

**PATIENT INFORMATION LEAFLET**

**GENCALQ Capsules**

**SCHEDULING STATUS**

**S4**

**GENCALQ** (100 mg hard gelatin capsules)

Acalabrutinib

Sugar free

**Read all of this leaflet carefully before you start taking GENCALQ**

- 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
- GENCALQ 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 GENCALQ is and what it is used for.
2. What you need to know before you take GENCALQ.

3. How to take GENCALQ.
4. Possible side effects.
5. How to store GENCALQ.
6. Contents of the pack and other information.

## **1. What GENCALQ is and what it is used for**

### **What GENCALQ is**

GENCALQ is a medicine used to treat cancer.

- GENCALQ contains the active substance: acalabrutinib.
- GENCALQ belongs to a class of anti-cancer medicines called Bruton tyrosine kinase (BTK) inhibitors.

### **What GENCALQ is used for**

GENCALQ is used to treat adults with a type of cancer called:

- Mantle cell lymphoma (MCL), who have received at least one prior treatment for their cancer
- Chronic lymphocytic leukaemia (CLL), which is a cancer of white blood cells called B-lymphocytes (or B-cells). These cells are part of the immune system (the body's defences)
- GENCALQ works by blocking BTK, a protein in the body that helps these cancer cells grow and survive. By blocking BTK, GENCALQ helps to kill and can reduce the number of cancer cells which can slow down the worsening of the disease.

## 2. What you need to know before you take GENCALQ

### Do not take GENCALQ:

- if you are allergic (hypersensitive) to acalabrutinib or any of the other ingredients of GENCALQ listed in **section 6**. If you think you may be allergic, ask your doctor for advice.

### Warnings and precautions

Tell your doctor or health care provider before taking GENCALQ if:

- you have an infection, see **section 4** 'Possible side effects'
- you have ever had unusual bruising or bleeding problems or are on any medicines that increase your risk of bleeding (see **section 4**)
- you have had recent operation or are planning to have operation. Your healthcare provider may stop GENCALQ before and after a medical, surgical, or dental procedure
- you are pregnant or plan to become pregnant. GENCALQ may harm your unborn baby and problems during childbirth
- you are breastfeeding or plan to breastfeed. It is not known if GENCALQ passes into your breast milk. Do not breastfeed during treatment with GENCALQ and for at least 2 days after your final dose
- you have ever had hepatitis B (a liver infection) – this is because GENCALQ could cause hepatitis B to become active again and so that your doctor will look out for signs of this infection coming back (see **section 4**)
- you have or ever had irregular heartbeat (see **section 4**)

- Talk to your doctor if you develop a new lesion or any change in the appearance of an area on the skin as you are at a high risk of developing skin cancer, see **section 4**. Use sun protection and make regular skin examination.

**When you take GENCALQ, 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 GENCALQ 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 GENCALQ.
- second primary cancers. Other cancers may happen during treatment with GENCALQ, 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**

GENCALQ is not recommended for use in children and adolescents aged less than 18 years old.

This is because it has not been studied in this age group.

### **Other medicines and GENCALQ**

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

Inform your doctor if you take:

- antibiotics for bacterial infections – such as clarithromycin, rifampicin
- medicines for fungal infections – such as itraconazole, voriconazole
- medicines for HIV infections – such as indinavir and ritonavir
- medicines for hepatitis C – such as telaprevir
- medicine for low blood sodium – conivaptan
- medicine for high blood sugars – metformin
- medicines for fits (seizures) or epilepsy – such as carbamazepine and phenytoin
- St. John's wort – a herbal medicine for depression
- medicines for reducing stomach acid:
  - antacids – such as calcium carbonate: Take GENCALQ 2 hours before or 2 hours after you take these medicines.
  - histamine-2 receptor blockers – such as ranitidine and famotidine: Take GENCALQ 2 hours before.
  - proton pump inhibitors – such as omeprazole: Avoid taking these medicines while you are taking GENCALQ.

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 GENCALQ.

### **Taking GENCALQ with food, drink, and alcohol**

GENCALQ can be taken with or without food, preferably with water.

### **Pregnancy, breastfeeding and fertility**

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 GENCALQ.

### **Breastfeeding**

You should not breastfeed your baby when taking GENCALQ.

### **Driving and using machines**

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

### **GENCALQ contains sodium starch glycolate**

GENCALQ contains less than 1 mmol sodium (23 mg) per dose, in the form of sodium starch glycolate, essentially 'sodium-free'.

### 3. How to take GENCALQ

Do not share medicines prescribed for you with any other person.

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

- The usual dose is one 100 mg capsule twice a day (to be taken in 12 hours apart)
- Swallow the capsule whole with water at approximately the same time each day
- Do not open, dissolve, or chew the capsules
- You can take GENCALQ with or without food
- If you take medicine called antacids (e.g. calcium carbonate), take the antacid medicine 2 hours before or 2 hours after you take
- If you take medicines called histamine-2 receptor blockers (e.g. ranitidine or famotidine), take GENCALQ, 2 hours before the histamine-2 receptor blocker.

Your doctor will tell you how long your treatment with GENCALQ will last. Do not stop treatment early because you feel better. If you have the impression that the effect of GENCALQ is too strong or too weak, tell your doctor or pharmacist.

#### **If you take more GENCALQ than you should**

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

**If you forget to take GENCALQ**

- If less than 3 hours have passed after your usual time for taking a dose, take the missed dose right away. Take the next dose at your usual time.
- If more than 3 hours have passed after your usual time for taking a dose, skip the missed dose. Take the next dose at your usual time.
- Do not take a double dose of GENCALQ to make up for a forgotten dose.

**4. Possible side effects**

GENCALQ can have side effects.

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

If any of the following happens, stop taking GENCALQ and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Bleeding: Symptoms may be black stools or stools with blood, pink or brown urine, nosebleeds, bruising, unexpected bleeding, vomiting, or coughing up blood, dizziness, weakness, confusion
- Infections: Signs may include fever, chills, feeling weak or confused, cough, shortness of breath.

These are all very serious side effects. If you have them, you may have had a serious reaction to GENCALQ. You may need urgent medical attention or hospitalisation.



Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

**Frequent side effects** (may affect up to 1 in 10 people):

- Fast heart rate, missed heart beats, weak or uneven pulse, dizziness, feeling faint, chest discomfort, or shortness of breath (signs of heart rhythm problems known as atrial fibrillation and atrial flutter).

These are all serious side effects. You may need urgent medical attention.

**Other side effects**

Tell your doctor if you notice any of the following:

*Frequent side effects:*

- muscle or joint pain
- headache
- rash
- feeling tired (fatigue), weakness or lack of energy
- feeling sick to your stomach (nausea),
- vomiting,
- stomach pain,
- constipation (infrequent or hard to pass stool),
- diarrhoea (frequent or loose stools)
- dizziness
- nose bleeds
- bleeding

- new cancers, including cancers of the skin, may happen during treatment with GENCALQ (see **section 2**)
- non-melanoma skin cancer
- bruising

*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 (may affect up to 1 in 100 people):*

- Fever, chills, nausea, vomiting, confusion, shortness of breath, seizures, irregular heartbeat, dark or cloudy urine, unusual tiredness, or muscle or joint pain. This can be symptoms of tumour lysis syndrome (TLS) – a condition caused by the fast breakdown of cancer cells.

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 “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8> or [drugsafetysa@cipla.com](mailto:drugsafetysa@cipla.com). By reporting side effects, you can help provide more information on the safety of GENCALQ.

## **5. How to store GENCALQ**

**Store all medicines out of reach of children.**

- Store at or below 25 °C.
- Store in the original package / container
- Do not use after the expiry date stated on the bottle
- Return all unused medicine 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 GENCALQ contains**

The active substance is: Acalabrutinib

The other ingredients are:

Magnesium stearate (Vegetable Grade)

Pregelatinized Starch (Starch 1500)

Silicified Microcrystalline Cellulose (Prosolv SMCC 90)

Sodium starch glycolate (Primogel Type – A)

Hard gelatin capsule: The composition of empty hard gelatin capsule is:

Gelatin

Iron Oxide red E172

Purified water

Titanium dioxide E171

Composition of ink used for printing on Capsule Shell are:

Black Iron Oxide E172

Butyl Alcohol

Dehydrated Alcohol E1510

Isopropyl Alcohol

Potassium Hydroxide E525

Propylene Glycol E1520

Purified water

Shellac E904

Strong Ammonia Solution E527

#### **What GENCALQ looks like and contents of the pack**

GENCALQ 100 mg hard capsules, is a white to off white to light yellow blend, filled in size “1”

Opaque, hard gelatin capsules, with pink cap and white body, printed with black ink “Cipla” on the cap and “100 mg” on the body.

GENCALQ is packed in a 75cc white HDPE bottle, with 38 mm White Child Resistant cap. Pack size of 60`s capsules.

**Holder of certificate of registration**

**CIPLA MEDPRO (PTY) LTD.**

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