

Ibrutinib Oral Targeted Therapy

Names The generic drug name is ibrutinib (*eye-BROO-ti-nib*). Imbruvica® is the brand name. There may be other names for this medication.

Why am I Taking Ibrutinib? Ibrutinib is used for chronic lymphocytic leukemia (CLL) and mantle cell lymphoma (MCL). Ibrutinib may also be used for other conditions if your physician feels it may be beneficial.

How is Ibrutinib Given?

- Ibrutinib comes as capsule(s) that you take by mouth, usually once a day. Your doctor will determine your exact dosage and schedule. Do not stop taking ibrutinib without notifying the doctor.
- Swallow the capsule whole with a glass of water— do not chew, crush, or break the tablets.. You can take it with or without food. Take it about the same time each day.
- Take ibrutinib every day, as prescribed. Consider using a pill box/ reminder system to help you remember to take it.
- Avoid grapefruit and grapefruit juice or extract - they may increase the blood levels and side effects of idelalisib.
- If you miss a dose, take the next scheduled dose at its regular time. Do not take 2 doses at once in order to catch up for the missed dose.
- Store this at room temperature and away from excess heat and moisture (not in the bathroom).

How Does it Work? Cancer is a group of diseases in which abnormal cells divide (reproduce) without control. Traditional chemotherapy drugs attack cells that divide quickly - both cancer cells and normal cells. Ibrutinib is not a traditional chemotherapy drug; it is a type of targeted therapy called a tyrosine kinase inhibitor (TKI).

Targeted therapies identify other differences between normal cells and cancer cells, and then use that difference to attack the cancer cells, sparing more normal cells. Ibrutinib works by blocking the action of an abnormal protein that signals cancer cells to divide.

What Should I Tell My Doctor Before I Begin?

Tell your doctor if you:

- have ever had an allergic reaction to ibrutinib
- are taking warfarin (Coumadin®), aspirin or products containing aspirin,
- over-the-counter pain medicines (especially ibuprofen), vitamins, or herbal supplements or products - especially St. John's wort
- have ever had heart, lung, thyroid, or liver disease; high blood pressure; a heart attack; or an irregular heartbeat
- smoke, use street drugs, drink alcohol, or have a history of heavy alcohol use
- are pregnant or breastfeeding

This drug may interact with other medications or cause harmful side effects. Tell your doctor and pharmacist about all prescription or over-the-counter medications, vitamins, or supplements that you are taking.

What Are Some Possible Side Effects?

- Low blood counts: Decreased levels of red blood cells, white blood cells, and platelets, which increases your risk of anemia/fatigue, infections, and bleeding problems. You may need blood transfusions while on ibrutinib. If the condition is severe, we may need to lower your dose.
- Diarrhea
- Nausea, vomiting, decreased appetite
- Generalized weakness, headache, dizziness
- Muscle or joint pain
- Mild swelling in the arms and legs (edema)
- Skin rash
- Changes in heart rhythm have been reported, and may be more common if you have a history of heart problems. Tell your doctor if you notice an irregular heartbeat or have breathing problems
- Unusual or serious bleeding (rare)

How Can I Manage These Side Effects?

- **Drink 2-3 quarts of water every day unless your doctor tells you to limit your fluids.** This is even more important in the days before and after you have chemotherapy. This will help flush the medications out and help prevent dehydration and constipation. Try to drink a variety of fluids to help provide the calories, sodium (salt), and other electrolytes your body needs. Broths are a good source of sodium, and some sports drinks provide additional electrolytes (check the labels).
- **Low red blood cell count/fatigue:** If you feel fatigued, take rest periods throughout the day, and try to limit your activities. Eat well and stay out

of bed as much as possible during your treatment to stay strong.

- **Low white blood cell count/risk of infection:** Stay away from people with colds or other infections. Wash your hands often with soap and water. Talk to your doctor before you have any vaccinations, such as flu shot.
- **Low platelet count/risk of bleeding:** Be careful when handling sharp objects. Avoid rough sports or other situations that could cause bruising or injury. Use an electric razor to minimize your risk of bleeding.
- **Diarrhea:** Loperamide (Imodium®) is available over the counter. You can take 2 tablets after the first episode of diarrhea, followed by 1 tablet (2mg) after each loose stool as needed. Do not take more than 8 tablets (16mg) in a 24-hour period. Call the clinic if this does not provide relief within 24 hours.
- **Nausea:** To help prevent nausea, avoid fried, spicy, and fatty foods on the days you receive chemo and for 2-3 days afterwards. Eating small, frequent meals may help. If nauseous, try foods and drinks that are 'easy on the stomach' - bland foods, ginger ale, dry crackers, and toast.
- **Skin care:** Use a sunblock with SPF 30 or higher that protects against both UVA and UVB rays when you are outdoors, even if it is just for a short time. Keep your neck, chest, and back covered. Wear sunglasses and protective clothes (brimmed hat, long sleeves, etc.) when in the sun. Do not use tanning beds. If you develop a rash, keep the area clean and dry. Check with your doctor before using creams on the area.
- Acetaminophen and other over the counter pain relievers may help with discomfort from fever, headache, and aches and pains **but talk to your doctor before taking any of these medications. Do not use any products containing ibuprofen (Advil®, Motrin®) while on ibrutinib.**
- Drinking alcoholic beverages should be kept to a minimum or avoided completely. Discuss this with your doctor.
- Keep all lab appointments so we can monitor your blood counts and how well your liver and kidneys are working.

When Should I
Call the Doctor?

Call 911 or go to the nearest hospital emergency department if you have any life-threatening symptoms such as signs of severe allergic reaction: Swelling or tingling in your face, tongue, mouth, or throat; chest tightness; wheezing; trouble breathing or swallowing; dizziness, shortness of breath

Please let us know if you go to the emergency room or are admitted to the hospital.

Call the clinic immediately if you have:

- signs of an infection: Fever of 100.4°F (38°C) or higher, chills, or any other signs of infection such as a sore throat, painful urination, or a skin wound that is red, swollen, painful, and/or warm to the touch
- unusual bruising or bleeding: bleeding lasts more than 10-15 minutes or that causes dizziness; black or bloody stools; vomit that is bloody or that looks like coffee grounds; blood in your urine or phlegm /mucus, unusually heavy menstrual bleeding, spontaneous bleeding from your gums or nose, or superficial bleeding into the skin that appears as a rash of pinpoint-sized reddish-purple spots (petechiae)
- new or worsening shortness of breath, chest pain, irregular heartbeat, fainting

Call your doctor within 24 hours if you have:

- nausea that interferes with eating and is not relieved with medication
- four (4) or more episodes of diarrhea or vomiting within 24 hours
- dark black or tarry stools or blood in stool or urine
- extreme fatigue that makes it difficult to care for yourself

**What Else Do I
Need to Know
About Ibrutinib?**

- Both men and women should use birth control during treatment and for 30 days afterwards. Barrier methods such as condoms are recommended. This drug may be harmful to a fetus.
- Tell your doctor if you are pregnant or may become pregnant.
- Breast feeding while on ibrutinib is discouraged. Talk to your doctor for more details.
- If you have any questions about ibrutinib, please talk to your doctor or pharmacist.