

Epcoritamab and R² (Lenalidomide and Rituximab)

Care Team Contact Information: _____

Pharmacy Contact Information: _____

Diagnosis: _____

- This treatment is used for follicular lymphoma (FL).
- 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

- Part of your treatment is called “R-squared” or “R².” R² stands for lenalidomide (**R**evlimid) and rituximab.

Treatment Name	How the Treatment Works	How the Treatment is Given
Epcoritamab (EP-koh-RIH-tah-mab): Epkiny (ep-KIN-lee)	Binds immune cells (T-cells) to cancer cells so T-cells can more effectively attack and destroy them.	Injection under the skin (subcutaneous injection) into the stomach area (abdomen) or thigh.
Lenalidomide (leh-nuh-LIH-doh-mide): Revlimid (REV-lih-mid)	Boosts the immune system, cuts off the cancer's blood supply, and directly attacks the cancer cells.	Capsule 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 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.”

Due to the risk of cytokine release syndrome (CRS), you will receive epcoritamab on a **“step-up dosing schedule.”**

- The step-up dosing schedule is when you receive 2 or 3 smaller “step-up” doses of epcoritamab during your first cycle of treatment (Cycle 1).
- You will receive your first full dose of epcoritamab a week after your last step-up dose (this will be Day 22 of Cycle 1).
- If your dose of epcoritamab is delayed for any reason, you may need to repeat the “step-up dosing schedule.”

Treatment Administration and Schedule (Continued)

Cycle 1

- Epcoritamab is given on Days 1, 8, 15, and 22.
 - You may be hospitalized after receiving your first full dose of epcoritamab on Day 22 of Cycle 1 due to the risk of CRS and neurologic problems.
- Rituximab is given on Days 1, 8, 15, and 22.
- Lenalidomide is taken 1 time a day for 21 days, followed by 7 days off.

Treatment Name	Cycle 1, Days																						
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23–28
Treatment Given at the Clinic or Hospital																							
Epcoritamab	✓							✓							✓							✓	
Rituximab	✓							✓							✓							✓	
Treatment Taken at Home																							
Lenalidomide	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	1 Week Break

Cycles 2 and 3

- Epcoritamab is given on Days 1, 8, 15, and 22.
- Rituximab is given on Day 1.
- Lenalidomide is taken 1 time a day for 21 days, followed by 7 days off.

Treatment Name	Cycle 2, Days																							Next Cycle
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23–28	1
Treatment Given at the Clinic or Hospital																								
Epcoritamab	✓							✓							✓							✓		✓
Rituximab	✓																							✓
Treatment Taken at Home																								
Lenalidomide	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	1 Week Break	✓

Cycles 4 and 5

- Epcoritamab is given on Day 1.
- Rituximab is given on Day 1.
- Lenalidomide is taken 1 time a day for 21 days, followed by 7 days off.

Treatment Name	Cycle 4, Days																						Next Cycle
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22–28	1
Treatment Given at the Clinic or Hospital																							
Epcoritamab	✓																						✓
Rituximab	✓																						✓
Treatment Taken at Home																							
Lenalidomide	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	1 Week Break	✓

Cycles 6 to 12

- Epcoritamab is given on Day 1.
- Lenalidomide is taken 1 time a day for 21 days, followed by 7 days off.
- Note: Rituximab is only given during Cycles 1 to 5.

Treatment Name	Cycle 6, Days																						Next Cycle
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22–28	1
Treatment Given at the Clinic or Hospital																							
Epcoritamab	✓																						✓
Treatment Taken at Home																							
Lenalidomide	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	1 Week Break	✓

Lenalidomide Instructions

Your lenalidomide dosing instructions:

- Lenalidomide comes in 6 capsule strengths: 2.5 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 25 mg.
- Your dose may differ, but lenalidomide is typically taken as 20 mg once daily for 21 days (3 weeks), followed by 7 days (1 week) off.
- Take lenalidomide 1 time a day, at about the same time each day.
- Swallow lenalidomide capsules whole with water. Do not open, break, or chew your capsules.
- Lenalidomide may be taken with or without food.
- If you miss a dose of lenalidomide and it has been less than 12 hours since your usual time, take it as soon as you remember. If it has been more than 12 hours, skip the missed dose. Do not take 2 doses at the same time.
- If you take too much lenalidomide, call your care team right away.

Storage and Handling of Lenalidomide

- Store lenalidomide at room temperature between 68°F to 77°F in a dry location away from light.
- Keep lenalidomide out of the reach of children and pets.
- Whenever possible, give lenalidomide to yourself and follow the steps below. If someone else gives it to you, they must also follow these steps:
 1. Wash hands with soap and water.
 2. Put on gloves to avoid touching the medication. Note: Gloves are not needed if you give the drug to yourself.
 3. Transfer the lenalidomide from its package to a small medicine or other disposable cup.
 4. Administer the medicine immediately by mouth with water.
 5. Remove gloves, if used, and throw them and medicine cup in household trash.
 6. Wash hands with soap and water.
- Do not open or break lenalidomide capsules or handle them any more than needed.
 - If powder from the lenalidomide capsule comes in contact with your skin, wash the skin right away with soap and water.
 - If powder from the lenalidomide capsule comes in contact with the inside of your eyes, nose, or mouth, flush well with water.
- If you plan to use a daily pill box or pill reminder, contact your care team before using it.
 - When the box or reminder is empty, wash it with soap and water before refilling.
 - The person refilling the box or reminder should:
 - Wear gloves. Note: Gloves are not needed if you are refilling it yourself.
 - Wash their hands with soap and water after completing the task, regardless of whether gloves were worn.
- Ask your care team how to safely throw away any unused lenalidomide. Do not throw it in the trash or flush it down the sink or toilet.

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 an appointment, call your care team as soon as possible to reschedule it.

Supportive Care to Prevent and Treat Side Effects

Description	Supportive Care Given at the Clinic or Hospital	Supportive Care Taken at Home
To help lower the risk of Cytokine Release Syndrome (CRS)		
To help lower the risk of infusion-related reactions		
To help lower the risk of blood clots		
To help lower the risk of infections		
Other		

Common Side Effects

Side Effect	Important Information
Cytokine Release Syndrome (CRS) (Boxed Warning)	Description: CRS happens when your immune system becomes very active after treatment. Most CRS events are mild, get better with treatment, and happen during the first few doses. However, some CRS events can be serious and life-threatening. Symptoms can include fever, chills, fatigue, headache, dizziness or feeling lightheaded, or difficulty breathing. Recommendations: - Keep a symptom diary to record any new or worsening symptoms such as fever, chills, fatigue, or difficulty breathing. - Your care team may ask you to monitor your temperature, blood pressure, heart rate, or oxygen level. - Stay hydrated by drinking plenty of fluids to help manage symptoms and support overall health. - If you develop CRS, do not drive or operate dangerous machinery until your care team says it is safe. - Your care team may prescribe medications for CRS. Talk to your care team if you have: - Fever of 100.4°F (38°C) or higher - Trouble breathing - Chills - Dizziness or light-headedness - Fast heartbeat - Headache Note: Your care team may have specific numbers for blood pressure, heart rate, and blood oxygen levels. If your numbers go beyond those limits, call your care team or get emergency help.
Infusion-Related Reactions (Boxed Warning)	Description: Infusion reactions are common with rituximab and can sometimes be severe or life-threatening. Recommendations: - Your care team will prescribe medicines before each infusion to help decrease your risk for infusion reactions or to help make any infusion reaction less severe. - You will be monitored for infusion reactions during each infusion. - Your care team may slow down or stop your infusion, or completely stop treatment if you have an infusion reaction. Get medical help right away if you develop any of the following during or after your infusion: - Chills or shaking - Itching, rash, or flushing - Trouble breathing, wheezing, or tongue swelling - Dizziness or feeling faint - Feeling of impending doom - Fever of 100.4°F (38°C) or higher - New or severe pain in your back or neck

Low White Blood Cell (WBC) Count (Neutropenia) and Increased Risk of Infection (Boxed Warning)	Description: WBCs help protect your body from infections. A low WBC count increases your risk of infection. Recommendations: • Wash your hands often and bathe regularly. • Avoid crowded places and close contact with people who are sick. • Follow food safety and wound care advice from your care team. • Your care team may prescribe medicine to help your WBCs recover. Talk to your care team if you have: • Fever of 100.4°F (38°C) or higher • Chills • New or worsening cough or sore throat • Painful urination or signs of a urinary infection • Feeling much more tired than usual • Red, swollen, warm, or painful areas on the skin (possible skin infection)
Low Platelet Count (Thrombocytopenia) (Boxed Warning)	Description: Platelets help your blood clot and wounds heal. A low platelet count increases your risk of bruising and bleeding. Recommendations: • Blow your nose gently and avoid picking it. • Brush your teeth gently with a soft toothbrush and keep good oral hygiene. • Use an electric razor for shaving and a nail file instead of nail clippers. • Avoid over-the-counter medicines that can increase bleeding risk (for example, nonsteroidal anti-inflammatory drugs (NSAIDs) like ibuprofen). • Talk with your care team or dentist before medical or dental procedures — you may need to pause treatment. Talk to your care team if you have: • A nosebleed lasting more than 5 minutes despite pressure • A cut that continues to bleed • Heavy gum bleeding when brushing or flossing • Sudden or severe headache • Blood in your urine or stool • Blood in your spit after coughing
Low Red Blood Cell (RBC) Count and Hemoglobin (Hgb) (Anemia)	Description: RBCs and Hgb carry oxygen to your body's tissues and remove carbon dioxide. Low RBC or Hgb (anemia) can make you feel weak or very tired, or may make you look pale. Recommendations: • Aim for 7 to 8 hours of sleep each night. • Do not drive, operate heavy machinery, or do other dangerous activities if you are very tired. • Balance activity and rest — stay as active as you can, but rest when needed. • Eat a balanced diet and follow any nutrition or supplement advice from your care team. Talk to your care team if you have: • Shortness of breath • Dizziness or fainting • Fast or irregular heartbeats • Sudden or severe headache

Fatigue	Description: Fatigue is a constant and sometimes strong feeling of tiredness. Recommendations: • Routine exercise can help reduce fatigue. Talk with your care team to find the right type and amount of activity for you. • Ask family and friends for help with daily tasks and for emotional support. • Try healthy ways to feel better, such as meditation, journaling, yoga, or guided imagery, to reduce anxiety and improve well-being. • Aim for 7 to 8 hours of sleep each night. Limit daytime naps to help you sleep better at night. • Do not drive, operate heavy machinery, or do other potentially dangerous activities if you are very tired. Talk to your care team if you have: • Tiredness that affects your daily life or prevents you from doing normal activities • Tiredness that does not get better with rest • Dizziness or weakness along with severe tiredness
Diarrhea	Description: Diarrhea is loose, watery stools or more frequent bowel movements than usual. It can cause dehydration and weakness. Recommendations: • Keep track of how often you go to the bathroom each day. • Drink 8 to 10 glasses of water or other fluids daily, unless your care team tells you otherwise. • Eat small meals of mild, low-fiber foods (such as bananas, applesauce, potatoes, chicken, rice, and toast). • If you have diarrhea, avoid high-fiber foods (such as raw vegetables, fruits, and whole grains), gas-producing foods (such as broccoli and beans), dairy (such as milk and yogurt), and spicy, fried, or greasy foods. • Your care team may recommend an antidiarrheal medicine such as loperamide (Imodium). Talk to your care team if you have: • 4 or more bowel movements above your usual number in 24 hours • Dizziness or lightheadedness while having diarrhea • Signs of dehydration (very thirsty, dry mouth, dizziness, or dark urine) • Bloody diarrhea

Constipation	Description: Constipation means hard, dry stools or fewer bowel movements than normal. It can cause discomfort or pain. Recommendations: • Track how often you have bowel movements each day. • Drink 8 to 10 glasses of fluids daily, unless your care team says otherwise. • Stay active and exercise regularly. • Eat more high-fiber foods (such as raw fruits, vegetables, and whole grains) unless advised otherwise. • Your care team may recommend laxatives such as polyethylene glycol (MiraLAX) or senna. Talk to your care team if you have: • Constipation lasting 3 or more days • No bowel movement 48 hours after using a laxative
Rash or Itchy Skin	Description: Rash or itchy skin can cause redness, swelling, and a variety of bumps or patches (small red spots, welts, blisters, or scaly dry areas). Recommendations: • Keep your skin moisturized with creams or lotions to reduce rash and itchiness. • Wear loose-fitting clothing. • Avoid perfumes and colognes, as they may worsen rash symptoms. • Limit time spent in the heat to prevent worsening symptoms. • Avoid sun exposure, especially between 10 AM and 4 PM, to lower the risk of sunburn. • Wear long-sleeved clothing with ultraviolet (UV) protection and broad-brimmed hats. • Apply broad-spectrum sunscreen (UVA/UVB) with sun protective factor (SPF) 30 or higher as directed. • Use lip balm with SPF 30 or higher. • Avoid tanning beds. • Your care team may recommend medicines for symptoms. Talk to your care team if you have: • Rash or itching that continues to worsen

Muscle or Joint Pain or Weakness	Description: Muscle pain is soreness, aching, cramps, stiffness, tenderness, or weakness in one or more muscles. Joint pain is pain, stiffness, swelling, or reduced movement where two bones meet. Recommendations: • Keep a pain diary: note pain levels, locations, and activities that make it better or worse. • Do gentle exercise (walking, stretching, yoga) to maintain mobility and strength. Check with your care team before starting a new activity. • Use a warm compress for stiff muscles or a cold pack to reduce swelling and numb pain—use what helps the area. • Your care team may recommend or prescribe medicines, including over-the-counter pain relievers. Talk to your care team if you have: • Pain you cannot control with usual measures • Swelling, redness, or warmth in a joint • New weakness • Trouble walking or moving
Injection-Site Reactions	Description: An injection-site reaction is a local skin reaction where the medicine is given under the skin (subcutaneous injection). It can cause pain, redness, swelling, itching, or a lump at the injection site. Recommendations: • Tell your nurse or care team right away if you feel burning, stinging, or pain during the injection. • After the injection, you may use a cool compress on the area for 10–15 minutes to ease pain or swelling. • Keep the area clean and dry. Gently wash with mild soap and water if needed. • Avoid scratching, rubbing, or massaging the site. • Wear loose, soft clothing over the area to reduce rubbing. Talk to your care team if you have: • Increasing redness, warmth, swelling, or pain at the injection site • A lump that gets bigger or does not improve • Drainage of pus or fluid, or a bad smell from the area • Red streaks on the skin near the injection site • Fever or chills along with injection-site redness or pain

Select Rare Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms		
Neurologic Problems (Boxed Warning)	Treatment can cause serious neurologic (brain and nerve) problems that can be life-threatening and may lead to death. These problems can include a condition called Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS). Neurologic problems may occur days or weeks after treatment. Your care team may refer you to a specialist who treats neurologic problems. If you develop neurologic side effects, do not drive or operate dangerous machinery until your care team says it is safe. - Headache - Agitation, trouble staying awake, confusion or disorientation, seeing or hearing things that are not real (hallucinations) - Trouble speaking, thinking, remembering things, paying attention, or understanding things - Problems walking, muscle weakness, shaking (tremors), loss of balance, or muscle spasms - Numbness and tingling (feeling like “pins and needles”) - Burning, throbbing, or stabbing pain - Changes in your handwriting		
Blood Clots (Boxed Warning)	Signs or symptoms of a blood clot in the lung, arm, or leg may include: - Shortness of breath - Chest pain - Arm or leg swelling	Signs or symptoms of a heart attack may include: - Chest pain that may spread to the arms, neck, jaw, back, or stomach area (abdomen) - Feeling sweaty - Shortness of breath - Feeling sick or vomiting	Signs or symptoms of stroke may include: - Sudden numbness or weakness, especially on one side of the body - Severe headache or confusion - Problems with vision, speech, or balance
Severe Skin and Mouth Reactions (Boxed Warning)	- Painful sores or ulcers on your skin, lips, or in your mouth - Blisters - Peeling skin - Rash - Pustules		
Hepatitis B Virus (HBV) Reactivation (Boxed Warning)	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. If you have an active hepatitis B infection, your care team may delay treatment until it can be safely managed. - Worsening tiredness - Yellowing of your skin or white part of your eyes		

Progressive Multifocal Leukoencephalopathy (PML) (Boxed Warning)	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. • Confusion • Dizziness or loss of balance • Difficulty walking or talking • Decreased strength or weakness on one side of your body • Vision problems, such as blurred vision or loss of vision
Tumor Lysis Syndrome (TLS)	Tumor lysis happens when cancer cells break apart and release large amounts of substances into your bloodstream faster than your body can handle. TLS is a group of conditions that affect your heart, kidneys, and muscles. • Severe nausea, vomiting, or diarrhea • Urinating smaller amounts or having dark-colored urine • Muscle cramps or twitching • Rapid heartbeats or chest pain • Confusion or weakness • Seizures
Risk of New Cancers	There is a risk of developing one or more new cancers during or after treatment. Talk with your care team about this risk, and ask about the signs and symptoms to watch for.

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 cause **birth defects or death of an unborn baby**. If you are pregnant or plan to become pregnant, you must not take lenalidomide.

You must not get pregnant:

- For at least 4 weeks before starting lenalidomide.
- During treatment with epcoritamab and R².
- For at least 4 weeks after stopping lenalidomide.
- For 4 months after your last dose of epcoritamab.
- For at least 12 months after your last dose of rituximab.

If you can become pregnant:

- You will have pregnancy tests weekly for 4 weeks, then every 4 weeks if your menstrual cycle is regular, or every 2 weeks if your menstrual cycle is irregular.
- If you miss your period or have unusual bleeding, you will need to have a pregnancy test and receive counseling.
- You must agree to use 2 acceptable forms of birth control at the same time, for at least 4 weeks before, while taking, during any breaks (interruptions) in your treatment, and for at least 4 weeks after stopping lenalidomide.
- Talk with your healthcare provider to find out about options for acceptable forms of birth control that you may use to prevent pregnancy before, during, and after treatment with lenalidomide.
- If you had unprotected sex or if you think your birth control has failed, stop taking lenalidomide immediately and call your healthcare provider right away.

If you become pregnant while taking lenalidomide, stop taking it right away and call your healthcare provider. If your healthcare provider is not available, you can call the REMS Call Center at 1-888-423-5436. Healthcare providers and patients should report all cases of pregnancy to:

- FDA MedWatch at 1-800-FDA-1088, and
- The Lenalidomide REMS program at 1-888-423-5436

A pregnancy exposure registry collects information about pregnancies that occur when a patient takes lenalidomide or when a pregnant partner may have been exposed through semen. Call the Lenalidomide REMS program for more information.

Intimacy, Pregnancy, and Breastfeeding (Continued)

Lenalidomide can pass into human semen:

- Even if you have had a vasectomy, you must always use a latex or synthetic condom during any sexual contact with anyone who is or can become pregnant while taking lenalidomide, during any breaks (interruptions) in your treatment with lenalidomide, and for up to 4 weeks after stopping lenalidomide.
- Do not have unprotected sexual contact with anyone who is or could become pregnant. Tell your healthcare provider if you do have unprotected sexual contact with anyone who is or could become pregnant.
- Do not donate sperm while taking lenalidomide, during any breaks (interruptions) in your treatment, and for up to 4 weeks after stopping lenalidomide. If anyone becomes pregnant with your sperm, the baby may be exposed to lenalidomide and may be born with birth defects.

If your partner becomes pregnant, you should call your healthcare provider right away.

- **Do NOT breastfeed** during treatment with epcoritamab and R², for 4 months after your last dose of epcoritamab, and for 6 months after your last dose of rituximab.

Handling Body Fluids and Waste

Some drugs you receive may stay in your urine, stool, sweat, or vomit for many days after treatment. Because many cancer drugs are toxic, your body waste may also be dangerous to touch. To help protect yourself, your loved ones, and the environment, **follow these instructions** for at least **48 hours** after each dose of **lenalidomide**:

- People who are pregnant should avoid touching anything that may be soiled with body fluids from the patient.
- You can use your usual toilet. Always close the lid and flush to discard all waste. If you have a low-flow toilet, flush twice.
- If the toilet or seat is soiled with urine, stool, or vomit, clean the surface after each use before others use it.
- Wash your hands with soap and water for at least 20 seconds after using the toilet.
- If you need a bedpan, inform your caregiver so they can wear gloves and assist with cleanup. Wash the bedpan with soap and water daily.
- If you cannot control your bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb waste.
- Wash any skin exposed to body waste with soap and water.
- Wash soiled linens or clothing separately from other laundry. If you don't have a washer, place them in a plastic bag until they can be washed.
- Wash your hands with soap and water after touching soiled linens or clothing.

- **Tell your care team about all the medicines you take.**

- **Do not donate blood** while taking lenalidomide, during any treatment breaks, or for 4 weeks after your last dose.

- **Lenalidomide cannot be automatically refilled.** You must complete the required REMS steps for each prescription.

- **This Patient Education Sheet may not describe all possible side effects.**

Notes

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ACCC
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Hematology/Oncology
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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 to gather information and develop this patient education guide. This guide is a summary of the medication, based on information provided by the drug manufacturer and other sources.

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