

# Ibrutinib and Rituximab

**Care Team Contact Information:** \_\_\_\_\_

**Pharmacy Contact Information:** \_\_\_\_\_

**Diagnosis:** \_\_\_\_\_

- This treatment is often used for chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL), and Waldenström macroglobulinemia (WM). It may also be used for other reasons.

**Goal of Treatment:** \_\_\_\_\_

- Treatment may continue for a certain time period, until it no longer works, or until side effects are no longer controlled.

## Treatment Regimen

Treatment Name	How the Treatment Works	How the Treatment is Given
Ibrutinib (i-BROO-tih-nib): Imbruvica (im-BROO-vih-kuh)	Slows down or stops the growth of cancer cells by blocking a specific protein that helps them survive.	Capsule(s) taken by mouth. Tablet(s) taken by mouth. Oral suspension taken by mouth.
Rituximab (rih-TUK-sih-mab): Rituxan (rih-TUK-sun), Riabni, Ruxience, Truxima	Helps your immune system find and attack cancer cells by targeting a specific protein on their surface.	Infusion into a vein (intravenous (IV) infusion).

**Note:** Your care team may use rituximab and hyaluronidase (Rituxan Hycela) instead of rituximab. Rituximab and hyaluronidase is given as an injection under the skin (subcutaneous injection) into the stomach area (abdomen) over 5 to 7 minutes.

**Treatment Administration and Schedule:** Treatment is typically repeated every 4 weeks. This length of time is called a “cycle”.

### Cycle 1

- Ibrutinib is taken 1 time a day.

### Cycle 2

- Rituximab is given weekly.
- Ibrutinib is taken 1 time a day

Treatment Name	Cycle 1, Day																												Next Cycle
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	1
<b>Treatment Given at the Hospital or Clinic</b>																													
Rituximab	✓						✓							✓							✓								✓
<b>Treatment Taken at Home</b>																													
Ibrutinib	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

### Cycles 3 through 6

- Rituximab is given on Day 1.
- Ibrutinib is taken 1 time a day.

Treatment Name	Cycle 1, Day																												Next Cycle
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	1
<b>Treatment Given at the Hospital or Clinic</b>																													
Rituximab	✓																												✓
<b>Treatment Taken at Home</b>																													
Ibrutinib	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

### Cycle 7 and Beyond

- Ibrutinib is taken 1 time a day

Your ibrutinib dosing instructions:

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- Take or give ibrutinib 1 time a day at about the same time each day.
- Ibrutinib comes as capsules, tablets, and oral suspension.
- If your care team prescribes ibrutinib **capsules or tablets**:
  - Swallow ibrutinib capsules or tablets whole with a glass of water.
  - Do not open, break, or chew the capsules.
  - Do not cut, crush, or chew the tablets.
- If your care team prescribes ibrutinib **oral suspension**:
  - See the detailed Instructions for Use that comes with ibrutinib oral suspension for information about the correct way to take or give a dose. If you have questions about how to take or give ibrutinib oral suspension, talk to your care team.
  - Do not use if the carton seal is broken or missing.
- If you miss a dose of ibrutinib, take or give it as soon as you remember on the same day. Take or give the next dose of ibrutinib at the regular time on the next day. Do not take or give extra doses of ibrutinib to make up for a missed dose.
- If you take too much ibrutinib, call your care team or go to the nearest hospital emergency room right away.

## Storage and Handling of Ibrutinib

- Store ibrutinib capsules and tablets at room temperature between 68°F and 77°F (20°C and 25°C).
- Keep ibrutinib capsules in the original container with the lid tightly closed.
- Keep ibrutinib tablets in the original carton.
- Store ibrutinib oral suspension bottle between 36°F and 77°F (2°C and 25°C). Do not freeze.
- Use ibrutinib oral suspension within 60 days after first opening the bottle. Throw away (dispose of) any unused portion 60 days after opening.
- Ibrutinib capsules and oral suspension come in a bottle with a child-resistant cap.
- Keep ibrutinib and all medicines out of the reach of children and pets.
- Ask your care team how to safely throw away any unused ibrutinib.

**Appointments:** Appointments may include regular check-ups with your care team, treatment appointments, lab visits, and imaging tests. It's important to keep your appointments whenever you can. If you miss any appointments, call your care provider as soon as possible to reschedule your appointment.

## Supportive Care to Prevent and Treat Side Effects

Description	Supportive Care Given at the Clinic or Hospital	Supportive Care Taken at Home
To help prevent infusion-related reactions	<hr/> <hr/> <hr/>	<hr/> <hr/> <hr/>
To help prevent or treat nausea and vomiting	<hr/> <hr/> <hr/>	<hr/> <hr/> <hr/>
To help lower the risk of infections	<hr/> <hr/> <hr/>	<hr/> <hr/> <hr/>
To lower the risk of Tumor Lysis Syndrome (TLS)	<hr/> <hr/> <hr/>	<hr/> <hr/> <hr/>
Other	<hr/> <hr/> <hr/>	<hr/> <hr/> <hr/>

Common Side Effects

Side Effect	Important Information
<b>Infusion Reactions (Boxed Warning)</b>	<p>Description: Infusion reactions are common with rituximab and can sometimes be severe or life-threatening.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>• Your care team may prescribe medicines before each infusion of rituximab to help decrease your risk for infusion reactions or to help make any infusion reaction less severe.</li> <li>• You may be monitored for infusion reactions during each infusion of rituximab.</li> <li>• Your care team may slow down or stop your infusion or completely stop treatment with rituximab if you have an infusion reaction.</li> </ul> <p>Get medical help right away if you develop any of the following symptoms of infusion reaction during or after an infusion of rituximab:</p> <ul style="list-style-type: none"> <li>• Chills or shaking</li> <li>• Itching, rash, or flushing</li> <li>• Trouble breathing or wheezing; tongue swelling</li> <li>• Dizziness or feeling faint</li> <li>• Fever of 100.4°F (or 38°C) or higher</li> <li>• Pain in your back or neck</li> </ul>
Low White Blood Cell (WBC) Count (Neutropenia) and Increased Infection Risk	<p>Description: WBCs help protect the body against infections. If you have a low WBC count, you might have a higher risk of infection.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>• Wash your hands and bathe regularly.</li> <li>• Avoid crowded places.</li> <li>• Stay away from people who are sick.</li> <li>• Your care team may prescribe a drug that promotes the growth of WBCs.</li> </ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>• Fever of 100.4°F (38°C) or higher</li> <li>• Chills</li> <li>• Cough</li> <li>• Shortness of breath</li> <li>• Sore throat</li> </ul>
Low Platelet Count (Thrombocytopenia)	<p>Description: Platelets help the blood clot and heal wounds. If you have low platelet counts, you might have a higher risk of bruising and bleeding.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>• Blow your nose gently and avoid picking it.</li> <li>• Brush your teeth gently with a soft toothbrush and maintain good oral hygiene.</li> <li>• Use an electric razor for shaving and a nail file instead of nail clippers.</li> <li>• Consult your care team or dentist before medical or dental procedures, as you may need to pause your medication.</li> </ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>• Nosebleed lasting over 5 minutes despite pressure</li> <li>• Cut that continues to bleed</li> <li>• Significant gum bleeding when flossing or brushing</li> <li>• Severe headaches</li> <li>• Blood in your urine or stool</li> <li>• Blood in your spit after a cough</li> </ul>

<p>Low Red Blood Cell (RBC) Count and Hemoglobin (Hgb) (Anemia)</p>	<p>Description: RBCs and Hgb help bring oxygen to your body's tissues and take away carbon dioxide. If you have low RBC counts or Hgb, you might feel weak, tired, or look pale.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>• Get 7 to 8 hours of sleep each night.</li> <li>• Avoid operating heavy machinery when tired.</li> <li>• Balance work and rest, staying active but resting when needed.</li> </ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>• Shortness of breath</li> <li>• Dizziness</li> <li>• Fast or abnormal heartbeats</li> <li>• Severe headache</li> </ul>
<p>Fatigue</p>	<p>Description: Fatigue is a constant and sometimes strong feeling of tiredness.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>• Routine exercise has been shown to decrease levels of fatigue. Work with your care team to find the right type of exercise for you.</li> <li>• Ask your family and friends for help with daily tasks and emotional support.</li> <li>• Try healthy ways to feel better, like meditation, writing in a journal, doing yoga, and using guided imagery to lower anxiety and feel good.</li> <li>• Make a regular sleep schedule and limit naps during the day so you can sleep better at night, aiming for 7 to 8 hours of sleep.</li> <li>• Don't use heavy machines or do things that need your full attention if you're very tired to avoid accidents.</li> </ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>• Tiredness that affects your daily life</li> <li>• Tiredness all the time, and it doesn't get better with rest</li> <li>• Dizziness and weakness, along with being tired</li> </ul>
<p>High Blood Pressure (Hypertension)</p>	<p>Description: Treatment can cause high blood pressure. It usually has no symptoms and can be dangerous if not treated. High blood pressure increases the risk of stroke, heart attack, and other health problems.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>• Exercise regularly, control your weight, and limit alcohol and sodium intake.</li> <li>• If you are already being treated for high blood pressure, your care team may change your blood pressure medicine.</li> <li>• Your care team may ask you to track your blood pressure.</li> </ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>• Headaches</li> <li>• Dizziness or lightheadedness</li> <li>• Blurred vision</li> <li>• Trouble breathing</li> <li>• Nose bleeds</li> <li>• A pounding sensation in the chest, neck, or ears</li> <li>• Irregular heartbeats</li> <li>• Chest pain or pressure</li> </ul>

<p>Nausea and Vomiting</p>	<p>Description: Nausea is an uncomfortable feeling in your stomach or the need to throw up. This may or may not cause vomiting.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>• Eat smaller, more frequent meals.</li> <li>• Avoid fatty, fried, spicy, or highly sweet foods.</li> <li>• Eat bland foods at room temperature and drink clear liquids.</li> <li>• If you vomit, start with small amounts of water, broth, or other clear liquids when you are ready to eat again. If that stays down, then try soft foods (such as gelatin, plain cornstarch pudding, yogurt, strained soup, or strained cooked cereal). Slowly work up to eating solid food.</li> <li>• Your care team may prescribe medicine for these symptoms.</li> </ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>• Vomiting for more than 24 hours</li> <li>• Vomiting that's nonstop</li> <li>• Signs of dehydration (like feeling very thirsty, having a dry mouth, feeling dizzy, or having dark urine)</li> <li>• Blood or coffee-ground-like appearance in your vomit</li> <li>• Bad stomach pain that doesn't go away after vomiting</li> </ul>
<p>Diarrhea</p>	<p>Description: Diarrhea is when you have loose, watery bowel movements more often than usual. The need to use the bathroom may occur urgently.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>• Keep track of how many times you go to the bathroom each day.</li> <li>• Drink 8 to 10 glasses of water or other fluids every day, unless your care team tells you otherwise.</li> <li>• Eat small meals of mild, low-fiber foods like bananas, applesauce, potatoes, chicken, rice, and toast.</li> <li>• Avoid eating foods with high fiber (like raw vegetables, fruits, and whole grains), foods that cause gas (like broccoli and beans), dairy foods (like yogurt and milk), and spicy, fried, and greasy foods.</li> <li>• Your care team may recommend medicine (such as loperamide) for diarrhea.</li> </ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>• 4 or more bowel movements than normal in 24 hours</li> <li>• Dizziness or lightheadedness while having diarrhea</li> <li>• Bloody diarrhea</li> </ul>
<p>Liver Problems</p>	<p>Description: Treatment can harm your liver. This may cause nausea, stomach pain, and bleeding or bruising. It can also turn your skin and eyes yellow and make your urine dark. Lab tests may be performed to monitor liver function.</p> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>• Yellowing of your skin or the whites of your eyes</li> <li>• Severe nausea or vomiting</li> <li>• Pain on the right side of your stomach area (abdomen)</li> <li>• Dark urine (tea colored)</li> <li>• Bleeding or bruising more easily than normal</li> </ul>

<p>Rash or Itchy Skin</p>	<p>Description: Rash or itchy skin can cause symptoms like redness, swelling, and varying bumps, such as small red spots, welts, or patches.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>• Keep your skin moisturized with creams or lotions to reduce rash and itchiness; wear loose-fitting clothing.</li> <li>• Avoid perfumes and colognes, as they may worsen rash symptoms.</li> <li>• Limit time spent in heat to prevent worsening symptoms.</li> <li>• Avoid sun exposure, especially between 10 AM and 4 PM, to lower the risk of sunburn.</li> <li>• Wear long-sleeved clothing with UV protection and broad-brimmed hats.</li> <li>• Apply broad-spectrum sunscreen (UVA/UVB) with at least SPF 30 as directed.</li> <li>• Use lip balm that contains at least SPF 30.</li> <li>• Avoid tanning beds.</li> <li>• Your care team may recommend medicines for symptoms.</li> </ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>• Rash or itching that continues to worsen</li> </ul>
<p>Muscle, Bone, and Joint Pain</p>	<p>Description: Muscle pain feels like soreness, aches, cramps, or stiffness in one or more muscles. It may also include tenderness or weakness. Joint pain happens where two bones come together and can feel sharp, dull, throbbing, or burning. It often causes stiffness, swelling, and difficulty moving.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>• Track your pain levels, areas of discomfort, and any activities that worsen or improve your symptoms.</li> <li>• Engage in gentle exercises like walking, stretching, or yoga to maintain mobility and strength, but consult your care team before starting any new exercise routine.</li> <li>• Apply a warm compress to relax stiff muscles or use cold packs to reduce swelling and numb pain in affected areas.</li> <li>• Your care team may prescribe or recommend medications, including over-the-counter pain relievers.</li> </ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>• Uncontrolled muscle or joint pain</li> <li>• Swelling, redness, or warmth in the joints</li> <li>• Weakness</li> <li>• Difficulty walking or moving</li> </ul>

<p>Headache</p>	<p>Description: A headache can cause you to feel pain or discomfort in your head, making it hard to concentrate or feel your best.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>• Keep a headache diary to track the frequency, duration, intensity, and triggers of your headaches.</li> <li>• Stay hydrated by drinking plenty of water, as dehydration can contribute to headaches.</li> <li>• Apply a cold or warm compress to your forehead or neck to help ease headache pain.</li> <li>• Get adequate sleep (7-8 hours per night) and establish a regular sleep schedule.</li> <li>• Limit caffeine intake.</li> <li>• Your care team may recommend medicine for headaches.</li> </ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>• Severe headache</li> <li>• More frequent headaches</li> <li>• Dizziness or light-headedness</li> <li>• Confusion</li> <li>• Vision changes</li> </ul>
<p>Cough</p>	<p>Description: A cough is a reflex action that forcefully expels air from the lungs to clear the airways of irritants or mucus.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> <li>• Tell your care team what your cough feels like and when it happens.</li> <li>• Use a humidifier and drink plenty of water.</li> <li>• Keep your house clean by dusting and vacuuming regularly</li> <li>• Avoid exposure to smoke or strong chemicals.</li> <li>• Your care team may recommend medicine for cough.</li> </ul> <p>Talk to your care team if you have:</p> <ul style="list-style-type: none"> <li>• Trouble breathing</li> <li>• Chest pain or tightness</li> <li>• Blood in your sputum</li> </ul>

Select Rare Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms
<b>Severe Skin and Mouth Reactions (Boxed Warning)</b>	<ul style="list-style-type: none"> <li>• Painful sores or ulcers on your skin, lips, or in your mouth</li> <li>• Blisters</li> <li>• Peeling skin</li> <li>• Rash</li> <li>• Pustules</li> </ul>
<b>Hepatitis B Virus (HBV) Reactivation (Boxed Warning)</b>	<p>Before you start treatment, your care team will do blood tests to check for HBV infection. If you have had hepatitis B or are a carrier of hepatitis B virus, receiving rituximab could cause the virus to become an active infection again. Hepatitis B reactivation may cause serious liver problems, including liver failure and death. You should not receive rituximab if you have active hepatitis B liver disease. Your care team will monitor you for hepatitis B infection during and for several months after you stop receiving rituximab.</p> <ul style="list-style-type: none"> <li>• Worsening tiredness</li> <li>• Yellowing of your skin or white part of your eyes</li> </ul>
<b>Progressive Multifocal Leukoencephalopathy (PML) (Boxed Warning)</b>	<p>PML is a rare, serious brain infection caused by a virus that can happen in people who receive rituximab. People with weakened immune systems can get PML. PML can result in death or severe disability. There is no known treatment, prevention, or cure for PML.</p> <ul style="list-style-type: none"> <li>• Confusion</li> <li>• Dizziness or loss of balance</li> <li>• Difficulty walking or talking</li> <li>• Decreased strength or weakness on one side of your body</li> <li>• Vision problems</li> </ul>
<b>Heart Problems</b>	<p>Serious heart rhythm problems (ventricular arrhythmias, atrial fibrillation, and atrial flutter), heart failure and death have happened in people treated with ibrutinib, especially in people who have an infection, an increased risk for heart disease, or have had heart rhythm problems in the past. Your heart function will be checked before and during treatment with ibrutinib.</p> <ul style="list-style-type: none"> <li>• Feeling as if your heart is beating fast and irregular</li> <li>• Lightheadedness</li> <li>• Dizziness</li> <li>• Shortness of breath</li> <li>• Swelling of the feet, ankles, or legs</li> <li>• Chest discomfort</li> <li>• Feeling faint</li> </ul>
<b>Kidney Problems</b>	<ul style="list-style-type: none"> <li>• Decrease in your amount of urine</li> <li>• Blood in your urine</li> <li>• Swelling of your ankles</li> <li>• Loss of appetite</li> </ul>
<b>Tumor Lysis Syndrome (TLS)</b>	<p>Tumor lysis happens when cancer cells break apart and flood your bloodstream with chemicals and toxins faster than your body can get rid of them. TLS is a group of conditions that affect your heart, kidneys, and muscles.</p> <ul style="list-style-type: none"> <li>• Severe nausea, vomiting, or diarrhea</li> <li>• Urinating smaller amounts or dark-colored urine</li> <li>• Muscle cramps or twitching</li> <li>• Rapid heartbeats or chest pain</li> <li>• Confusion or weakness</li> <li>• Seizures</li> </ul>

Stomach and Serious Bowel Problems	<ul style="list-style-type: none"> <li>• Severe stomach-area (abdomen) pain</li> <li>• Repeated vomiting during treatment</li> </ul>
Risk of New Cancers	There is a risk of developing new cancers during or after treatment. Talk with your care team about this risk, and ask about the signs and symptoms of new cancers.

**Before starting treatment, ask your care team when to call 9-1-1 or seek emergency help. If you experience any new, worsening, or uncontrolled side effects, contact your care team immediately.**

### Intimacy, Pregnancy, and Breastfeeding

- Treatment may **change how you feel about intimacy and your body**. However, physical closeness—such as holding hands and hugging—remains safe. It is common to have questions about intimacy. If needed, talk to your care team for guidance.
- Treatment may **harm an unborn baby**.
  - If you are able to become pregnant, take a pregnancy test before starting treatment.
  - Use an effective method of birth control during treatment, for 1 month after your last dose of ibrutinib, and for 12 months after your last dose of rituximab.
  - If you think you might be pregnant or if you become pregnant, tell your care team right away.
  - If your partner(s) could become pregnant, use an effective method of birth control—such as condoms—during treatment with ibrutinib and rituximab and for 1 month after your last dose of ibrutinib.
- **Do NOT breastfeed** during treatment, for 1 week after your last dose of ibrutinib, and for 6 months after your last dose of rituximab.

### Additional Information

- **Tell your care team about all the medicines you take.**  
This includes prescriptions, over-the-counter drugs, vitamins, and herbal products. Before starting any new medicine, supplement, or vaccine, ask your care team first.
- **You should not drink grapefruit juice, eat grapefruit, or eat Seville oranges** (often used in marmalades) during treatment with ibrutinib. These products may increase the amount of ibrutinib in your blood.
- **Higher risk of bleeding after surgery.** Tell your care team if you plan to have any surgery before starting or during treatment. Your care team may ask you to stop taking ibrutinib for 3 to 7 days before and after your surgery, depending on the type of surgery and your risk of bleeding.
- **This Patient Education Sheet may not describe all possible side effects.**  
Call your healthcare provider for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

## Notes

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Scan the QR code below to access this education sheet.



Important notice: The Association of Cancer Care Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), Network for Collaborative Oncology Development & Advancement, Inc. (NCODA), and Oncology Nursing Society (ONS) have collaborated in gathering information for and developing this patient education guide. This guide represents a brief summary of the medication derived from information provided by the drug manufacturer and other resources.

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