READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

Pr BRUKINSA®
zanubrutinib capsules

Read this carefully before you start taking **BRUKINSA** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **BRUKINSA**.

Serious Warnings and Precautions

- Take BRUKINSA only under the care of a doctor who is experienced in the use of anti-cancer drugs.
- **Haemorrhage (serious or fatal bleeding problems)** may occur when you take BRUKINSA. This can be bleeding a lot, or bleeding that is difficult to stop. Your risk of bleeding is increased when taking BRUKINSA with blood thinner medications or other medications that prevent blood clots.

What is BRUKINSA used for?

BRUKINSA is used in adults to treat cancers such as:

- Waldenström's Macroglobulinemia (WM**).**
- Mantle Cell lymphoma (MCL). BRUKINSA is only used in patients who already have received at least one treatment for MCL.
- Marginal Zone Lymphoma (MZL). BRUKINSA is used in patients who have received at least one previous antibody (anti-CD20) therapy against their cancer.
- Chronic Lymphocytic Leukemia (CLL).
- Returning or unmanageable Follicular Lymphoma (FL). BRUKINSA is used with obinutuzumab in patients who received at least two previous treatments for FL.

How does BRUKINSA work?

BRUKINSA blocks a specific protein in the body that helps cancer cells live and grow. This protein is called "Bruton's Tyrosine Kinase." By blocking this protein, BRUKINSA may help kill and reduce the number of cancer cells and slow the spread of the cancer.

What are the ingredients in BRUKINSA?

Medicinal ingredients: zanubrutinib
Non-medicinal ingredients: ammonium hydroxide (trace), colloidal silicon dioxide, croscarmellose sodium, dehydrated ethanol (trace), gelatin, iron oxide black (trace), isopropyl alcohol (trace), magnesium stearate, microcrystalline cellulose, n-butyl alcohol (trace), propylene glycol (trace), purified water (trace), shellac glaze in ethanol (trace), sodium lauryl sulphate, titanium dioxide.

BRUKINSA comes in the following dosage forms:

Capsules: 80 mg

Do not use BRUKINSA if:

- You are allergic to zanubrutinib or any other ingredients in BRUKINSA. If you are not sure about this, talk to your doctor before taking BRUKINSA.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take BRUKINSA. Talk about any health conditions or problems you may have, including if you:

- have had recent surgery or plan to have surgery. Your healthcare provider may stop treatment with BRUKINSA for 3 to 7 days before or after a surgery. This includes any planned medical, surgical, or dental procedure.
- have or had heart rhythm problems. Your risk for heart rhythm problems is increased if you have or had heart problems, high blood pressure or acute infections. Speak to your doctor immediately if you have ever experienced any of the following: fast and/or irregular heartbeat, dizziness, chest pain, shortness of breath, or if you faint. Your doctor may monitor the condition of your heart during your treatment with BRUKINSA.
- have or had liver problems.
- have severe kidney disease or are on dialysis.

Other warnings you should know about:

Treatment with BRUKINSA can increase your risk of certain side effects, including:

- **Interstitial lung disease:** Lung diseases that inflame or scar lung tissue.
- **New Cancers**: New cancers have developed during treatment with BRUKINSA. This includes cancers of the skin or other organs. Use sun protection when you are outside in sunlight.
- **Infections**: Serious and fatal infections have been reported in patients who are treated with BRUKINSA. Taking BRUKINSA may increase your risk of developing the following infections
    - Pneumonia. Pneumonia is an infection deep in the lungs.
    - Hepatitis B infection. Hepatitis B infection is a viral infection in the liver.
    - Shingles. Shingles is due to a virus that causes a painful skin rash.
- **Tumour Lysis Syndrome:** This condition is caused by the sudden, rapid death of cancer cells due to treatment**.**

Pregnancy, breastfeeding and fertility

Female patients

If you are pregnant, able to get pregnant or think you are pregnant, there are specific risks you should discuss with your doctor.

- Avoid becoming pregnant while you are taking BRUKINSA. It may harm or cause death of your unborn baby.
- If you are able to become pregnant, your doctor will do a pregnancy test before you start treatment with BRUKINSA.
- Effective birth control methods should be used during treatment with BRUKINSA. Talk to your doctor about birth control methods that may be right for you. You should use appropriate birth control methods for at least one week after your final dose of BRUKINSA.
- If you are breastfeeding or plan to breastfeed. It is not known if BRUKINSA passes into your breast milk. Do not breastfeed during treatment with BRUKINSA and for 2 weeks after your final dose of BRUKINSA. Talk to your doctor about the best way to feed your baby during this time.

Male Patients

- Use highly effective birth control while you are on BRUKINSA and for at least 3 months after your last dose if your partner can get pregnant.

Children and adolescents
BRUKINSA is not for use in patients under 18 years of age.

Driving and Using Machines: Before you do tasks that may require special attention, wait until you know how you respond to BRUKINSA. If you have blurred vision, feel tired or dizzy, do not drive or use tools or machines.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with BRUKINSA:
- Antibiotics used to treat bacterial infections (clarithromycin, erythromycin, rifampin).
- Medicines for fungal infections (e.g., 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).
- St. John's Wort.
- Grapefruit, grapefruit juice and Seville oranges.

* May not be available in Canada

How to take BRUKINSA:
- Take it exactly as your healthcare provider tells you. Do not decrease, stop or change your dose on your own.
- Take at about the same time each day.
- Take with or without food.
- Swallow whole with a glass of water. Do NOT chew, dissolve or open the capsule.

Usual Adult Dose:
Take 320 mg daily. Take two 80 mg capsules twice a day (twelve hours apart) OR four 80 mg capsules once a day.

Treatment of FL: Refer to the obinutuzumab product monograph for the recommended dosing and product information.

Do not take BRUKINSA with the following:
- grapefruit, grapefruit juice and Seville oranges
- St. John's wort

Your doctor may change your usual dose depending on whether you experience side effects while taking BRUKINSA.

Overdose:

If you think you, or a person you are caring for, have taken too much BRUKINSA, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed Dose:

If you miss a dose, take it as soon as possible on the same day. Take your next dose of BRUKINSA at the normal schedule the following day. Do not take an extra dose to make up for a missed dose.

Treatment of FL: Refer to the obinutuzumab product monograph for the missed dose recommendation and product information.

What are possible side effects from using BRUKINSA?

These are not all the possible side effects that you may feel when taking BRUKINSA. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- allergic inflammation of the nasal passages
- cataracts in the eyes, blurred vision, dry eye
- dizziness
- ear pain, ringing, buzzing or clicking in the ears (tinnitus)
- enlarged prostate
- fall, cuts/ lacerations, arm or leg injury, pain from procedures, sciatic nerve pain, insect bite headache, pain, tingling, or numbness in the arms/legs, fainting, reduced sense of touch
- fever, chest pain or discomfort, chills
- increase in blood sugar
- low blood pressure
- muscle spasms, joint pain and/or swelling, muscle pain/aches, pain in the arms and legs or neck, back pain, arthritis, muscle weakness
- nausea
- protein in the urine, frequent, abnormal urination during the day (pollakiuria), frequent sudden kidney injury or failure, retained urine
- tiny red or purple spots on the skin, itching, rash, raised rash, dry skin, excessive sweating, hair loss, night sweats, thick scaly patches on skin, skin lesion
- toothache, mouth sore, bleeding gums, dry mouth
- trouble sleeping, anxiety, depression
- vomiting, constipation, stomach (abdominal) pain or bloating (abdominal distension), indigestion (dyspepsia), acid reflux disease, stomach inflammation (gastritis), stomach gas (flatulence), hemorrhoids, inguinal hernia

BRUKINSA can cause abnormal blood test results. Your doctor may do blood tests before you start BRUKINSA and while you take it. Your doctor will decide when to perform blood tests and will interpret the results.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	

VERY COMMON			
High blood pressure shortness of breath, fatigue, dizziness or fainting, chest pain or pressure, swelling in your ankles and legs, bluish colour to your lips and skin, racing pulse or heart palpitations.		√	
Infections (from bacteria, a virus or fungus): Cough, infection in your blood (sepsis), nose (sinus infection), sore throat, fatigue, fever, chills and flu-like symptoms.		√	
Anaemia (low red blood cells): Being short of breath. Feeling very tired. Having pale skin. Fast heartbeat. Loss of energy, or weakness.		√	
Neutropenia (low white blood cells, neutrophils): Fever, or infection. Fatigue. Aches and pains. Flu-like symptoms.		√	
Thrombocytopenia (low blood platelets): Bruising or bleeding for longer than usual if you hurt yourself. Fatigue and weakness.		√	
Diarrhoea: Increased number of bowel movements. Watery stool. Stomach pain and/or cramps.	√		
Urinary tract infection: Pain or burning when urinating, bloody or cloudy urine, foul smelling urine.		√	
Pneumonia, Bronchitis (infection in the lungs): Cough with or without mucus. Fever, chills.		√	
Haemorrhage (serious bleeding problems): Bleeding a lot or uncontrollably. Blood in your stool or urine. Long-lasting headache. Feeling dizzy or confused. Nose bleeds. Coughing up blood. Increased bruising.		√	
New cancers of skin and other types of cancer.		√	
COMMON			
Being short of breath		√	
Haematuria		√	

(blood in the urine): pink, red or very dark urine.			
Arrhythmia (heart rhythm problems): Racing, slow, or uncomfortable or irregular heartbeat. Flip-flop feeling, or pain in your chest. Feeling dizzy or confused. Chest flutter.		√	
Pleural effusion (fluid around the lungs): chest pain, difficult or painful breathing, cough.		√	
UNCOMMON			
Tumour lysis syndrome (sudden, rapid death of cancer cells due to the treatment): nausea, vomiting, decreased urination, irregular heartbeat, confusion, delirium, seizures.		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (MedEffect Canada - Canada.ca) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:
Store at room temperature between 15 to 30°C in original bottle.
Keep out of reach and sight of children.

If you want more information about BRUKINSA:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (Drug Product Database: Access the database - Canada.ca); the manufacturer's website beigene.com or by calling 1-877-828-5598.

This leaflet was prepared by BeiGene Switzerland GmbH.
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