

Rusfertide

Care Team Contact Information: _____

Pharmacy Contact Information: _____

Diagnosis: _____

- This treatment is used for erythrocytosis (high number of red blood cells) in adults with a type of blood cancer called polycythemia vera (PV).
- 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
Rusfertide (rus-fer-tide): Mimrylo (mim-rah-y-loh)	Helps the body make fewer red blood cells.	Injection under the skin (subcutaneous injection) into the stomach area (abdomen), thigh, or upper outer arm.

Treatment Administration and Schedule

Your rusfertide dosing instructions:

- Rusfertide comes in 5 injection strengths: 9.5 mg, 19 mg, 28 mg, 41 mg, and 54 mg.
- Your dose is based on many factors, including your overall health and diagnosis.
- See the detailed Instructions for Use that comes with rusfertide for information on how to prepare and inject a dose of rusfertide.
- Inject rusfertide under the skin in the stomach area (abdomen) at least 2 inches away from the belly button (navel), front of the thigh, or the upper outer arm. Choose a different site each time you inject rusfertide.
- Your care team should show you or your caregiver how to prepare and inject rusfertide. Contact your care team if you have questions. Do not inject yourself or someone else until you have been shown how to inject rusfertide.
- Rusfertide is available in more than 1 strength. Make sure the rusfertide strength you have matches your prescribed strength.
- Your prescribed dose may require more than 1 injection.
- Do not give more than two injections a day.

Treatment Administration and Schedule (Continued)

- If your weekly dose is 9.5 mg to 54 mg, you will give **one injection** once a week on Day 1.
- If your weekly dose is 69 mg or 82 mg, you will give **two injections** once a week on Day 1.
- If your weekly dose is greater than 82 mg, give your **first injection** on Day 1 and the **second injection** on Day 4 or 5.
- Do not change your dose or stop taking rusfertide unless your care team tells you to.
- Your care team may tell you to change your dose, temporarily stop, or completely stop taking rusfertide if you develop certain side effects.
- If you inject one time a week and miss a dose:
 - If you miss a dose by 1 to 4 days, take the missed injection as soon as you remember. Then continue with your regular weekly schedule.
 - If you miss a dose by more than 4 days, take the missed injection as soon as you remember. Take your next injection 3 days later and then return to your regular weekly schedule.
- If you inject two times a week and miss a dose:
 - If you miss a dose by 1 to 2 days, take the missed injection as soon as you remember. Take your next injection 3 days later and then return to your regular schedule.
 - If you miss a dose by more than 2 days, skip the dose and continue with your regular injection schedule.
- Contact your care team if you do not know when to inject a missed dose.
- If you take too much rusfertide, call your care team or go to the nearest hospital emergency room right away.

☐ Weekly Dosing

- Rusfertide is given on Day 1.

Treatment Name	Week 1							Next Week
	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 1
Rusfertide	✓							✓

☐ Option #1: Twice Weekly Dosing

- Rusfertide is given on Day 1 and 4 (or 5).

Treatment Name	Week 1							Next Week
	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 1
Rusfertide	✓			✓				✓

Storage and Handling of Rusfertide

- Store rusfertide at room temperature between 68°F and 77°F (20°C and 25°C).
- Do not freeze.
- Store rusfertide in the original carton to protect it from light.
- Do not use the vial or diluent syringe after the expiration date on the carton.
- After mixing (reconstitution), rusfertide may be stored at room temperature between 68°F and 77°F (20°C and 25°C) for up to 4 hours.
- Use rusfertide within 4 hours after mixing.
- Throw away (dispose of) mixed rusfertide if not used within 4 hours.
- Keep rusfertide and all medicines out of the reach of children and pets.
- Ask your care team how to safely throw away any unused rusfertide.

How to Use Rusfertide

1. Gather Supplies for Injection
 - Check your prescribed dose. Rusfertide comes in more than 1 strength, so make sure the strength on the carton matches your prescribed strength.
 - Gather the rusfertide medicine vial, prefilled diluent syringe, vial adapter, needle, alcohol swabs, cotton ball or gauze, adhesive bandage, and sharps disposal container.
 - Check the expiration date and make sure none of the supplies are opened, damaged, or missing.
 - Your prescribed dose may require more than 1 injection. Do not give more than 2 injections in 1 day.
 - If your weekly dose is greater than 82 mg, give the first injection on Day 1 and the second injection on Day 4 or 5.
2. Wash Hands and Prepare the Medicine Vial
 - Wash your hands well with soap and water.
 - Remove all supplies from the carton. Hold the prefilled diluent syringe by the syringe body. Do not hold it by the plunger or syringe cap.
 - Remove the cap from the medicine vial and throw the cap away.
 - Clean the gray rubber stopper on top of the medicine vial with a new alcohol swab. Let it dry and do not touch the stopper after cleaning.
3. Attach the Vial Adapter
 - Open the vial adapter package. Do not let the vial adapter spike touch your hands or any surface.
 - Keep the vial adapter inside its plastic package while attaching it.
 - Place the medicine vial on a flat surface.
 - Hold the medicine vial with 1 hand. With the other hand, place the vial adapter over the vial.
 - Push the vial adapter straight down until it snaps into place and is fully attached.
 - Do not attach the vial adapter at an angle or remove it after it has been attached.
4. Attach the Diluent Syringe
 - Lightly squeeze and remove the plastic packaging from the vial adapter. Do not touch the tip of the vial adapter.
 - Hold the diluent syringe by the syringe body.
 - Remove the syringe cap by turning it to the left (counterclockwise). Throw the cap away.
 - Do not let the syringe tip touch your hands or any surface.
 - Hold the vial adapter with 1 hand and attach the diluent syringe by turning it to the right (clockwise) until it is snug. Do not tighten it too much.

5. Mix the Rusfertide
 - Place the medicine vial on a flat surface with the attached syringe pointing down.
 - Slowly push the syringe plunger all the way down to put all of the diluent into the medicine vial.
 - Do not remove the syringe from the vial.
 - Slowly and gently swirl the vial in a circular motion until all of the powder is dissolved. This may take about 2 minutes.
 - Do NOT shake the vial.
 - Place the vial on a clean, flat surface and let it sit for about 1 minute so the liquid can settle and any extra foam can go away. It is normal if the syringe plunger moves up by itself.
6. Check the Mixed Medicine
 - Check the liquid after it has settled.
 - The medicine should be clear, colorless, have very little foam, and have no visible particles.
 - Do NOT use the medicine if the liquid is colored or contains particles.
 - Rusfertide must be injected within 4 hours after mixing. Throw away the mixed medicine if it is not used within 4 hours.
7. Draw the Medicine into the Syringe
 - Make sure the syringe plunger is pushed all the way down to remove air.
 - While holding the plunger down, turn the syringe and vial upside down so the medicine vial is on top.
 - Slowly pull the syringe plunger down to draw all of the mixed medicine into the syringe.
 - It is normal to see an air gap or bubbles in the syringe after drawing up the medicine.
8. Remove the Medicine Vial and Attach the Needle
 - Hold the syringe by the body with 1 hand.
 - With the other hand, hold the vial adapter and turn it to the left (counterclockwise) to remove the empty medicine vial.
 - Throw the empty medicine vial into a sharps disposal container. Do not throw it into household trash.
 - Open the needle package. Do not touch the open end of the needle.
 - Hold the syringe by the body and attach the needle by turning it to the right (clockwise) until it is snug.
 - Do not touch or push the syringe plunger until you are ready to inject.
9. Choose and Clean the Injection Site
 - Choose one of the following injection sites:
 - Stomach (abdomen) area, at least 2 inches away from the belly button
 - Front of the thigh
 - Outer area of the upper arm
 - The outer upper arm should only be used if a caregiver is giving the injection.
 - Do not inject into skin that is tender, bruised, red, irritated, hard, or broken.
 - Do not inject into the same spot twice in a row. Rotate (change) the injection site with each injection.
 - Clean the chosen injection site with a new alcohol swab and let it air dry.
 - Do NOT touch, fan, or blow on the injection site after it has been cleaned.

10. Remove the Needle Cap and Air Bubbles

- Hold the syringe by the body with the needle pointing up.
- Pull the needle shield back. Do not remove the needle shield.
- Carefully pull the needle cap straight off and throw it away.
- Do NOT recap the needle.
- Do not use the needle if it is bent or damaged.
- Hold the syringe with the needle pointing straight up.
- Tap the syringe with your finger to move air bubbles toward the needle.
- Slowly push the plunger to remove the air or bubbles. It is okay if a small air gap or some bubbles remain in the syringe.

11. Inject Rusfertide

- Pinch the skin at the chosen injection site.
- Insert the needle into the pinched skin at a 45- to 90-degree angle.
- You may release the pinched skin after the needle is inserted.
- Slowly push the plunger all the way down to inject all of the medicine.
- After all of the medicine has been injected, pull the needle and syringe out of the skin at the same angle it was inserted.

12. Cover the Needle and Throw Away Supplies

- Right after the injection, place the needle shield against a hard surface and carefully push it over the needle until it snaps into place and covers the needle.
- Do NOT recap or touch the needle. Do not try to remove the needle from the syringe.
- Place the used syringe with the needle attached into a sharps disposal container.
- If there is bleeding at the injection site, gently press a cotton ball or gauze over the area for about 10 seconds. Apply an adhesive bandage if needed.
- Do NOT rub the injection site.
- If your prescribed dose requires 2 injections, repeat the preparation and injection steps for the second injection.

Disposing of (Throwing Away) Used Needles

- Put your used syringes and needles in an FDA-cleared sharps disposal container right away after use. Do not throw away loose syringes 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.

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 rusfertide medicine. Do not put rusfertide through X-ray screening.
- You're allowed to carry rusfertide in your carry-on bag. It doesn't need to be placed in a separate clear plastic bag.
- After your trip, any syringes and needles 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 an appointment, call your care team as soon as possible to reschedule it.

Common Side Effects

Side Effect	Important Information
Low Red Blood Cell (RBC) Count and Hemoglobin (Hgb) (Anemia)	Description: Red blood cells carry oxygen throughout your body. Low levels can make you feel tired, weak, dizzy, or short of breath. 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
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, swelling, warmth, or pain at the site - A growing lump or hard area that does not get better - Drainage of pus or fluid from the site - Heavy or prolonged bleeding or new bruising at the site - Fever or chills with the injection-site reaction

Select Rare Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms
High Platelet Count (Thrombocytosis)	- Unusual bruising or bleeding - Chest pain - Shortness of breath - Leg pain or swelling - Sudden, severe headache

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.

- 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:
 - Your care team will verify your pregnancy status before treatment.
 - Use an effective method of birth control during treatment and for 30 days after your last dose of rusfertide.
 - If you think you might be pregnant or if you become pregnant, tell your care team right away.
 - If your partner is able to become pregnant, use an effective method of birth control—such as condoms—during treatment with rusfertide.
- **Do not breastfeed** during treatment and for 30 days after your last dose of rusfertide.

- **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.
- **This Patient Education Sheet may not describe all possible side effects.**
Call your care team for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

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