SCHEDULING STATUS: **S4**

CALQUENCE 100 mg capsules

(acalabrutinib**)**

Read all of this leaflet carefully before you start taking CALQUENCE

- 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 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 is and what it is used for
2. What you need to know before you take CALQUENCE
3. How to take CALQUENCE
4. Possible side effects
5. How to store CALQUENCE
6. Contents of the pack and other information

1. What CALQUENCE is and what it is used for

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

CALQUENCE 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)

CALQUENCE blocks BTK and can reduce the number of cancer cells and slow the progression of the disease. CALQUENCE 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 works or why this medicine has been prescribed for you, ask your doctor.

2. What you need to know before you take CALQUENCE

Do not take CALQUENCE

- If you are hypersensitive (allergic) to acalabrutinib or any of the other ingredients of CALQUENCE (listed in section 6.)

Warnings and precautions

Special care should be taken with CALQUENCE

Talk to your doctor before taking CALQUENCE if you:

- have recently undergone surgery or are about to undergo surgery.
  Your doctor may stop treatment with CALQUENCE 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 breastfeeding or planning to breastfeed.

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

When you take CALQUENCE, 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 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.
- second primary cancers. Other cancers may happen during treatment with CALQUENCE, 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 has not been established in children or adolescents. Do not give this medicine to children or adolescents aged less than 18 years.

Other medicines and CALQUENCE

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

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. 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 in your body. Also, CALQUENCE 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

- 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)
- 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.

Pregnancy and breastfeeding

Pregnancy

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking CALQUENCE. You should not get pregnant while you are taking CALQUENCE. If you are pregnant, you should not take CALQUENCE.

Breastfeeding

You should not breastfeed your baby when taking CALQUENCE.

Driving and using machines

CALQUENCE may affect the ability to drive and use machines. If you feel dizzy, weak or tired while taking CALQUENCE, you should not drive or use machines.

CALQUENCE contains sodium

This medicine contains less than 1 mmol (23 mg) of sodium per dose, that means it is essentially ‘sodium-free’.

3. How to take CALQUENCE

Do not share medicines prescribed for you with any other person. Always take CALQUENCE exactly as your doctor or pharmacist has instructed you.

Check with your doctor or pharmacist if you are not sure.

- 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 at approximately the same time each day.
- Take CALQUENCE with or without food.

- You can check when you last took a capsule of CALQUENCE 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, dissolve, or open the capsules.
- Avoid taking medicines called proton pump inhibitors (e.g. omeprazole) while you are taking CALQUENCE.
- If you take medicine called antacids (e.g. calcium carbonate), take the antacid medicine 2 hours before or 2 hours after you take CALQUENCE.
- If you take medicines called histamine-2 receptor blockers (e.g. ranitidine or famotidine), take CALQUENCE 2 hours before the histamine-2 receptor blocker.

Your doctor will tell you how long your treatment with CALQUENCE will last.
If you have the impression that the effect of CALQUENCE is too strong or too weak, tell your doctor or pharmacist.

If you take more CALQUENCE than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take CALQUENCE

- 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 capsules of CALQUENCE to make up for a missed dose.

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

Although not everybody gets them. These side effects may occur with certain frequencies, which are defined as follows:

Frequent side effects:

- infection, signs include fever, chills, or flu-like symptoms
- headache
- diarrhoea
- bruising
- muscle and bone pain
- nausea
- tiredness
- rash
- joint pain
- constipation
- dizziness
- vomiting
- stomach pain
- bleeding
- new cancers
- 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)

Frequent side effects 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:

- 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 of side effects

If you get side effects, talk to your doctor or, pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of CALQUENCE.

5. How to store CALQUENCE

Keep this medicine out of the reach of children.
Store at or below 30 ºC.
Store in original package.
Do not use CALQUENCE after the expiry date (EXP) which is stated on the white plastic bottle, blister foil, and carton. The expiry date refers to the last day of that month.
There is no special storage instructions for CALQUENCE.
Return all used medicines to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CALQUENCE contains

- The active substance is acalabrutinib.
- The other ingredients are
  Capsule Content: microcrystalline cellulose, colloidal silicon dioxide, partially pregelatinized starch (maize), magnesium stearate (E572), and sodium starch glycolate (Type A).
  Capsule Shell: gelatine, titanium dioxide (E171), yellow iron oxide (E172), and FD&C Blue 2 (Indigotine/Indigo carmine) (E132).
  Printing Ink: Shellac, black iron oxide (E172), propylene glycol (E1520), and ammonium hydroxide.

What CALQUENCE looks like and contents of the pack

CALQUENCE is a hard gelatine capsule with a yellow body and blue cap, marked in black ink with 'ACA 100 mg'.
CALQUENCE is supplied in cartons containing either blisters of 7 x 8 or 10 x 6 capsules. Not all packs sizes may be marketed.

Holder of certificate of registration

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This leaflet was last revised in

29 March 2022

Registration Number

55/26/0390

Access to the corresponding Professional Information

AstraZeneca Logo

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Ref: CALQUENCE 100 mg acalabrutinib capsules – EPI 29 March 2022