

# Drug Information Sheet("Kusuri-no-Shiori")

Internal

Revised: 03/2025

The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic response, patients should understand their medication and cooperate with the treatment.

## Brand name: Brukinsa Capsules 80mg

**Active ingredient:** Zanubrutinib

**Dosage form:** white to grayish-white opaque capsule, length: 22mm, diameter: 7.6 mm

**Imprint or print on wrapping:** (Face) ブルキンザカプセル 80mg, 80mg, ZANU80

(Back) ブルキンザカプセル 80mg, Brukinsa Capsules 80mg



## Effects of this medicine

This medicine suppresses malignant B cell proliferation and tumor growth by inhibiting the enzyme activity of Bruton's tyrosine kinase (BTK) related to B cell activation.

It is usually used to treat chronic lymphocytic leukemia (including small lymphocytic lymphoma), Waldenstrom's macroglobulinemia, and lymphoplasmacytic lymphoma.

## The following patients may need to be careful when using this medicine. Be sure to tell your doctor and pharmacist.

- If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines or foods.
- If you are prone to bleeding. If you plan to have surgery or have just had surgery. If you have an infectious disease.
- If you have had herpes zoster. If you have heart disease (such as arrhythmia) or its history. If you have interstitial lung disease. If you have hepatitis B virus infection or its history. If you have hypertension. If you have liver dysfunction.
- If you are pregnant or breastfeeding.
- If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)

## Dosing schedule (How to take this medicine)

- Your dosing schedule prescribed by your doctor is(( to be written by a healthcare professional))
- Chronic lymphocytic leukemia (including small lymphocytic lymphoma) : In general, for adults, take two capsules (160mg of the active ingredient) at a time, twice a day.
- Waldenstrom's macroglobulinemia and lymphoplasmacytic lymphoma : In general, for adults, take two capsules (160mg of the active ingredient) at a time, twice a day.
- In any case, the dosage may be decreased according to your condition. Strictly follow the instructions.
- If you miss a dose, take the missed dose as soon as possible when it is more than 8 hours until your next scheduled dose. However, skip the missed dose when it is within 8 hours of your next scheduled dose, and take the next dose at the scheduled time. You should never take two doses at one time. Continue your regular dosing schedule from the following day.
- If you accidentally take more than your prescribed dose, consult with your doctor or pharmacist.
- Do not stop taking this medicine unless your doctor instructs you to do so.

## Precautions while taking this medicine

- If you plan to have surgery, please consult your doctor or pharmacist because there is a risk of bleeding.
- Infections and herpes zoster may occur. If you notice any of these symptoms, please contact your doctor or pharmacist.
- Since bone marrow function may decrease, you may need to take blood tests regularly.
- Since arrhythmia may occur, you may need to have regular heart function tests, such as electrocardiography. If you notice any irregularities in your pulse, please contact your doctor or pharmacist.
- Since interstitial lung disease may occur, you may need to undergo chest imaging.
- Since hepatitis B may occur, you may need to undergo liver function tests or hepatitis screening.
- Women who may become pregnant and men whose partners may become pregnant should use appropriate contraception while taking this medicine and for one week after last dose.
- Be careful not to consume foods containing St. John's Wort because they may weaken the effects of the medication.
- The ingredients contained in grapefruit can increase the blood level of the medicine, and adverse reactions may appear more strongly, so please avoid taking grapefruit juice.

## Possible adverse reactions to this medicine

The most commonly reported adverse reactions include contusions, upper respiratory tract infections, hypertension,

diarrhea, constipation, rashes, petechiae, and fatigue. If any of these symptoms occur, consult with your doctor or pharmacist.

**The symptoms described below are rarely seen as initial symptoms of the adverse reactions indicated in brackets. If any of these symptoms occur, stop taking this medicine and see your doctor immediately.**

- prolonged bleeding, decreased consciousness, paralysis on one side [bleeding]
- sudden fever, malaise, cold-like symptoms [infections]
- fever, easily fatigued, bleeding tendency [myelosuppression]
- palpitations, cold sweats, skipping pulse [arrhythmia]
- tightness in the chest, palpitations, cold sweats [cardiac disorders]
- cough, difficulty breathing, fever [interstitial lung disease]

**The above symptoms do not describe all the adverse reactions to this medicine. Consult with your doctor or pharmacist if you notice any symptoms of concern other than those listed above.**

**Storage conditions and other information**

- Keep out of the reach of children. Store away from direct sunlight, heat and moisture.
- Discard the remainder. Do not store them. If you do not know how to discard, consult your pharmacy or medical institution about how to discard them. Do not give this medicine to anyone else.

**For healthcare professional use only**        /        /

For further information, talk to your doctor or pharmacist.