PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

BRUKINSA®, 80 mg, capsule

Zanubrutinib

Sugar free

Read all of this leaflet carefully before you start taking BRUKINSA

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

BRUKINSA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What BRUKINSA is and what it is used for

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.

BRUKINSA is used to treat cancers such as:

- Waldenström’s Macroglobulinaemia (WM**),** a rare type of cancer that begins in the white blood cells.
- Mantle Cell Lymphoma (MCL), a rare blood cancer that starts in white blood cells in your lymph nodes. BRUKINSA is only used in patients who already have received at least one treatment for MCL.
- Marginal Zone Lymphoma (MZL), a cancer of the lymphatic system. BRUKINSA is used in patients who have received at least one previous antibody (anti-CD20) therapy against their cancer.
- Chronic Lymphocytic Leukemia (CLL)/small lymphocytic lymphoma (SLL), a slow-growing types of blood cancer that affect lymphocytes.

2. What you need to know before you take BRUKINSA

Do not take BRUKINSA:

if you are hypersensitive (allergic) to zanubrutinib or any of the other ingredients of BRUKINSA (listed in section 6).

Warnings and precautions

Take special care with BRUKINSA:

- If you are taking BRUKINSA with blood thinner medications or other medications that prevent blood clots. 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;

- 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;
- If you 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;
- If you have or had liver problems;
- If you 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 happened in people 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: Infrequently reported during treatment with BRUKINSA.

Children/ and adolescents

Do not give BRUKINSA to children under the age of 18 years.

Other medicines and BRUKINSA

Always tell your health care provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

- 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).
- St. John's Wort.

BRUKINSA with food and drink

BRUKINSA must not be taken with grapefruit juice, grapefruit and /or Seville oranges.

Pregnancy and breastfeeding and fertility

Female patients

You should not take BRUKINSA if you are pregnant or breastfeeding your baby.

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 planning 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.

Driving and using machinery

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.

BRUKINSA is sugar free.

3. How to take BRUKINSA

Do not share medicines prescribed for you with any other person.

Always take BRUKINSA exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is 320 mg daily.

- Take two 80 mg capsules twice a day (twelve hours apart) OR four 80 mg capsules once a day.
- 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.

For oral use.

Do not take BRUKINSA with the following:

- grapefruit, grapefruit juice and Seville oranges
- St. John's wort

Your doctor will tell you how long your treatment with BRUKINSA will last.

Do not stop treatment early because it may affect the outcome of your treatment.

If you have the impression that the effect of BRUKINSA is too strong or too weak, tell your doctor or pharmacist.

If you take more BRUKINSA than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take / missed a dose of BRUKINSA

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

BRUKINSA can have side effects.

Not all side effects reported for BRUKINSA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BRUKINSA, please consult your health care provider for advice.

If any of the following happens, stop taking BRUKINSA and tell your doctor immediately or go to the casualty department at your nearest hospital:

Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;

rash or itching;

fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to BRUKINSA. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- 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.
- Arrhythmia (heart rhythm problems): Racing or uncomfortable or irregular heartbeat. Flip-flop feeling, or pain in your chest. Feeling dizzy or confused.
- 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.
- 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.
- 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.
- New cancers of skin and other types of cancer.
- Being short of breath
- Haematuria (blood in the urine): pink, red or very dark urine.
- Pleural effusion (fluid around the lungs): chest pain, difficult or painful breathing, cough.

These are all serious side effects. You may need urgent medical attention.

The following side effects have been reported:

- abdominal pain, joint pain, muscle pain/aches, pain in the arms and legs, back pain,
- acid reflux disease,
- blurred vision,
- chest pain,
- constipation,
- decrease in weight and appetite,
- depression,
- dizziness,

- dry mouth,
- excessive sweating,
- fainting,
- fever,
- headache,
- mouth sores,
- muscle spasms,
- nausea or vomiting,
- numbness, tingling, muscle weakness and pain,
- rash or redness of the skin,
- ringing, buzzing, clicking or hissing in the ears,
- swelling of the joints, legs or hands,
- tiny red or purple spots on the skin, bruising, itching,
- tiredness,
- waking up at night to urinate.

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.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse.

You can also report side effects to SAHPRA on the SAHPRA website at: https://medsafety.sahpra.org.za/#download, via email at: adr@sahpra.org.za or via telephone at: 0125010311.

By reporting side effects, you can help provide more information on the safety of BRUKINSA.

5. How to store BRUKINSA

Store all medicines out of reach of children.

Store at or below 30 °C.

Store in the original container.

Keep the container in the outer carton.

Do not store in a bathroom.

Do not use after the expiry date stated on the label / carton / bottle.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What BRUKINSA contains:

The active substance is zanubrutinib.

The other ingredients are 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.

What BRUKINSA looks like and contents of the pack:

Size 0, white to off-white, opaque hard capsule imprinted with black “ZANU 80” printing on cap, which contains white to off-white powder. 120 capsules are packed in a 200 mL white

HDPE round bottle with a child-resistant screw cap with a printed heat sealable foil laminate liner.

Holder of Certificate of Registration and Manufacturer

BeiGene South Africa (Pty) Ltd.

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South Africa

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Access to the corresponding Professional Information

Can be obtained on the SAHPRA website, www.sahpra.org.za