines for cancer.

If you have any questions about how CALQUENCE Tablets works or why this medicine has been prescribed for you, ask your doctor.

2. What you need to know before you take CALQUENCE Tablets

Warnings and precautions

Talk to your doctor before taking CALQUENCE Tablets if you:

- have recently undergone surgery or are about to undergo surgery. Your doctor may stop treatment with CALQUENCE Tablets before a medical, surgical or dental procedure.
- have a bleeding disorder.
- have an infection.
- have liver problems.
- have or had 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 had heart rhythm problems.
- are pregnant or planning to become pregnant.
- are breast-feeding or planning to breast-feed.

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist or nurse before taking CALQUENCE Tablets.

When you take CALQUENCE Tablets, you can have some serious side effects.

If you have any of the following, call or see your doctor right away. Your doctor may tell you to decrease your dose, temporarily stop, or completely stop taking CALQUENCE Tablets if you have certain side effects.

- bleeding problems (haemorrhage). Signs and symptoms may include black stools or stools with blood, pink or brown urine, nosebleeds, bruising, unexpected bleeding, vomiting or coughing up

blood, dizziness, weakness, confusion, changes in your speech, or headache lasting a long time.

- infections (bacterial, viral, or fungal). Signs and symptoms may include fever or chills, or flu-like symptoms.
- decreased number of blood cell counts. These may be a decreased number of red blood cell counts, decreased number of low white blood cell counts, or decreased number of cells that help blood clot (platelets). Your doctor will check your blood cell counts as needed during treatment with CALQUENCE Tablets.
- second primary cancers. Other cancers may happen during treatment with CALQUENCE Tablets, including cancers of the skin.
- heart rhythm problems (atrial fibrillation or atrial flutter). Signs and symptoms may include fast or abnormal heartbeat, dizziness, feeling faint, chest discomfort, or shortness of breath.

Children and Adolescents

The safety and efficacy of CALQUENCE Tablets has not been established in children or adolescents.

Do not give this medicine to children or adolescents aged less than 18 years.

Pregnancy

Talk to your doctor before taking CALQUENCE Tablets if you are pregnant, think you may be pregnant or are planning on having a baby. This is because CALQUENCE Tablets may harm your unborn baby.

If you are pregnant, you should not take CALQUENCE Tablets. You should not get pregnant while you are taking this medicine.

Breastfeeding

Before taking CALQUENCE Tablets, tell your doctor if you are breast-feeding. It is not known if CALQUENCE Tablets passes into your breast milk. Do not breast-feed during treatment with CALQUENCE Tablets and for 2 days after your final dose of CALQUENCE Tablets.

Driving and using machines

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

machines.

Taking other medicines

Tell your doctor and pharmacist if you are taking or have recently taken any other medicines, including medicines not prescribed, herbal medicines, and supplements.

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. This includes:

- acetyl salicylic acid and non-steroidal anti-inflammatories (NSAIDs)
- medicines used to prevent blood clots, such as antiplatelet therapy or blood thinners

Some medicines can affect the levels of CALQUENCE Tablets in your body. Also, CALQUENCE Tablets can affect the way some other medicines work. Tell your doctor if you are taking any of the following:

- antibiotics used to treat bacterial infections (e.g. clarithromycin)
- medicines to treat fungal infections (e.g. posaconazole, ketoconazole, itraconazole, voriconazole)
- medicines used to treat HIV infections (e.g. indinavir)
- medicines used to treat hepatitis C (e.g. telaprevir)
- rifampin, an antibiotic used to treat bacterial infections
- medicines used to prevent seizures or to treat epilepsy (e.g. carbamazepine, phenytoin)
- St. John's wort, a herbal medicine, used for instance to treat depression
- methotrexate, a medicine used to treat immune disorders

Tell your doctor or pharmacist if you take any of these or any other medicines. The medicines listed here may not be the only ones that could interact with CALQUENCE Tablets.

3. How to take CALQUENCE Tablets

Your doctor has prescribed CALQUENCE Tablets film-coated tablets for you.

Always take CALQUENCE Tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- 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 at approximately the same time each day.

- Take CALQUENCE Tablets with or without food.
- You can check when you last took a tablet of CALQUENCE Tablets by looking on the blister. There is a sun (for the morning) and a moon (for the evening). This will tell you whether you have taken the dose.
- Do not chew, crush, dissolve, or divide the tablets.

If you forget to take a dose

- If you miss 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 any extra tablets of CALQUENCE Tablets to make up for a missed dose.

If you take more CALQUENCE Tablets than you should

If you may have taken more CALQUENCE Tablets than you should, see a doctor or go to the nearest hospital straight away.

If you stop taking CALQUENCE Tablets

Do not stop taking CALQUENCE Tablets unless your doctor tells you. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

CALQUENCE Tablets can have side effects.

Not all side effects reported for CALQUENCE Tablets are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CALQUENCE Tablets, please consult your health care provider for advice.

These side effects may occur with certain frequencies, which are defined as follows:

Frequent side effects (affects more than 1 in 10 people):

- infection, signs include fever, chills, or flu-like symptoms

- headache
- diarrhoea
- bruising
- muscle and bone pain
- nausea
- tiredness
- rash
- joint pain
- diarrhoea
- constipation
- dizziness
- vomiting
- stomach pain
- bleeding
- new cancers

The following side effects are frequently shown in blood tests:

- decreased number of white blood cells
- decreased number of red blood cells
- decreased number of cells that help blood clot (platelets)

Less frequent side effects (affects up to 1 in 10 people):

- nose bleeds
- non-melanoma skin cancer
- weakness or lack of energy
- fast heart rate, missed heart beats, weak or uneven pulse, dizziness, feeling faint, chest pain, shortness of breath (symptoms of atrial fibrillation)
- condition called tumour lysis syndrome (TLS), affecting up to 1 in 100 people. TLS is when there are unusual levels of chemicals in the blood caused by the fast breakdown of cancer cells, has happened during treatment of cancer and sometimes even without treatment. Signs of TLS are changes in kidney function, abnormal heartbeat, or seizures.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of CALQUENCE Tablets.

5. How to store CALQUENCE Tablets

Store at or below 30 °C

Store in the original package

Do not use CALQUENCE Tablets after the expiry date (EXP) which is stated on the blister foil, and carton.

6. Contents of the pack and other information

What CALQUENCE Tablets contains

- The active substance is acalabrutinib.
- The other ingredients are:

Tablet Core: mannitol, microcrystalline cellulose, low-substituted hydroxypropyl cellulose, sodium stearyl fumarate

Tablet Coating: hypromellose 2910, copovidone, titanium dioxide, macrogol 3350, medium-chain triglycerides, iron oxide yellow (E172), iron oxide red (E172), purified water

What CALQUENCE Tablets looks like and contents of the pack

CALQUENCE Tablets is an orange, 7.5 x 13 mm, oval, biconvex tablet, debossed with 'ACA 100' on one side and plain on the reverse.

CALQUENCE Tablets is supplied in cartons containing either blisters of 56 or 60 tablets.

Not all packs sizes will be marketed.

Holder of Certificate of Registration

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