Ropeginterferon Alfa-2b

Patient Education Sheets
Understanding Your Cancer Treatment

Care Team Contact Information: _____

Pharmacy Contact Information: _____

Diagnosis: _____

- This treatment is often used for a blood disorder called polycythemia vera and a type of blood cancer called essential thrombocythemia (ET), but it may also be used for other diagnoses.

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
Ropeginterferon Alfa-2b (roh-peg-IN-ter-FEER-on AL-fuh): Besremi (bez-REH-mee)	Helps your body make fewer red blood cells so your blood stays thin and flows easily.	Injection given under the skin into your stomach area or top of the thighs.

Treatment Administration and Schedule:

Your ropeginterferon alfa-2b dose:

_____

_____

_____

- Ropeginterferon alfa-2b comes as a 500 microgram per 1 milliliter (mcg/mL) single-dose prefilled syringe.
- The typical starting dosage of ropeginterferon alfa-2b is 100 micrograms (or 50 micrograms in people currently taking hydroxyurea) every 2 weeks.
- Your care team will tell you the prescribed dose that you should take and the right amount of ropeginterferon alfa-2b to measure in the prefilled syringe for your dose. Do not inject more than your prescribed dose.
- Each time you inject, be sure that you know the prescribed dose of ropeginterferon alfa-2b to inject. Your dose may change over time.
- You should not use ropeginterferon alfa-2b until your care team has shown you how to use it correctly.

Treatment Name	Cycle 1							Next Cycle
	Day 1	Day 2	Day 3	Day 4	Day 5	…	Day 14	Day 1
Ropeginterferon Alfa-2b	✓							✓

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Storage and Handling of Ropeginterferon Alfa-2b

- Store ropeginterferon alfa-2b in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Keep ropeginterferon alfa-2b away from heat.
- Do not freeze ropeginterferon alfa-2b.
- Keep the ropeginterferon alfa-2b pre-filled syringe in the outer carton to protect it from light.
- Keep ropeginterferon alfa-2b, needles, and all medicines out of the reach of children and pets.

How to Use Ropeginterferon Alfa-2b

1. Gather Supplies for Injection
    - Take ropeginterferon alfa-2b carton out of the refrigerator and let it come to room temperature for 15 to 30 minutes inside the carton.
    - Gather an alcohol swab, a sharps disposal container, and a paper towel, sink, or trash can to minimize mess during dose adjustment. Optional items include gauze or cotton ball and an adhesive bandage.
2. Wash Hands and Remove the Syringe or Pen from Tray
    - Wash hands with soap and water.
    - Remove syringe and needle or pen and needle package from tray, checking for expiration and damage.
    - Ensure liquid is clear and colorless to slightly yellow. Do NOT use the prefilled syringe or pen if the liquid is cloudy, discolored, or contains particles.
3. Prepare Syringe or Pen for Injection
    - Syringe: Attach needle to syringe securely.
        - Carefully open the needle package, remove the needle, and set it aside. Throw away the packaging into household trash.
        - Remove the prefilled syringe cap by unscrewing it counter-clockwise. Throw away the syringe cap into household trash. Do not allow the tip of the prefilled syringe to touch anything.
        - Attach the needle to the prefilled syringe by firmly pushing it into the collar of the syringe and then screwing (turn clock-wise) it on until it feels securely attached.
    - Pen: Remove the pen cap by pulling it straight off the pen and throw it away.
        - Check the pen to see if it is damaged or broken. Do not use the pen if it shows any signs of damage or breakage.
        - Clean the rubber topper on the tip of the pen with a new alcohol swab. Throw away the alcohol swab after use.
        - Peel off the protective seal from the needle and throw it away.
        - Attach the capped needle by pushing it straight onto the pen until you feel or hear it “snap” into place.
        - Turn or rotate the needle in either direction until it “clicks” into place. The needle is attached when it no longer turns or rotates freely.
4. Choose and Clean Injection Site
    a. Choose one of the following injection sites:
        i. Lower stomach (abdomen) area, at least 2 inches away from the belly button
        ii. Top of thighs
    b. Do not inject into skin that is irritated, red, bruised, infected, or scarred.
    c. Rotate (change) the injection site for each injection.
    d. Clean the chosen injection site with an alcohol swab and let it air dry. Do NOT blow on or touch the injection site after it has been cleaned.

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5. Uncap Needle and Move Air Bubbles
    a. Syringe
        i. Pull the pink needle shield back.
            1. Note: The pink needle shield will be used after the injection to cover the needle and protect you from needle-stick injuries.
        ii. Hold the syringe from the syringe body. Remove the clear needle cap by pulling it straight off. Throw away the needle cap into household trash. Do NOT recap needle.
        iii. Hold the prefilled syringe with the needle pointing up. Tap on the body of the prefilled syringe to move any air bubbles to the top.
        iv. Remove needle cap and tap syringe to move air bubbles to top.
    b. Pen
        i. Remove the needle cover by pulling it straight off. Throw away the needle cap into household trash. Do NOT recap needle.
        ii. Turn the dose selector until the flow check water drop symbol is centered in the dose window. Do not dial your prescribed dose when doing the flow check.
        iii. Hold the pen with the needle pointing up. Press and hold the injection button all the way in until the dose window turns to “0.”
        iv. Repeat these steps (dial to drop symbol and press injection button) 3 more times for a total of 4 cycles.
        v. After 4 cycles, check the tip of the needle to make sure there is liquid medicine. If you do not see liquid at the tip of the needle, repeat the steps of dialing to drop symbol and pressing injection button up to 3 more times for a total of 7 cycles. If you still do not see liquid at the tip of the needle after 7 cycles, get a new pen carton and start over.
6. Set Your Dose
    a. Syringe
        i. Check your prescription to identify your prescribed dose. Depending on your prescribed dose, you may have to adjust the dose in the syringe by getting rid of (discarding) some medicine from the prefilled syringe before you inject the medicine.
        ii. To set your dose, follow the 4 steps below:
            1. Hold the prefilled syringe at eye level with the needle pointing straight up over a paper towel, sink, or trash can.
            2. Check that you can see the dose lines and number markings on the prefilled syringe.
            3. Pinch the end of the plunger.
            4. Slowly push up on the plunger to remove liquid medicine until the top edge of the gray stopper lines up with the marking for your prescribed dose. Keep holding straight up as you set the dose.
    b. Pen
        i. Check your prescription to identify your prescribed dose. You will need to set your prescribed dose before giving the injection.
        ii. Set your dose by turning the dose selector clockwise until the prescribed dose is centered in the dose window. It is normal to hear a clicking sound as you dial.
        iii. Check to make sure the number in the dose window is the correct prescribed dose before giving the injection. If you accidentally turn the dose selector past the prescribed dose, turn the dose selector back to the correct dose.

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7. Inject Ropeginterferon Alfa-2b
    a. Syringe
        i. Pinch the chosen injection site.
        ii. While pinching the skin, insert the needle at a 45 to 90 degree angle into the pinched skin. Then release the pinched skin.
        iii. Inject the medicine by slowly pressing down on the plunger all the way until it stops.
        iv. Pinch skin and insert needle at 45 to 90-degree angle.
        v. After all the liquid medicine is injected, remove the needle from the skin.
        vi. Cover needle
            1. Carefully push the pink needle shield over the needle until it snaps into place and covers the needle (Figure AE). This helps prevent needle-stick injuries.
            2. Do not recap the needle using the needle cap. Only use the pink needle shield to cover the needle. Inject medicine slowly, then remove needle.
    b. Pen
        i. Hold the pen over the cleaned injection site at a 90-degree angle.
        ii. Without touching the injection button, push the pen down to fully insert the needle into the skin.
        iii. Press and hold the injection button all the way down until it stops. The number in the dose window will go back to “0.”
        iv. Keep holding the injection button down after the dose window returns to “0” and count to 5 to make sure the full dose is delivered. There may still be liquid remaining in the pen cartridge after the injection. This is normal.
        v. Remove the needle from the skin by lifting the pen straight up. The blue needle shield will cover the needle.

Disposing of (Throwing Away) Used Prefilled Syringes and Needles

- Put your used prefilled syringes and needles or pen with the needle still attached in an FDA-cleared sharps disposal container right away after use. Do not throw away loose prefilled syringes, pens, and needles in the household trash.
- If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:
    - made of a heavy-duty plastic,
    - can be closed with a tight-fitting, puncture-resistant lid without sharps being able to come out,
    - upright and stable during use,
    - leak-resistant, and
    - properly labeled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: http://www.fda.gov/safesharpsdisposal.
- Do not dispose of your sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.
- Always keep the sharps disposal container out of the reach of children.

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Travel Tips

- Be sure to tell the Transportation Security Administration (TSA) officer that you're carrying a liquid medicine. Ask the TSA officer for a visual inspection of your ropeginterferon alfa-2b medicine. Do not put ropeginterferon alfa-2b through X-ray screening.
- You're allowed to carry ropeginterferon alfa-2b in your carry-on bag. It doesn't need to be placed in a separate clear plastic bag. It's important to keep ropeginterferon alfa-2b cold at all times in a cooler pack until you need it.
- After your trip, any syringes that you used must be transported back in an FDA-cleared sharps disposal container. You can put the container in your checked bag or carry-on bag.

Appointments: Appointments may include regular check-ups with your care team, 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.

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Common Side Effects

Side Effect	Important Information
Low White Blood Cell (WBC) Count and Increased Risk of Infection	Description: WBCs help protect the body against infections. If you have a low WBC count, you may be at a higher risk of infection. Recommendations: • Wash your hands and bathe regularly. • Avoid crowded places. • Stay away from people who are sick. Talk to your care team if you have: • Fever of 100.4 °F (38°C) or higher • Chills • Cough • Sore throat • Painful urination • Tiredness that is worse than normal • Skin infections (red, swollen, or painful areas)
Low Platelet Count	Description: Platelets help the blood clot and heal wounds. If you have low platelet counts, you are at a higher risk of bruising and bleeding. Recommendations: • Blow your nose gently and avoid picking it. • Brush your teeth gently with a soft toothbrush and maintain good oral hygiene. • Use an electric razor for shaving and a nail file instead of nail clippers. • Avoid over-the-counter medications that may increase the risk of bleeding, such as NSAIDs. • Talk with your care team or dentist before medical or dental procedures, as you may need to pause your treatment. Talk to your care team if you have: • Nosebleed lasting over 5 minutes despite pressure • Cut that continues to bleed • Significant gum bleeding when flossing or brushing • Severe headaches • Blood in your urine or stool • Blood in your spit after a cough
Flu Like Symptoms	Description: Treatment can cause flu like symptoms, including tiredness, weakness, fever, chills, muscle aches, and joint pain. Talk to your care team if you have: • Tiredness or weakness • Fever of 100.4 °F (38°C) or higher • Chills • Muscle aches • Joint pain

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Diarrhea	Description: Diarrhea is when you have loose, watery bowel movements more often than usual. The need to use the bathroom may occur urgently. Recommendations: • Keep track of how many times you go to the bathroom each day. • Drink 8 to 10 glasses of water or other fluids every day, unless your doctor tells you otherwise. • Eat small meals of mild, low-fiber foods like bananas, applesauce, potatoes, chicken, rice, and toast. • Stay away from 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. • Your care team might suggest a medicine for diarrhea. Talk to your care team if you have: • 4 or more bowel movements than normal in 24 hours • Dizziness or lightheadedness while having diarrhea • Bloody diarrhea
Skin Problems	Description: Treatment can cause a rash with itchy, dry, red, or puffy skin. Hair loss or hair thinning may also occur. Recommendations: • Keep your skin soft and moisturized with lotions or creams. • Wear loose, comfortable clothes. • Don’t use perfumes and colognes. • Stay out of the sun, especially between 10 AM and 4 PM. • Wear long-sleeved shirts with UV protection and a wide hat to block the sun. • Use sunscreen with at least SPF 30 and put on lip balm with SPF too. • Don't use tanning beds. • Your care team may suggest taking certain medicines or applying special creams. Talk to your care team if you have: • Rash • Itching • Skin blistering or peeling • Painful sore or ulcers in the mouth or nose, throat, or genital area
Headache	Description: A headache can cause you to feel pain or discomfort in your head, making it hard to concentrate or feel your best. Recommendations: • Keep a headache diary to track the frequency, duration, intensity, and triggers of your headaches. • Stay hydrated by drinking plenty of water, as dehydration can contribute to headaches. • Your care team may recommend the use of over-the-counter pain relief medications. • Apply a cold or warm compress to your forehead or neck to help ease headache pain. • Get adequate sleep (7-8 hours per night) and establish a regular sleep schedule. • Limit caffeine intake. Talk to your care team if you have: • A headache that is severe and does not improve with over-the-counter medications • A headache lasts longer than a few days or becomes more frequent • Vision changes, confusion, weakness, or difficulty speaking • A sudden onset of a severe headache, described as a "thunderclap" headache. • Fever of 100.4°F (38°C) or higher

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Muscle or Joint Pain	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. Recommendations: • Track your pain levels, areas of discomfort, and any activities that worsen or improve your symptoms. • 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. • Apply a warm compress to relax stiff muscles or use cold packs to reduce swelling and numb pain in affected areas. • Your care team may prescribe or recommend medications, including over-the-counter pain relievers. Talk to your care team if you have: • Persistent or worsening muscle or joint pain that does not improve with home treatments • New symptoms, such as swelling, redness, or warmth in the joints • Weakness that affects your ability to perform daily activities • Side effects from pain relief medications that you are unable to manage
Fatigue	Description: Fatigue is a constant and sometimes strong feeling of tiredness. Recommendations: • Routine exercise has been shown to decrease levels of fatigue. Work with your care team to find the right type of exercise for you. • Ask your family and friends for help with daily tasks and emotional support. • Try healthy ways to feel better, like meditation, writing in a journal, doing yoga, and using guided imagery to lower anxiety and feel good. • 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. • Don't use heavy machines or do things that need your full attention if you're very tired to avoid accidents. Talk to your care team if you have: • Tiredness that affects your daily life • Tiredness all the time, and it doesn't get better with rest • Dizziness and weakness, along with being tired
Injection Site Reactions	Description: An injection reaction is a bad response that happens during or not long after getting medicine through an injection. Skin reactions at or near the injection site are possible. Symptoms may include itching, swelling, bruising, pain, rash, bleeding, or redness. Talk to your care team if you have: • Chills or shaking • Itching, rash, or flushing • Trouble breathing or wheezing • Tongue-swelling • Dizziness or feeling faint • Fever of 100.4°F (or 38°C) or higher • Pain in your back or neck

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Select Rare or Serious Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms	
Mental Health Problems, Including Suicide (Boxed Warning)	• Irritability (getting upset easily) • Restlessness and agitation • Confusion • Depression (feeling low, feeling bad about yourself or feeling hopeless)	• Unusually grand ideas • Acting aggressive • Acting impulsively • Thoughts of hurting yourself or others, or thoughts of suicide
New or Worsening Autoimmune Problems	• Tiredness • Urinating often	• You are very thirsty
Heart Problems	• Swelling of your stomach-area (abdomen), legs, hands, feet, or ankles • Shortness of breath • Nausea or vomiting • New or worsening chest discomfort, including pain or pressure • Weight gain • Pain or discomfort in your arms, back, neck, or jaw • Protruding neck veins • Breaking out in a cold sweat	• Feeling lightheaded or dizzy • Palpitations (rapid or irregular heartbeat) • Dizziness or lightheadedness • Shortness of breath • Chest discomfort or pain • Fatigue • Confusion • Fainting or near-fainting spells
Eye Problems	• Dry or red eyes • Eye pain or swelling • Vision changes	• Increased tears • Sensitivity to light • Blurred vision
Liver Problems	• Yellowing of your skin or the whites of your eyes • Severe nausea or vomiting, pain on the right side of your stomach area (abdomen)	• Dark urine (tea colored) • Bleeding or bruising more easily than normal
Kidney Problems	• Changes in the amount or color of your urine • Swelling in your ankles	• Blood in your urine • Loss of appetite
Serious Allergic Reactions and Skin Reactions	Get medical help right away if you get any of the following symptoms: • Skin rash or hives • Itching swelling of your face, eyes, lips tongue, or throat	• Trouble breathing • Chest pain • Feeling faint

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.

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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 might get pregnant, take a pregnancy test before starting treatment.
  - Use an effective method of birth control during treatment and for 8 weeks after your last dose.
  - If you think you might be pregnant or if you become pregnant, tell your care team right away.
  - If your partners could be pregnant, use an effective method of birth control—such as condoms—during treatment.
- **Do NOT breastfeed** during treatment and for 8 weeks after your last dose.

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.
- Treatment can cause **tooth and gum (periodontal) problems** which can lead to tooth loss.
  Ropeginterferon alfa 2-b can also cause problems with dry mouth that can damage your teeth and the lining of the mouth during long-term treatment. It is important for you to brush your teeth well, two times each day and have regular dental examinations during treatment.
- **Avoid driving or using machinery** if you develop dizziness, sleepiness, or hallucinations.
- Ropeginterferon alfa-2b is available through a **limited specialty pharmacy network**. Information regarding distribution is available from the manufacturer at 1-800-700-5053 or at https://www.pharmaessentiasource.com/hcp/forms-resources/.
- **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.

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