

# What is CALQUENCE?

CALQUENCE is a prescription medicine used to treat adults with mantle cell lymphoma (MCL) who have received at least one prior treatment for their cancer.

# How to take CALQUENCE



CALQUENCE is a 100 mg tablet taken by mouth approximately every 12 hours.



CALQUENCE can be taken with or without food. Swallow CALQUENCE tablets whole with a glass of water. Do not chew, crush, dissolve, or cut tablets.

# **How does CALQUENCE work?**

CALQUENCE is a Bruton tyrosine kinase (BROO-tuhn TY-ruh-seen KY-nays) inhibitor, or BTKi. In MCL, cancer cells interfere with the production of healthy blood cells. CALQUENCE works by targeting and helping to block the BTK proteins involved in the growth and survival of these cancer cells.

#### **Important Safety Information About CALQUENCE® (acalabrutinib)**

# Before taking CALQUENCE, tell your healthcare provider about all of your medical conditions, including if you:

- have had recent surgery or plan to have surgery. Your healthcare provider may stop CALQUENCE for any planned medical, surgical, or dental procedure.
- have bleeding problems.
- have or had heart rhythm problems.
- have an infection.
- have or had liver problems, including hepatitis B virus (HBV) infection.
- are pregnant or plan to become pregnant. CALQUENCE may harm your unborn baby and cause problems during childbirth (dystocia).
  - o If you are able to become pregnant, your healthcare provider may do a pregnancy test before you start treatment with CALQUENCE
  - Females who are able to become pregnant should use effective birth control (contraception) during treatment with CALQUENCE and for 1 week after the last dose of CALQUENCE
- are breastfeeding or plan to breastfeed. It is not known if CALQUENCE passes into your breast milk. Do not breastfeed during treatment with CALQUENCE and for 2 weeks after your last dose of CALQUENCE.

**Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking CALQUENCE with certain other medications may affect how CALQUENCE works and can cause side effects. Especially tell your healthcare provider if you take a blood thinner medicine.

#### **How should I take CALQUENCE?**

- Take CALQUENCE exactly as your healthcare provider tells you to take it.
- Do not change your dose or stop taking CALQUENCE unless your healthcare provider tells you to.
- Your healthcare provider may tell you to decrease your dose, temporarily stop, or completely stop taking CALQUENCE if you develop certain side effects.
- Do not switch (interchange) your CALQUENCE tablets with CALQUENCE capsules.
- Take CALQUENCE 2 times a day (about 12 hours apart).
- Take CALQUENCE with or without food.
- Swallow CALQUENCE capsules or tablets whole with a glass of water. Do not open, break, or chew capsules; do not chew, crush, dissolve, or cut tablets.
- If taking CALQUENCE <u>capsules</u>: If you need to take an antacid medicine (such as Tums® or Rolaids®), take it either 2 hours before or 2 hours after you take CALQUENCE capsules. If you need to take certain other medicines called acid reducers (H2-receptor blockers, such as Pepcid®), take CALQUENCE capsules 2 hours before the acid reducer medicine. Avoid taking proton pump inhibitors (such as Prevacid®, Prilosec® or Nexium®).
- If taking CALQUENCE tablets: CALQUENCE tablets can be taken with any stomach acid-reducing medicines, including proton pump inhibitors, H2-receptor blockers, or antacids.



# **Managing side effects**

The suggestions below are meant to help manage some of the most common side effects of CALQUENCE. Contact your healthcare provider if any of these side effects are severe, persist or worsen.



#### **DIARRHEA**

- Drink more fluids, eat smaller, more frequent, and easier-to-digest meals, and avoid spicy foods
- Your doctor may recommend taking an anti-diarrheal medication (like Imodium®)



#### **MUSCLE AND JOINT PAIN**

- Take the time to stretch in order to relax and ease aches
- Use over-the-counter pain relievers, like acetaminophen (Tylenol®), and alternate between heat and cold on the affected area



#### **HEADACHES**

- Can usually occur within 30 minutes of dosing and typically can be managed with acetaminophen (Tylenol®) or caffeine
- Can often be managed and typically resolve over a period of 4 weeks



#### **BRUISING**

• Elevate and ice the affected area to reduce swelling and ease tenderness



#### **FATIGUE**

- Getting adequate nighttime sleep and taking short naps early in the day
- Engage in regular, moderate exercise like walking (consult your doctor before any exercise plan)

Serious side effects may occur and may lead to death. See below for Important Safety Information.

IF YOU EXPERIENCE SIDE EFFECTS, ESPECIALLY SIDE EFFECTS THAT ARE SEVERE, PERSISTENT, OR WORSENING, TALK TO YOUR HEALTHCARE PROVIDER.

## To learn more about treatment with CALQUENCE, visit CALQUENCE.com and talk with your healthcare provider



The CALQUENCE Connections Facebook Group is a place to connect with others like you. Find support, advice, and friendship. Visit www.facebook.com/groups/calquenceconnections.

#### Important Safety Information About CALQUENCE® (acalabrutinib) (cont'd)

#### How should I take CALQUENCE? (cont'd)

If you miss a dose of CALQUENCE, take it as soon as you remember. If it is more
than 3 hours past your usual dosing time, skip the missed dose and take your next
dose of CALQUENCE at your regularly scheduled time. Do not take an extra dose to
make up for a missed dose.

### What are the possible side effects of CALQUENCE?

# **CALQUENCE** may cause serious side effects, including:

- Serious infections can happen during treatment with CALQUENCE and may lead to death. Your healthcare provider may prescribe certain medicines if you have an increased risk of getting infections. Tell your healthcare provider right away if you have any signs or symptoms of an infection, including fever, chills, or flu-like symptoms.
- Bleeding problems (hemorrhage) can happen during treatment with CALOUENCE and can be serious and may lead to death. Your risk of bleeding may increase if you are also taking a blood thinner medicine. Tell your healthcare provider if you have any signs or symptoms of bleeding, including blood in your stools or black stools (looks like tar), pink or brown urine, unexpected bleeding or bleeding that is severe or you cannot control, vomit blood or vomit that looks like coffee grounds, cough up blood or blood clots, dizziness, weakness, confusion, changes in your speech, headache that lasts a long time, or bruising or red or purple skin marks

Please see full Prescribing Information, including Patient Information.

- Decrease in blood cell counts. Decreased blood counts (white blood cells, platelets, and red blood cells) are common with CALQUENCE, but can also be severe. Your healthcare provider should do blood tests to check your blood counts regularly during treatment with CALQUENCE.
- Second primary cancers. New cancers have happened in people during treatment with CALQUENCE, including cancers of the skin or other organs. Your healthcare provider will check you for skin cancers during treatment with CALQUENCE. Use sun protection when you are outside in sunlight.
- Heart rhythm problems (atrial fibrillation and atrial flutter) have happened in people treated with CALQUENCE. Tell your healthcare provider if you have any of the following signs or symptoms: fast or irregular heartbeat, dizziness, feeling faint, chest discomfort, or shortness of breath

**The most common side effects of CALQUENCE include** headache, diarrhea, muscle and joint pain, upper respiratory tract infection, and bruising. These are not all the possible side effects of CALQUENCE. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

#### What is CALQUENCE?

CALQUENCE is a prescription medicine used to treat adults with mantle cell lymphoma (MCL) who have received at least one prior treatment for their cancer. It is not known if CALQUENCE is safe and effective in children.



