

Generic Name: **Acalabrutinib**

Brand Name: **Calquence**

Drug Classification: Covalent Bruton Tyrosine Kinase (BTK) Inhibitor

INDICATIONS FOR USE

- **For CLL or SLL without 17p deletion or TP53 mutation:** Acalabrutinib may be taken alone or in combination with obinutuzumab as a preferred initial (first-line) treatment, or alone as a second- or third-line treatment.
- **For CLL or SLL with 17p deletion or TP53 mutation:** Acalabrutinib may be taken alone or in combination with obinutuzumab as a preferred initial (first-line) treatment, or alone as a second- or third-line treatment.

ADMINISTRATION ROUTE

Taken orally by mouth (in tablet form).

LENGTH OF TIME ADMINISTERED

This medication should be taken indefinitely until either the disease progresses while on the medication (which would require switching to a new class of medications to treat the CLL or SLL), or until certain unacceptable side effects occur requiring discontinuation of the drug.

DOSING

100 mg taken two times per day (ideally every 12 hours).

MISSED DOSE

If a dose is missed by more than three hours, it should be skipped. Then take the next dose at the regularly scheduled time. Do not take an extra dose to make up for the missed dose.

HOW TO TAKE THIS MEDICATION

- Swallow the medication whole with water. Do not chew, break, or crush.
- May be taken with or without food.
- Tablets may be taken with stomach acid reducing medications or antacids.
- Do not ingest any starfruit, grapefruit juice, grapefruit, bitter orange/marmalade products, Seville oranges or pomegranate juice. Some citrus products are known to interfere with the metabolism of this medication and can potentially cause toxic levels of the drug to build up in the blood.

COMBINATION THERAPIES

This medication can be used in combination with other medications (such as obinutuzumab) and/or various combinations of medications being studied in clinical trials.

COMMON SIDE EFFECTS

Side effects can occur because of any medication, some of which may go away with time as your body adjusts to the new medication. Please notify your healthcare provider right away if any of the following side effects occur:

- Low red blood cell count, low white blood cell count, or low platelet count
- Headache
- Respiratory infection
- Constipation or diarrhea
- Fatigue or tiredness
- Muscle, joint, or bone pain
- Bruising or bleeding
- Rash

Side effects not mentioned above may also occur. Notify your healthcare provider of any other unusual symptoms, as they may be able to tell you about ways to prevent or reduce certain side effects.

MANAGING COMMON SIDE EFFECTS

Some side effects are more common than others, many of which will go away after a short period of time after staying on the medication. It is important to talk to your healthcare provider to discuss if you might be able to manage side effects in the short term in order to stay on the therapy until your body has time to adjust to the new medication. Here are some possible ways to help manage some of the most common side effects of acalabrutinib in consultation with your healthcare provider.

Headaches

- Increase your caffeine intake.
- Increase fluid intake, as it is important to stay hydrated.
- Take acetaminophen (such as Tylenol) per package instructions.
- It is important to avoid taking anti-inflammatories for mild pain (such as ibuprofen or aspirin) while taking acalabrutinib due to the slightly increased risk of bleeding.

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Diarrhea

- Increase your fluid intake.
- Take anti-diarrheal medications (such as Imodium) per package instructions.
- Eat a bland diet (such as bananas, rice, apples/ applesauce, toast, or plain pasta).

Constipation

- Increase your fluid intake.
- Consume more foods that are high in fiber (such as vegetables and whole grain bread).
- Consider over-the-counter fiber supplements (such as Fibercon, Miralax, or Metamucil).
- Move around more, as walking and other forms of exercise can help.
- Take over the counter stool softeners (such as Colace) to help soften bowel movements.

Fatigue or Tiredness

- Ensure you are eating a well-rounded diet that includes a balance of lean meats, fruits, vegetables, whole grains, and limited amounts of processed foods.
- Incorporate light types of exercise (such as walking).
- If you are able, take one short twenty-minute nap during the day. Frequent or longer naps during the day can affect the amount of sleep you are getting during the night and increase fatigue/tiredness.

Muscle, Joint, or Bone Pain

- Take acetaminophen (such as Tylenol) per package instructions.
- It is important to avoid taking anti-inflammatories (such as ibuprofen or aspirin) for mild pain while taking acalabrutinib due to the slightly increased risk of bleeding.
- Antihistamines (such as Allegra, Zyrtec, or Claritin) may help slightly with bone pain.
- Tonic water or magnesium supplements may help muscle cramping.
- Gentle stretching and application of heat or ice to the affected area(s) can provide temporary relief.
- If you are experiencing more severe joint pain, your healthcare provider may prescribe a short course of steroids.

REASONS TO TALK TO YOUR HEALTHCARE PROVIDER

The presence of other medical problems may affect the use of acalabrutinib. Make sure you share with your healthcare provider if you have any of the following conditions:

- Liver disease (acalabrutinib should be avoided with severe liver impairment)
- Hepatitis
- Heart problems (including high blood pressure, palpitations, fast or irregular heartbeat, dizziness, fainting, chest discomfort or shortness of breath)
- High uric acid level and/or gout
- Recent or current infection
- Bleeding problems, or if you are on any blood thinning medication
- If you are pregnant or breastfeeding (or if you plan to become pregnant or breastfeed)

SPECIAL CONSIDERATIONS

- Acalabrutinib can have a mild blood-thinning effect, so aspirin and other anti-inflammatory pain medications (such as ibuprofen/Advil) may need to be avoided. Stay away from rough sports or other situations where you could be bruised, cut, or injured. Brush and floss your teeth gently, be careful when using sharp objects, including razors and fingernail clippers.
- Serious bacterial, viral, or fungal infections can occur while taking acalabrutinib. But this can also occur in part from being immunocompromised due to having CLL or SLL. Avoid being near people who are sick and wash your hands often.
- If you have had hepatitis B before or carry the virus, talk with your healthcare provider. This drug can cause the dormant virus to become reactivated and protective medication may be needed.
- There are several medications that interfere with the metabolism of acalabrutinib and can cause toxic levels of the drug to build up in the blood, or that increase the breakdown of acalabrutinib which can decrease the drug's effectiveness. It is very important to tell your healthcare provider about all the medications you take, including prescription and over the counter medicines, vitamins, and herbal supplements (particularly in the case of acalabrutinib you should not be on St. John's Wort).
- Secondary cancers have been reported while taking the medication, but this is also a common finding associated with having CLL or SLL. Please be diligent about annual cancer screenings.
- You may be advised to briefly stop taking acalabrutinib for dental or surgical procedures, so let your CLL/SLL healthcare provider know about any planned procedures. Never hold or stop taking this medication without the supervision of your healthcare provider.