CLL

Adverse event management guide for CALQUENCE-based regimens in CLL

Tips for helping patients manage certain AEs with CALQUENCE monotherapy or in combination with venetoclax or obinutuzumab

Advise patients to inform you if they experience any of these adverse reactions associated with CALQUENCE, or if any of these reactions get worse, become severe, or do not go away.

Headache

- Can occur within 30 minutes of dosing and typically can be managed with acetaminophen or caffeine[1]
- Usually resolves over a period of 4 weeks[1]

Fatigue

- Advise patients to get adequate nighttime sleep and take short naps early in the day[2]
- Recommend relaxation through enjoyable activities or moderate exercise like walking (patients should consult their primary health care provider before starting any exercise plan)[2]

Diarrhea

- Advise patients to drink clear liquids such as water or oral rehydration drinks to replace lost fluids and electrolytes[3]
- Advise patients to eat smaller, more frequent, low-fiber meals[3]
- Grade 1 or 2 diarrhea may be managed at home with an antidiarrheal medication[3,4]

Muscle pain

- Advise patients to take pain medication as directed by their healthcare provider[5,6]
- Suggest treatments such as massage, physical therapy, applying heat or cold to the affected area, and mild stretching[5,6]

Bruising

- Advise patients to elevate and ice the affected area to reduce swelling and ease tenderness[7]

Upper and lower respiratory tract infection

- Advise patients to wash their hands regularly and wear a mask in crowds to avoid infection[8]
- Ask patients to call immediately at signs or symptoms of an infection, including fever, chills, or flu-like symptoms[8]

The most common adverse reactions (≥30%) in patients treated with CALQUENCE are upper respiratory tract infection, diarrhea, headache, and musculoskeletal pain. The most common Grade 3 or 4 laboratory abnormalities (≥10%) are absolute neutrophil count decreased, uric acid increased, absolute lymphocyte count decreased, and platelets decreased.[9]

These are not all of the possible adverse reactions of CALQUENCE. Recommendations for AE management are from organizations outside of AstraZeneca and should be considered along with the complete Prescribing Information and physicians' own clinical experience.

AEs=adverse events; CLL=chronic lymphocytic leukemia.

INDICATION AND USAGE

CALQUENCE is a Bruton tyrosine kinase (BTK) inhibitor indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

IMPORTANT SAFETY INFORMATION ABOUT CALQUENCE® (acalabrutinib) tablets

Serious and Opportunistic Infections

Fatal and serious infections, including opportunistic infections, have occurred in patients with hematologic malignancies treated with CALQUENCE.

Serious or Grade 3 or higher infections (bacterial, viral, or fungal) occurred in 29% of 2,055 patients exposed to CALQUENCE in clinical trials, most often due to respiratory tract infections (18% of all patients, including pneumonia in 14%). These infections predominantly occurred in the absence of Grade 3 or 4 neutropenia, with neutropenic infection reported in 8% of all patients. Opportunistic infections in recipients of CALQUENCE have included, but are not limited to, hepatitis B virus reactivation, fungal pneumonia, *Pneumocystis jirovecii* pneumonia, Epstein-Barr virus reactivation, cytomegalovirus, and progressive multifocal leukoencephalopathy (PML). Consider prophylaxis in patients who are at increased risk for opportunistic infections. Monitor patients for signs and symptoms of infection and treat promptly.

Hemorrhage

Fatal and serious hemorrhagic events have occurred in patients treated with CALQUENCE. Major hemorrhage (serious or Grade 3 or higher bleeding or any central nervous system bleeding) occurred in 4.7% of patients, with fatal hemorrhage occurring in 0.1% of 2,055 patients exposed to CALQUENCE in clinical trials. Bleeding events of any grade, excluding bruising and petechiae, occurred in 39% of patients.

Use of antithrombotic agents concomitantly with CALQUENCE may further increase the risk of hemorrhage. In clinical trials, major hemorrhage occurred in 5% of patients taking CALQUENCE without antithrombotic agents and 3.2% of patients taking CALQUENCE with antithrombotic agents. Consider the risks and benefits of antithrombotic agents when co-administered with CALQUENCE. Monitor patients for signs of bleeding.

Consider the benefit-risk of withholding CALQUENCE for 3 to 7 days pre- and post-surgery depending upon the type of surgery and the risk of bleeding.

Cytopenias

CALQUENCE can cause Grade 3 or 4 cytopenias. Grade 3 or 4 cytopenias included absolute neutrophil count decreased (28%), absolute lymphocyte count decreased (10%), hemoglobin decreased (9%), and platelets decreased (9%) in 1,758 patients

Please see Important Safety Information throughout, and full Prescribing Information, including Patient Information.

CALQUENCE®
acalabrutinib 100 mg tablets

CALQUENCE + venetoclax (fixed-duration regimen)[1]

CALQUENCE + venetoclax dosage information

In the AMPLIFY Phase 3 trial, patients with previously untreated CLL who were randomized to the CALQUENCE + venetoclax arm received CALQUENCE 100 mg PO BID* starting at Cycle 1 for a maximum of 14 cycles, and venetoclax PO QD starting at Cycle 3 for a maximum of 12 cycles. Venetoclax had a 5-week dose ramp-up (debulking) period. Treatment regimen was designed to be completed in 14 cycles, unless disease progression or unacceptable toxicity warranted earlier discontinuation. Each cycle was 28 days.[9-11]

Refer to the venetoclax Prescribing Information for recommended venetoclax dosage and administration information.

Most common ARs (≥15% Any Grade)†[9]

Event	CALQUENCE + venetoclax (n=291)	
	Any Grade (%)	Grade ≥3 (%)
Headache	35	1.4
Diarrhea	33	1.7
Musculoskeletal pain‡	25	0.7
COVID-19	21	6
Fatigue§	18	0.3
Bruising‖	17	0
Rash¶	16	1
Nausea	15	0

Values >5 are rounded to the nearest whole number.

Select events of clinical interest (Any Grade/Grade ≥3) with CALQUENCE + venetoclax included cardiac events (9%/1.7%), atrial fibrillation or flutter (0.7%/0.3%), hypertension (4.1%/2.7%), hemorrhage (32%/1.0%), major hemorrhage (1.0%/1.0%), infection (51%/12%), second primary malignancy (5%/1.7%), and TLS (0.3%/0.3%), with 0 cases of clinical TLS.[#11,12]

Laboratory abnormalities (≥20%, Any Grade) in patients with previously untreated CLL who received CALQUENCE + venetoclax (n=291) included neutrophils decreased (78%), glucose increased (74%), lymphocytes decreased (56%), platelets decreased (43%), hemoglobin decreased (35%), calcium decreased (30%), ALT increased (26%), urate increased (25%), LDH increased (24%), AST increased (22%), potassium increased (22%), ALP increased (20%), and glucose decreased (20%).[9]

Neutropenia rates (Any Grade/Grade ≥3) were 31%/27%, and febrile neutropenia rates were 1.7%/1.7%.**[11]

Median duration of exposure was 12.9 months with CALQUENCE and 11.1 months with venetoclax.[1]

*Approximately every 12 hours.† ‡At 42.6-month median follow-up.§ ‖Includes back pain, bone pain, musculoskeletal chest pain, musculoskeletal pain, musculoskeletal discomfort, myalgia, neck pain, pain in extremity, and spinal pain.¶ #Includes fatigue and asthenia.‡ ‖Includes bruise, contusion, and ecchymosis.§ ¶Includes rash, dermatitis, and other related terms.† #TLS observed with CALQUENCE + venetoclax (n=1, during venetoclax ramp-up) was limited to laboratory TLS only; no clinical TLS was observed.[12] **At 40.8-month median follow-up (range: 0.0-59.0 months).[11]

1L=first-line; ALP=alkaline phosphatase; ALT=alanine transferase; ARs=adverse reactions; AST=aspartate transferase; BID=twice daily; COVID-19=coronavirus disease 2019; LDH=lactate dehydrogenase; PO=by mouth; QD=once daily; TLS=tumor lysis syndrome.

IMPORTANT SAFETY INFORMATION ABOUT CALQUENCE® (acalabrutinib) tablets (cont'd)

Cytopenias (cont'd)

treated with CALQUENCE alone and in combination with obinutuzumab or venetoclax; Grade 4 neutropenia developed in 14% of patients.

Monitor complete blood counts regularly during treatment. Interrupt treatment, reduce the dose, or discontinue treatment as warranted.

Second Primary Malignancies

Second primary malignancies, including skin cancers and other solid tumors, occurred in 16% of 2,055 patients exposed to CALQUENCE in clinical trials. The most frequent second primary malignancy was non-melanoma skin cancer, reported in 9% of patients, followed by other solid tumors in 8% (including melanoma, lung cancer, gastrointestinal cancers, and genitourinary cancers) and hematologic malignancies (1.1%). Fatal second primary malignancies occurred in 0.8% of patients. Monitor patients for the development of second cancers and advise protection from sun exposure.

Cardiac Arrhythmias

Fatal and serious cardiac arrhythmias have occurred in patients treated with CALQUENCE. Grade 3 or 4 atrial fibrillation or flutter was reported in 2.2% of 2,055 patients treated with CALQUENCE, with all grades of atrial fibrillation or flutter reported in 7% of all patients. Grade 3 or higher ventricular arrhythmia events were reported in 0.5% of patients, including fatal cases in 0.3% of all patients. The risk of arrhythmias may be increased in patients with cardiac risk factors, hypertension, previous arrhythmias, and acute infection. Monitor for symptoms of arrhythmia (eg, palpitations, dizziness, syncope, dyspnea) and manage as appropriate.

Hepatotoxicity, Including Drug-Induced Liver Injury

Hepatotoxicity, including severe, life-threatening, and potentially fatal cases of drug-induced liver injury (DILI), has occurred in patients treated with Bruton tyrosine kinase inhibitors, including CALQUENCE.

Evaluate bilirubin and transaminases at baseline and throughout treatment with CALQUENCE. For patients who develop abnormal liver tests after CALQUENCE, monitor more frequently for liver test abnormalities and clinical signs and symptoms of hepatic toxicity. If DILI is suspected, withhold CALQUENCE. Upon confirmation of DILI, discontinue CALQUENCE.

ADVERSE REACTIONS

Chronic Lymphocytic Leukemia

The most common adverse reactions (≥30%) of any grade in patients with CLL in the ELEVATE-TN and ASCEND studies exposed to CALQUENCE (n=511) were anemia,* neutropenia,* thrombocytopenia,* headache, upper respiratory tract infection, and diarrhea.

*Treatment-emergent decreases (all grades) of hemoglobin, platelets, and neutrophils were based on laboratory measurements and adverse reactions.

In patients with previously untreated CLL in the ELEVATE-TN study exposed to CALQUENCE (n=357), fatal adverse reactions that occurred in the absence of disease progression and with onset within 30 days of the last study treatment were reported in 2% for each treatment arm, most often from infection. Serious adverse reactions were reported in 39% (69/178) of patients in the CALQUENCE plus obinutuzumab arm (n=178) and 32% (57/179) in the CALQUENCE monotherapy arm (n=179), most often due to events of pneumonia (2.8% to 7%).

Adverse reactions led to CALQUENCE dose reduction in 7% and 4% of patients in the CALQUENCE plus obinutuzumab arm and CALQUENCE monotherapy arm, respectively. Adverse reactions led to discontinuation in 11% and 10% of patients, respectively. Increases in creatinine to 1.5 to 3 times ULN occurred in 3.9% and 2.8% of patients in the CALQUENCE combination arm and monotherapy arm, respectively.

CALQUENCE ± obinutuzumab (continuous regimens)[1]

CALQUENCE ± obinutuzumab dosage information

In the ELEVATE-TN Phase 3 trial, patients with previously untreated CLL who were randomized to the CALQUENCE monotherapy arm received CALQUENCE 100 mg PO BID* until disease progression or unacceptable toxicity. Patients who were randomized to the CALQUENCE + obinutuzumab arm received CALQUENCE 100 mg PO BID† starting at Cycle 1 until disease progression or unacceptable toxicity, and obinutuzumab starting at Cycle 2 for a maximum of 6 cycles. Each cycle was 28 days. CALQUENCE was administered prior to obinutuzumab when given on the same day.[9-11]

Refer to the obinutuzumab Prescribing Information for recommended obinutuzumab dosage and administration information.

Most common ARs (≥30%, Any Grade)†[9]

Event	CALQUENCE monotherapy (n=179)		CALQUENCE + obinutuzumab (n=178)	
	Any Grade (%)	Grade ≥3 (%)	Any Grade (%)	Grade ≥3 (%)
Infection‡	65	14§	69	22§
Neutropenia	23	13	53	37
Anemia	53	10	52	12
Thrombocytopenia	32	3.4	51	12
Headache	39	1.1	40	1.1
Diarrhea	35	0.6	39	4.5
Musculoskeletal pain‖	32	1.1	37	2.2
Fatigue¶	23	1.1	34	2.2
Bruising#	21	0	31	0

Values >5 are rounded to the nearest whole number.

Select events of clinical interest (Any Grade/Grade ≥3) with CALQUENCE monotherapy included cardiac events (14%/5%), atrial fibrillation (3.9%/0%), bleeding (39%/1.7%), hypertension (4.5%/2.2%), infection (65%/14%), and second primary malignancy (any) (9% Any Grade). **Select events of clinical interest (Any Grade/Grade ≥3) with CALQUENCE + obinutuzumab** included cardiac events (14%/4.5%), atrial fibrillation (3.4%/0.6%), bleeding (43%/1.7%), hypertension (7%/2.8%), infection (69%/21%), tumor lysis syndrome (1.7%/1.1%), and second primary malignancy (any) (11% Any Grade).[13]

Median duration of exposure was 27.7 months with CALQUENCE monotherapy and CALQUENCE + obinutuzumab.[9]

*Approximately every 12 hours.† ‡At 28.3-month median follow-up (range: 0.0-40.8 months).† §Includes any adverse reactions involving infection or febrile neutropenia.† ‖Includes 3 fatal cases in the CALQUENCE + obinutuzumab arm and 3 fatal cases in the CALQUENCE monotherapy arm.† ¶Includes back pain, bone pain, musculoskeletal chest pain, musculoskeletal pain, musculoskeletal discomfort, myalgia, neck pain, pain in extremity and spinal pain.† #Includes asthenia, fatigue, and lethargy.† #Includes bruise, contusion, and ecchymosis.§

References: 1. O'Brien SM, Brown JR, Byrd JC, et al. Monitoring and managing BTK inhibitor treatment-related adverse events in clinical practice. *Front Oncol*. 2021;11:720704. **2.** American Cancer Society. Cancer-related fatigue. Revised July 16, 2024. Accessed February 24, 2026. https://www. cancer.org/cancer/managing-cancer/side-effects/fatigue-weakness-sleep/fatigue.html **3.** MedlinePlus. Diarrhea. National Institutes of Health. Updated July 20, 2016. Accessed February 24, 2026. https://medlineplus.gov/diarrhea.html **4.** National Cancer Society. Diarrhea and cancer treatment. National Institutes of Health. Updated May 16, 2025. Accessed February 24, 2026. https://www.cancer.gov/about-cancer/treatment/side-effects/diarrhea **5.** Healy M. Arthralgias and myalgias (joint or muscle pain). Oncolink. Updated August 5, 2024. Accessed February 24, 2026. https://www.oncolink.org/support/side-effects/other-side-effects/arthralgias-and-myalgias-joint-or-muscle-pain **6.** Cleveland Clinic. Myalgia (muscle pain). Reviewed October 1, 2024. Accessed February 24, 2026. https://my.clevelandclinic.org/health/symptoms/myalgia-muscle-pain **7.** Cleveland Clinic. Bruises. Updated December 5, 2025. Accessed February 24, 2026. https://my.clevelandclinic.org/health/diseases/15235-bruises **8.** American Cancer Society. Preventing infections in people with cancer. Updated December 4, 2025. Accessed February 24, 2026. https://www.cancer.org/cancer/managing-cancer/side-effects/infections/preventing-infections-in-people-with-cancer.html **9.** CALQUENCE® (acalabrutinib) tablets [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2026. **10.** Venclexta® (venetoclax) [prescribing information]. North Chicago, IL: AbbVie and South San Francisco, CA: Genentech USA, Inc.; 2026. **11.** Brown JR, Seymour JF, Jurczak W, et al. Fixed-duration acalabrutinib combinations in untreated chronic lymphocytic leukemia and supplementary appendix. *N Engl J Med*. 2025;392(8):748-762. **12.** Seymour J, Aw A, Ribrag V, et al. Safety analysis of fixed-duration acalabrutinib-venetoclax combinations vs chemotherapy: a post hoc analysis from the phase 3 AMPLIFY trial. Poster 1424 presented at: XXI International Workshop on CLL (iwCLL); September 12-15, 2025; Krakow, Poland. **13.** Sharman JP, Egyed M, Jurczak W, et al. Acalabrutinib with or without obinutuzumab versus chlorambucil and obinutuzumab for treatment-naive chronic lymphocytic leukaemia (ELEVATE-TN): a randomised, controlled, phase 3 trial [published correction appears in *Lancet*. 2020;395(10238):1694]. *Lancet*. 2020;395(10232):1278-1291 and supplementary appendix.

IMPORTANT SAFETY INFORMATION ABOUT CALQUENCE® (acalabrutinib) tablets (cont'd)

ADVERSE REACTIONS (cont'd)

In patients with previously untreated CLL in the AMPLIFY study who received CALQUENCE plus venetoclax (AV) (n=291), the most common adverse reactions (≥15%) of any grade were headache (35%), diarrhea (33%), musculoskeletal pain (25%), COVID-19 (21%), fatigue (18%), bruising (17%), rash (16%), and nausea (15%).

The most common laboratory abnormalities (≥15%) of any grade in patients with previously untreated CLL who received AV were neutrophils decreased (78%), glucose increased (74%), lymphocytes decreased (56%), platelets decreased (43%), hemoglobin decreased (35%), calcium decreased (30%), ALT increased (26%), urate increased (25%), LDH increased (24%), potassium increased (22%), AST increased (22%), ALP increased (20%), glucose decreased (20%), creatinine increased (19%), and sodium increased (15%). Grade 4 laboratory abnormalities in >15% of patients treated with AV include absolute neutrophil count decreased (15%).

Serious adverse reactions occurred in 25% of patients receiving AV. The most common serious adverse reactions (≥2%) were COVID-19 including COVID-19 pneumonia (9%), second primary malignancies (2.7%), and neutropenia (2.1%). Fatal adverse events occurred in 3.4% of patients. The most common fatal adverse events included COVID-19 and COVID-19 pneumonia.

Treatment discontinuation of CALQUENCE due to adverse reactions occurred in 8% of patients receiving AV. The most common adverse reaction (≥2%) leading to treatment discontinuation was COVID-19 pneumonia (2.1%). Dose reduction of CALQUENCE occurred in 6% of patients. Neutropenia was the only adverse reaction leading to dose reduction that occurred in ≥1% of patients.

DRUG INTERACTIONS

Strong CYP3A Inhibitors: Avoid co-administration of CALQUENCE with a strong CYP3A inhibitor. If these inhibitors will be used short-term, interrupt CALQUENCE. After discontinuation of strong CYP3A inhibitor for at least 24 hours, resume previous dosage of CALQUENCE.

Moderate CYP3A Inhibitors: Reduce the dosage of CALQUENCE to 100 mg once daily when co-administered with a moderate CYP3A inhibitor.

Strong CYP3A Inducers: Avoid co-administration of CALQUENCE with a strong CYP3A inducer. If co-administration is unavoidable, increase the dosage of CALQUENCE to 200 mg approximately every 12 hours.

SPECIFIC POPULATIONS

Based on findings in animals, CALQUENCE may cause fetal harm and dystocia when administered to a pregnant woman. There are no available data in pregnant women to inform the drug-associated risk. Advise pregnant women of the potential risk to a fetus.

Pregnancy testing is recommended for females of reproductive potential prior to initiating CALQUENCE therapy. Advise female patients of reproductive potential to use effective contraception during treatment with CALQUENCE and for 1 week following the last dose of CALQUENCE.

Please see Important Safety Information throughout, and full Prescribing Information, including Patient Information.

CALQUENCE®
acalabrutinib 100 mg tablets

Recommended dosage modifications for ARs[9]

CLL

CALQUENCE + venetoclax

Event*	1st occurrence	2nd occurrence	≥3rd Subsequent occurrences
Grade 3 or 4 neutropenia with or without fever and/or infection; **Grade 4** neutropenia lasting more than 7 days	• Interrupt CALQUENCE and/or venetoclax[†] • Once toxicity resolves to Grade ≤1 or baseline, restart CALQUENCE and/or venetoclax at same dose	• Interrupt CALQUENCE and/or venetoclax[†] • Once toxicity resolves to Grade ≤1 or baseline, restart CALQUENCE at same dose and venetoclax at one lower dose level[‡]	• Withhold CALQUENCE and/or venetoclax until toxicity resolves to Grade ≤1 or baseline[†]
Grade 3 or 4 thrombocytopenia and/or bleeding[‖]	• Interrupt CALQUENCE and/or venetoclax. When bleeding resolves and thrombocytopenia is Grade ≤1 or baseline without transfusion support for 5 consecutive days, restart CALQUENCE and/or venetoclax at same dose	• Interrupt CALQUENCE and venetoclax until resolution of bleeding and thrombocytopenia resolves to Grade ≤1 or baseline • Restart CALQUENCE at same dose and/or restart venetoclax at one lower dose level[§]	For severe thrombocytopenia: • Interrupt CALQUENCE and venetoclax until resolution of bleeding and thrombocytopenia resolves to Grade ≤1 or baseline • Restart CALQUENCE at a reduced frequency of 100 mg once daily and/or venetoclax at one lower dose level[‡§]
Grade 3 or 4 tumor lysis syndrome (TLS)	**First and subsequent episodes** • If a subject experiences blood chemistry changes suggestive of TLS, the following day's venetoclax and acalabrutinib dose should be withheld. If resolved within 24–48 hours of last dose, treatment can be resumed at the same dose • For events of clinical TLS or blood chemistry changes requiring more than 48 hours to resolve, venetoclax should be resumed at one lower dose level.[‡] When resuming treatment after interruption due to TLS, monitor for TLS and provide prophylaxis		
Grade 3 other non-hematologic events[¶]	• Interrupt CALQUENCE and/or venetoclax until toxicity resolves to Grade ≤1 • Restart CALQUENCE and/or venetoclax at same dose	• Interrupt CALQUENCE and/or venetoclax until toxicity resolves to Grade ≤1	
Grade 4 other non-hematologic events[¶]	• Interrupt CALQUENCE and/or venetoclax until toxicity resolves to Grade ≤1. Restart CALQUENCE at a reduced frequency of 100 mg once daily and/or venetoclax at one lower dose level[‡§]	• Interrupt CALQUENCE and/or venetoclax until toxicity resolves to Grade ≤1	

CALQUENCE (+/- obinutuzumab)

Event	1st & 2nd occurrence	3rd occurrence	4th occurrence
Grade 3 or greater non-hematologic toxicities, **Grade 3** thrombocytopenia with bleeding, **Grade 4** thrombocytopenia, **or** **Grade 4** neutropenia lasting longer than 7 days	• Interrupt CALQUENCE • Once toxicity has resolved to Grade 1 or baseline level, CALQUENCE may be resumed at 100 mg approximately every 12 hours	• Interrupt CALQUENCE • Once toxicity has resolved to Grade 1 or baseline level, CALQUENCE may be resumed at a reduced frequency of 100 mg once daily	• Discontinue CALQUENCE

CALQUENCE recommended dosage=100 mg approximately every 12 hours.[9]

Clinical judgment of the treating physician should guide the management plan of each patient based on the individual benefit/risk assessment for treatment with CALQUENCE in combination with venetoclax.

Please refer to the venetoclax or obinutuzumab Prescribing Information for additional information for management of toxicities.

*Adverse reactions graded by the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 5.0. [†]Growth factor may be used at physician discretion. [‡]See venetoclax USPI for dose level reductions details. [§]CALQUENCE dose may be re-escalated at the discretion of the physician if patient tolerates a reduced dose for ≥4 weeks. [‖]Platelets may be used at physician discretion.[¶]Certain treatment-emergent non-hematologic AEs (eg, venous thromboembolic events) may be managed and become clinically stable following medical intervention but may not improve to Grade ≤1 according to the NCI CTCAE definitions. In such cases, if a subject is clinically stable, resumption of CALQUENCE may be possible based on clinical judgment of the treating physician.

IMPORTANT SAFETY INFORMATION ABOUT CALQUENCE® (acalabrutinib) tablets (cont'd)

SPECIFIC POPULATIONS (cont'd)

It is not known if CALQUENCE is present in human milk. Advise lactating women not to breastfeed while taking CALQUENCE and for 2 weeks after the last dose.

Of patients that received AV in AMPLIFY, 33% (97/291) were ≥65 years, and 4.5% (13/291) were ≥75 years of age. In patients ≥65 years and <65 years of age, the fatal adverse reactions were 5% and 2.6%, respectively.

Avoid use of CALQUENCE in patients with severe hepatic impairment (Child-Pugh class C). No dosage adjustment of CALQUENCE is recommended in patients with mild (Child-Pugh class A) or moderate (Child-Pugh class B) hepatic impairment.

Please see Important Safety Information throughout, and full Prescribing Information, including Patient Information.

You may report side effects related to AstraZeneca products.

CALQUENCE® acalabrutinib 100 mg tablets

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