

BRUKINSA® (BROO-kin-sah)
(zanubrutinib)
capsules

BRUKINSA® (BROO-kin-sah)
(zanubrutinib)
tablets

What is BRUKINSA?

BRUKINSA is a prescription medicine used to treat adults with:

- Mantle cell lymphoma (MCL) who have received at least one prior treatment for their cancer.
- Waldenström's macroglobulinemia (WM).
- Marginal zone lymphoma (MZL) when the disease has come back or did not respond to treatment and who have received at least one certain type of treatment.
- Chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).
- Follicular lymphoma (FL), in combination with the medicine obinutuzumab, when the disease has come back or did not respond to treatment and who have received at least two prior treatments.

It is not known if BRUKINSA is safe and effective in children.

Before taking BRUKINSA, tell your healthcare provider about all of your medical conditions, including if you:

- have bleeding problems.
- have had recent surgery or plan to have surgery. Your healthcare provider may stop BRUKINSA for any planned medical, surgical, or dental procedure.
- have an infection or have been advised that you are at increased risk of infection.
- have or had heart rhythm problems.
- have high blood pressure.
- have liver problems, including a history of hepatitis B virus (HBV) infection.
- are pregnant or plan to become pregnant. BRUKINSA can harm your unborn baby.

Females who are able to become pregnant:

- You should avoid getting pregnant during treatment and for 1 week after the last dose of BRUKINSA.
- Your healthcare provider may do a pregnancy test before starting treatment with BRUKINSA.
- You should use effective birth control (contraception) during treatment and for 1 week after the last dose of BRUKINSA.
- Tell your healthcare provider right away if you become pregnant or think you are pregnant during treatment with BRUKINSA.

Males with female partners who are able to become pregnant:

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

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you take a blood thinner medicine. Taking BRUKINSA with certain other medications may affect how BRUKINSA works and can cause side effects.

How should I take BRUKINSA?

- Take BRUKINSA exactly as your healthcare provider tells you to take it.
- Do not change your dose or stop taking BRUKINSA unless your healthcare provider tells you to.
- Your healthcare provider may tell you to decrease your dose, temporarily stop, or completely stop taking BRUKINSA if you develop certain side effects.
- Take BRUKINSA with or without food.
- Swallow BRUKINSA capsules whole with a glass of water. Do not open, break, or chew the capsules.
- Swallow BRUKINSA tablets whole with a glass of water. Do not chew or crush the tablets.
 - BRUKINSA tablets can be split in half as prescribed by your healthcare provider.
- If you miss a dose of BRUKINSA, take it as soon as you remember on the same day. Return to your normal schedule the next day.

What are the possible side effects of BRUKINSA?

BRUKINSA may cause serious side effects, including:

- **Bleeding problems (hemorrhage).** Bleeding problems are common with BRUKINSA, and can be serious and may lead to death. Your risk of bleeding may increase if you are also taking a blood thinner medicine. Tell your healthcare provider if you develop any signs or symptoms of bleeding, 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
 - change in speech
 - headache that lasts a long time
- **Infections** that can be serious and may lead to death. Tell your healthcare provider right away if you develop fever, chills, or flu-like symptoms during your treatment with BRUKINSA.
- **Decrease in blood cell counts** (white blood cells, platelets, and red blood cells). Your healthcare provider should do blood tests during treatment with BRUKINSA to check your blood counts.
- **Second primary cancers.** New cancers have happened in people during treatment with BRUKINSA, including cancers of the skin or other organs. Your healthcare provider will check you for other cancers during treatment with BRUKINSA. Use sun protection when you are outside in sunlight.
- **Heart rhythm problems.** Serious heart problems, including atrial fibrillation, atrial flutter, and ventricular arrhythmias, have happened in people treated with BRUKINSA and may lead to death. Your risk for heart rhythm problems may be increased if you have high blood pressure or have had heart rhythm problems in the past or have a short-term (acute) infection. Tell your healthcare provider if you develop any of the following signs or symptoms:
 - your heartbeat is fast or irregular
 - feel lightheaded or dizzy
 - pass out (faint)
 - shortness of breath
 - chest discomfort
- **Liver problems.** Liver problems, which may be severe or life-threatening, or lead to death, can happen in people treated with BRUKINSA. Your healthcare provider will do blood tests to check your liver before and during treatment with BRUKINSA. Tell your healthcare provider or get medical help right away if you develop any signs of liver problems, including stomach pain or discomfort, dark-colored urine, or yellow skin and eyes.

The most common side effects of BRUKINSA include:

- decreased white blood cell count
- decreased platelet count
- cold-like symptoms (upper respiratory tract infection)
- muscle, bone, or joint pain

These are not all the possible side effects of BRUKINSA.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store BRUKINSA?

- Store BRUKINSA at room temperature between 68°F and 77°F (20°C and 25°C).
- BRUKINSA comes in a bottle with a child-resistant cap.

Keep BRUKINSA and all medicines out of the reach of children.

General information about the safe and effective use of BRUKINSA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use BRUKINSA for a condition for which it was not prescribed. Do not give BRUKINSA to other people, even if they have the same symptoms that you have. It may harm them. You can ask your healthcare provider or pharmacist for more information about BRUKINSA that is written for healthcare professionals.

What are the ingredients in BRUKINSA?

Active ingredient: zanubrutinib

Capsule inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, and sodium lauryl sulfate. The capsule shell contains edible black ink, gelatin, and titanium dioxide.

Tablet inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, and sodium lauryl sulfate. The film-coating contains FD&C Blue No. 1, FD&C Blue No. 2, hypromellose, titanium dioxide, and triacetin.

BRUKINSA Capsules:

Manufactured for: BeOne Medicines USA, Inc., Pennington, NJ 08534

BRUKINSA Tablets:

Manufactured for: BeOne Medicines USA, Inc., Pennington, NJ 08534

Manufactured by: Catalent Pharma Solutions, LLC, Winchester, KY 40391

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For more information, go to www.BRUKINSA.com or call 1-833-969-2463.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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