BRUKINSA®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I using BRUKINSA?

BRUKINSA contains the active ingredient zanubrutinib. BRUKINSA is used to treat:

- Waldenström's macroglobulinaemia (also known as lymphoplasmacytic lymphoma), a type of cancer causing white blood cells to make too much of a protein called IgM
- Mantle Cell Lymphoma, a type of cancer affecting the lymph nodes,
- Marginal Zone Lymphoma, a type of cancer affecting a category of white blood cells called B-lymphocytes which may cause enlargement of lymph nodes and spleen and may affect other organs.

For more information, see Section 1. Why am I using BRUKINSA? in the full CMI.

2. What should I know before I use BRUKINSA?

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use BRUKINSA? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with BRUKINSA and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use BRUKINSA?

- The recommended dose is 320 mg per day, either once daily (4 capsules) or twice daily (2 capsules in the morning and 2 capsules in the evening)

More instructions can be found in Section 4. How do I use BRUKINSA? in the full CMI.

5. What should I know while using BRUKINSA?

Things you should not do	• Do not stop taking this medicine unless your doctor tells you
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how BRUKINSA affects you • BRUKINSA may cause fatigue, dizziness or weakness in some people
Looking after your medicine	• Store it in a cool dry place away from moisture, heat or sunlight • Do not use this medicine after the expiry date

For more information, see Section 5. What should I know while using BRUKINSA? in the full CMI.

6. Are there any side effects?

Stop taking BRUKINSA and tell a doctor straight away if you notice any signs of an allergic reaction.

Other common side effects include fever, chills, body aches, feeling tired, cold or flu symptoms, being short of breath, frequent and painful urination, cough, bruising or increased tendency of bruising, contusions, bleeding, diarrhoea, skin rash, painful arms or legs (muscle pain), decrease of number of blood cells (white and red blood cells and platelets).

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ This medicine is subject to additional monitoring due to **provisional approval** of an extension of indication. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

BRUKINSA®

Active ingredient: *zanubrutinib*

This medicine has **provisional registration** in Australia for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy and for the treatment of adult patients with marginal zone lymphoma (MZL) who have received at least one prior therapy. The decision to provisionally register these two new uses of the medicine has been made on the basis of promising results from preliminary studies. More evidence is required to be submitted when available to substantiate the benefit of the medicine for this use.

Consumer Medicine Information (CMI)

This leaflet provides important information about using BRUKINSA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using BRUKINSA.**

Where to find information in this leaflet:

1. Why am I using BRUKINSA?
2. What should I know before I use BRUKINSA?
3. What if I am taking other medicines?
4. How do I use BRUKINSA?
5. What should I know while using BRUKINSA?
6. Are there any side effects?
7. Product details

1. Why am I using BRUKINSA?

BRUKINSA is an anticancer medicine that contains the active substance zanubrutinib. It belongs to a class of medicines called protein kinase inhibitors. BRUKINSA works by blocking Bruton's tyrosine kinase, a protein in the body that helps these cancer cells grow and survive. By blocking this protein, BRUKINSA helps kill and reduce the number of cancer cells. It also slows down the worsening of the cancer.

BRUKINSA is used to treat:

- **Waldenström's macroglobulinaemia (also known as lymphoplasmacytic lymphoma), a type of cancer causing white blood cells to make too much of a protein called IgM.** BRUKINSA is used when the disease has come back or has not responded to treatment or in patients for whom chemotherapy given together with an antibody is not recommended.

BRUKINSA also has provisional approval to treat:

- **Mantle Cell Lymphoma, a type of cancer affecting the lymph nodes.** BRUKINSA is used when the disease has come back or has not responded to treatment.
- **Marginal Zone Lymphoma, a type of cancer affecting a category of white blood cells called B-lymphocytes. This may cause enlargement of organs that are part of the body's natural defenses such as lymph nodes and spleen and may also affect various organs such as stomach, salivary glands, thyroid, bone marrow and blood.** BRUKINSA is used when the disease has come back or has not respond to treatment.

2. What should I know before I use BRUKINSA?

Check with your doctor if you:

- take any medicines for any other condition.
- if you have ever had unusual bruising or bleeding or are on any medicines or supplements that increase your risk of bleeding (see section "Other medicines and BRUKINSA"). If you have had recent surgery or plan to have surgery. your doctor may ask you to stop taking BRUKINSA for a short time (3 to 7 days) before and after your surgery or dental procedure.
- if you have an irregular heartbeat or have a history of irregular heartbeat or severe heart failure, or if you experience any of the following: shortness of breath, weakness, dizziness, light-headedness, fainting or near fainting, chest pain or swollen legs.
- if you have a history of or have been advised that you are at risk of infections.
- if you have ever had or might now have a Hepatitis B or Herpes Zoster infection. This is because BRUKINSA could cause Hepatitis B or Herpes Zoster to become active again. Patients will be carefully checked by their doctor for signs of this infection before treatment is started.
- if you have liver or kidney problems.
- if you have recently had any surgery, especially if this might affect how you absorb food or medicines from your stomach or gut.
- if you have high blood pressure.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Do not get pregnant while you are taking this medicine. BRUKINSA should not be used during pregnancy. BRUKINSA can harm your unborn baby.

Women of childbearing age must use a highly effective method of birth control during and at least one week after receiving BRUKINSA, to avoid becoming pregnant while being treated with BRUKINSA. If using hormonal

contraceptives such as birth control pills or devices, a barrier method of contraception (e.g. condoms) must also be used.

Males should avoid getting female partners pregnant during treatment and for at least 1 week after the last dose of BRUKINSA. You should use effective birth control (contraception) during treatment and for at least 1 week after the last dose of BRUKINSA.

Tell your doctor immediately if you become pregnant.

Do not breast-feed while you are taking this medicine and for at least 2 weeks after your last dose of BRUKINSA.

Tests and check-ups before and during treatment

- Lymphocytosis: Laboratory tests may show an increase in white blood cells (called “lymphocytes”) in your blood in the first few weeks of treatment. This is expected and may last for a few months. This does not necessarily mean that your blood cancer is getting worse. Your doctor will check your blood counts before or during the treatment and in rare cases they may need to give you another medicine. Talk to your doctor about what your test results mean.
- Decrease in blood cell counts: Decreased blood counts (white blood cells, platelets, and red blood cells) are common with BRUKINSA, but can also be severe. Your doctor should do blood tests during treatment with BRUKINSA to check your blood counts.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

BRUKINSA may make you bleed more easily. This means you should tell your doctor if you take other medicines that increase your risk of bleeding. This includes:

- aspirin and non-steroidal anti-inflammatories (NSAIDs) such as ibuprofen or naproxen,
- blood thinners such as warfarin, heparin or other medicines for blood clots,
- supplements that may increase your risk of bleeding such as fish oil, vitamin E or flaxseed.

BRUKINSA might interact with other medicines. This may result in greater or lesser effects or even side effects from these medicines. The following may interact with BRUKINSA:

- Antibiotics used to treat bacterial infections (clarithromycin, erythromycin, rifampin).
- Medicines for fungal infections (fluconazole, ketoconazole, itraconazole, posaconazole, voriconazole).
- Medicines for HIV infection (indinavir, ritonavir).
- Medicines to treat low blood sodium levels (conivaptan).
- Medicines to treat hepatitis C (telaprevir).
- Medicines used to prevent seizures or to treat epilepsy or medicines used to treat a painful condition of the face called trigeminal neuralgia (carbamazepine, phenytoin).
- Medicines used to treat heart conditions or high blood pressure (diltiazem, verapamil).

Do not take BRUKINSA with grapefruit or Seville oranges - this includes eating them, drinking the juice, or taking supplements that might contain them. This is because they can increase the amount of BRUKINSA in your blood.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect BRUKINSA.

4. How do I use BRUKINSA?

How much to take

- The recommended dose is 320 mg per day, either once daily (4 capsules) or twice daily (2 capsules in the morning and 2 capsules in the evening).
- Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

When to take BRUKINSA

- Take BRUKINSA about the same time each day.

How to take BRUKINSA

- Take the capsules orally (by mouth) with a glass of water.
- Swallow the capsules whole. Do not open, break or chew them.

If you forget to use BRUKINSA

BRUKINSA should be used regularly at the same time each day. If you miss your dose at the usual time, it can be taken as soon as possible on the same day with a return to the normal schedule the following day.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

- If you are not sure, talk to your doctor, pharmacist or nurse about when to take your next dose.

If you use too much BRUKINSA

If you think that you have used too much BRUKINSA, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre **(by calling 13 11 26)**, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using BRUKINSA?

Things you should not do

- Do not stop taking this medicine unless your doctor tells you.

Call your doctor straight away if you:

- do not feel well while you are taking BRUKINSA even if you do not think it is connected with the medicine.
- become pregnant while you are taking this medicine.
- develop signs of unusual bleeding, bruising more easily than normal, fatigue/tiredness, shortness of breath, fever.
- Remind any doctor, dentist or pharmacist you visit that you are using BRUKINSA.

Things you should not do:

- Do not give this medicine to anyone else, even if their condition seems similar to yours.
- Do not use it to treat any other complaints unless your
- doctor tells you to.
- Avoid eating grapefruit,grapefruit juice or Seville orange while taking BRUKINSA as it may interfere with how the medicine works.
- Do not stop taking your medicine or change the dose without checking with your doctor

Driving or using machines

Be careful before you drive or use any machines or tools until you know how BRUKINSA affects you.

BRUKINSA may cause fatigue, dizziness or weakness in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep your medicine in the original container until it is time to take it.
- Store it in a cool dry place away from moisture, heat or sunlight.
- Do not store in the bathroom or near a sink.
- Do not leave in the car or on windowsills.

Follow the instructions in the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Blood related: • Bruising or increased tendency of bruising, bleeding/mass of clotted blood (haematoma) • Contusions **Breathing related:** • Cough **Gastrointestinal related:** • Diarrhoea **Skin related:** • Skin rash	**Speak to your doctor if you have any of these less serious side effects and they worry you.**
Muscle related: • Painful arms or legs (muscle pain) **Heart related:** • Heart rhythm problems (atrial fibrillation and atrial flutter) **General:** • Feeling tired	

Serious side effects

Serious side effects	What to do
Allergic reaction: • Itchy, bumpy rash • Difficulty breathing • Swelling of the face, lips, tongue or throat **Signs of infection of the nose, sinus or throat, lung or bladder:** • Fever • Chills • Body aches • Feeling tired • Cold or flu symptoms • Being short of breath • Frequent and painful urination **Blood related:** • Bleeding problems, 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, increased bruising, dizziness, weakness, confusion, changes in speech, headache that lasts a long time	**Stop taking BRUKINSA and call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Other side effects not listed here may occur in some people and may only be found when your doctor does tests from time to time to check your progress. These include:

- low level of red blood cells (anaemia).
- low level of white blood cells (neutropenia).
- low level of platelet (thrombocytopenia)

New cancers have been observed in people during treatment with BRUKINSA, including cancers of the skin or other organs. Skin cancers were observed predominantly in patients at high risk of developing skin cancer (such as fair complexion, advanced age, high or prolonged UV exposure or with a past medical history of skin cancer). Your doctor will check you for other cancers during treatment with BRUKINSA. Use sun protection when you are outside in sunlight. Have regular skin checks.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What BRUKINSA contains

Active ingredient **(main ingredient)**	zanubrutinib
Other ingredients **(inactive ingredients)**	capsule content: microcrystalline cellulose croscarmellose sodium sodium lauryl sulphate colloidal anhydrous silica magnesium stearate capsule shell: gelatin titanium dioxide printable ink: shellac glaze iron oxide black polypropylene glycol
Potential allergens	None

What BRUKINSA looks like

BRUKINSA is a white to off-white hard capsule marked with “ZANU 80” in black ink on one side. The capsules are provided in a plastic bottle with a child resistant polypropylene closure. Each bottle contains 120 capsules. (Aust R 338475).

Who distributes BRUKINSA

BeiGene AUS Pty Ltd
1C/528 Compton Road
Stretton
Queensland 4116
Australia

www.beigene.com.au

Medical Information Line : 1800 512 109

This leaflet was prepared in November 2022.

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