Brukinsa®
zanubrutinib 160 mg tablets

NEW FORMULATION

BRUKINSA TABLETS

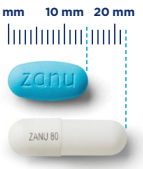
FREQUENTLY ASKED QUESTIONS

DAILY PILL BURDEN HALVED

With BRUKINSA 160 mg tablets, the daily pill burden is **reduced by 50%, from 4 capsules to 2 tablets**[1]

REDUCED SIZE FOR EASIER SWALLOWING

The film-coated tablet is almost **one-third smaller in length** than the capsule, making it **easier for patients to swallow**[1]



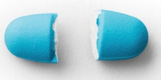
UNMATCHED DOSING FLEXIBILITY

BRUKINSA is still the only BTKi to offer the **flexibility of once- or twice-daily dosing**[1-3]

ONCE OR TWICE DAILY

REDUCE IN SMALL INCREMENTS

BRUKINSA tablets are scored, **making them easy for patients to split**[1]



NEW FORMULATION

SAME FLEXIBILITY

INDICATIONS

BRUKINSA is a kinase inhibitor indicated for the treatment of adult patients with:

- Chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)
- Waldenström's macroglobulinemia (WM)
- Mantle cell lymphoma (MCL) who have received at least one prior therapy
- Relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen
- Relapsed or refractory follicular lymphoma (FL), in combination with obinutuzumab, after two or more lines of systemic therapy

The MCL, MZL and FL indications are approved under accelerated approval based on overall response rate and durability of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trials.

Please see Important Safety Information throughout and accompanying full Prescribing Information.

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IMPORTANT SAFETY INFORMATION
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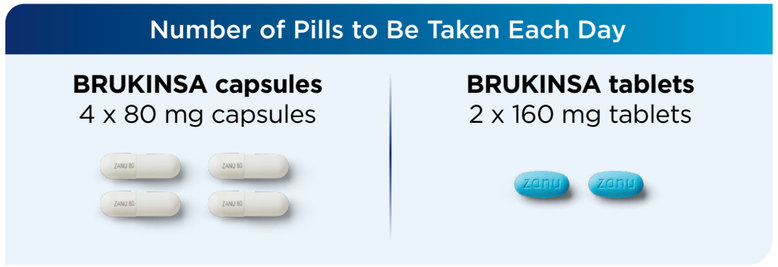
Hemorrhage

Fatal and serious hemorrhage has occurred in patients with hematological malignancies treated with BRUKINSA. Grade 3 or higher hemorrhage including intracranial and gastrointestinal hemorrhage, hematuria, and hemothorax was reported in 3.8% of patients treated with BRUKINSA in clinical trials, with fatalities occurring in 0.2% of patients. Bleeding of any grade, excluding purpura and petechiae, occurred in 32% of patients.

OVERVIEW | BRUKINSA TABLETS

What is the difference between BRUKINSA capsules and tablets?

The recommended daily dose of BRUKINSA remains 320 mg. BRUKINSA 80 mg capsules require patients to take 4 capsules daily, while the new BRUKINSA 160 mg tablets require only 2 tablets daily, reducing the pill burden by 50%. As an added benefit, BRUKINSA tablets are significantly smaller than capsules, with a film coating, making them easier to swallow for your patients.[1]



Actual sizes.

Will BRUKINSA capsules still be available?

No. BRUKINSA capsules are being replaced by BRUKINSA tablets in early October 2025. The capsules will only be available for a limited time. Once the tablets are available, patients will finish their last bottle of capsules and then begin receiving tablets.

Are the efficacy and safety of BRUKINSA tablets the same as the capsule formulation?

Based on bioequivalence, BRUKINSA tablets are expected to have the same efficacy and safety as BRUKINSA capsules.[4,5]

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)

Hemorrhage (continued)

Bleeding has occurred in patients with and without concomitant antiplatelet or anticoagulation therapy. Coadministration of BRUKINSA with antiplatelet or anticoagulant medications may further increase the risk of hemorrhage.

Please see Important Safety Information throughout and accompanying full Prescribing Information.

Brukinsa® zanubrutinib 160 mg tablets

DOSING & ADMINISTRATION | BRUKINSA TABLETS

Are there any changes to the BRUKINSA dose or schedule?

- BRUKINSA is still the only BTKi to offer the flexibility of once- or twice-daily dosing, with the ability to tailor the schedule to your patients[1-3]

Unmatched Dosing Flexibility[1]

ONCE DAILY (QD)

Consider for patients with compliance concerns or for those who prefer taking their medication once a day

320 mg daily dose

2 tablets taken once daily

TWICE DAILY (BID)

Consider for patients who take other twice-daily medications to maintain a consistent drug-dosing schedule

320 mg daily dose

1 tablet in the morning,
1 tablet in the evening

- BRUKINSA continues to be the only BTKi with a recommended dose for severe hepatic impairment—adjust dose to **80 mg (½ tablet) twice daily*[1-3]**

*Although the safety of BRUKINSA has not been evaluated in patients with severe hepatic impairment, there is no caution to avoid use in these patients. Monitor for adverse reactions in patients with hepatic impairment.[1]

How should BRUKINSA tablets be taken?

- BRUKINSA tablets should not be chewed or crushed[1]
- BRUKINSA tablets can be taken with or without food, including high-fat meals. They should be taken with water[1]

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)

Hemorrhage (continued)

Monitor for signs and symptoms of bleeding. Discontinue BRUKINSA if intracranial hemorrhage of any grade occurs. Consider the benefit-risk of withholding BRUKINSA for 3-7 days before and after surgery depending upon the type of surgery and the risk of bleeding.

Are dose modifications for adverse reactions different for BRUKINSA tablets?

Dose modification with BRUKINSA continues to be straightforward, with small, incremental dose reductions for adverse reactions. Please review the full Prescribing Information for more detailed dose modification information for BRUKINSA tablets.[1]

Straightforward dose modifications with ability to reduce in small increments[1]

Adverse Reaction Occurrence	Dose Modification
First	Resume 2 tablets daily (320 mg)
Second	Reduce to 1 tablet daily (160 mg)
Third	Reduce to ½ tablet daily (80 mg)
Fourth	Discontinue

Can BRUKINSA tablets be dosed as monotherapy or in combination with obinutuzumab?

BRUKINSA tablets can be dosed as monotherapy or in combination with obinutuzumab for approved indications.[1]

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)

Infections

Fatal and serious infections (including bacterial, viral, or fungal infections) and opportunistic infections have occurred in patients with hematological malignancies treated with BRUKINSA. Grade 3 or higher infections occurred in 26% of patients, most commonly pneumonia (7.9%), with fatal infections occurring in 3.2% of patients. Infections due to hepatitis B virus (HBV) reactivation have occurred.

Consider prophylaxis for herpes simplex virus, *pneumocystis jirovecii* pneumonia, and other infections according to standard of care in patients who are at increased risk for infections. Monitor and evaluate patients for fever or other signs and symptoms of infection and treat appropriately.

Please see Important Safety Information throughout and accompanying full Prescribing Information.

Brukinsa® 160 mg zanubrutinib tablets

ADDITIONAL QUESTIONS | BRUKINSA TABLETS

Is there a difference in cost for tablets versus capsules?

Due to price-reporting implications, pricing will not be available prior to the availability of BRUKINSA tablets.

Are new prescriptions required for BRUKINSA tablets?

Yes. New prescriptions will need to be written for BRUKINSA 160 mg tablets. The pharmacy will contact the prescriber when the new tablet script is needed.

Will BRUKINSA tablets be available through the same specialty pharmacies and distributors?

Yes. Access to BRUKINSA tablets will be available through the same sources.

Are reauthorizations required for BRUKINSA tablets?

Reauthorizations are not anticipated to be required. Please contact your BeOne representative for confirmation closer to the availability of BRUKINSA tablets.

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)

Cytopenias

Grade 3 or 4 cytopenias, including neutropenia (21%), thrombocytopenia (8%) and anemia (8%) based on laboratory measurements, developed in patients treated with BRUKINSA. Grade 4 neutropenia occurred in 10% of patients, and Grade 4 thrombocytopenia occurred in 2.5% of patients.

Monitor complete blood counts regularly during treatment and interrupt treatment, reduce the dose, or discontinue treatment as warranted. Treat using growth factor or transfusions, as needed.

Second Primary Malignancies

Second primary malignancies, including non-skin carcinoma, have occurred in 14% of patients treated with BRUKINSA. The most frequent second primary malignancy was non-melanoma skin cancers (8%), followed by other solid tumors in 7% of the patients (including melanoma in 1% of patients) and hematologic malignancies (0.7%). Advise patients to use sun protection and monitor patients for the development of second primary malignancies.

Cardiac Arrhythmias

Serious cardiac arrhythmias have occurred in patients treated with BRUKINSA. Atrial fibrillation and atrial flutter were reported in 4.4% of patients treated with BRUKINSA, including Grade 3 or higher cases in 1.9% of patients. Patients with cardiac risk factors, hypertension, and acute infections may be at increased risk. Grade 3 or higher ventricular arrhythmias were reported in 0.3% of patients.

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)

Cardiac Arrhythmias (continued)

Monitor for signs and symptoms of cardiac arrhythmias (e.g., palpitations, dizziness, syncope, dyspnea, chest discomfort), manage appropriately, and consider the risks and benefits of continued BRUKINSA treatment.

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 BRUKINSA.

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

Embryo-Fetal Toxicity

Based on findings in animals, BRUKINSA can cause fetal harm when administered to a pregnant woman. Administration of zanubrutinib to pregnant rats during the period of organogenesis caused embryo-fetal toxicity, including malformations at exposures that were 5 times higher than those reported in patients at the recommended dose of 160 mg twice daily. Advise women to avoid becoming pregnant while taking BRUKINSA and for 1 week after the last dose. Advise men to avoid fathering a child during treatment and for 1 week after the last dose. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus.

Please see Important Safety Information throughout and accompanying full Prescribing Information.

Brukinsa® zanubrutinib 160 mg tablets

BRUKINSA tablets improve ease of dosing for your patients—only 2 small tablets daily[1]

The tablet formulation continues to provide the unmatched dosing flexibility among BTKis that BRUKINSA has always offered:

Only BTKi with QD and BID dosing options to tailor the schedule to your patients[1-3]

Only BTKi with recommended dosing for severe hepatic impairment (80 mg BID)*[1-3]

Straightforward dose modifications with the ability to reduce in small increments[1]

*Although the safety of BRUKINSA has not been evaluated in patients with severe hepatic impairment, there is no caution to avoid use in these patients. Monitor for adverse reactions in patients with hepatic impairment.[1]

IMPORTANT SAFETY INFORMATION (continued)

ADVERSE REACTIONS

The most common adverse reactions (≥30%), including laboratory abnormalities, in patients who received BRUKINSA (N=1729) are decreased neutrophil count (51%), decreased platelet count (41%), upper respiratory tract infection (38%), hemorrhage (32%), and musculoskeletal pain (31%).

DRUG INTERACTIONS

CYP3A Inhibitors: When BRUKINSA is coadministered with a strong CYP3A inhibitor, reduce BRUKINSA dose to 80 mg once daily. For coadministration with a moderate CYP3A inhibitor, reduce BRUKINSA dose to 80 mg twice daily.

CYP3A Inducers: Avoid coadministration with strong or moderate CYP3A inducers. Dose adjustment may be recommended with moderate CYP3A inducers.

SPECIFIC POPULATIONS

Hepatic Impairment: The recommended dose of BRUKINSA for patients with severe hepatic impairment is 80 mg orally twice daily.

BTKi=Bruton's tyrosine kinase inhibitor; CLL=chronic lymphocytic leukemia; FL=follicular lymphoma; MCL=mantle cell lymphoma; MZL=marginal zone lymphoma; SLL=small lymphocytic lymphoma; WM=Waldenström's macroglobulinemia.

References: 1. BRUKINSA. Package insert. BeiGene USA, Inc.; 2025. **2.** CALQUENCE. Package insert. AstraZeneca Pharmaceuticals LP; 2025. **3.** IMBRUVICA. Package insert. Pharmacyclics LLC, Janssen Biotech, Inc; 2024. **4.** BeiGene. Bioequivalence of a zanubrutinib tablet compared to capsules in healthy adult participants. ClinicalTrials.gov website. NCT05767398. Last updated October 26, 2024. Accessed October 31, 2024. https://clinicaltrials.gov/study/NCT05767398 **5.** BeiGene. Relative bioavailability of zanubrutinib tablets compared to capsules and effects of food on the pharmacokinetics of the tablet in healthy adults. ClinicalTrials.gov website. NCT05547399. Last updated October 26, 2024. Accessed November 1, 2024. https://clinicaltrials.gov/study/NCT05547399

Please see Important Safety Information throughout and accompanying full Prescribing Information.

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