

FOR THE TREATMENT OF ERYTHROCYTOSIS IN ADULTS WITH POLYCYTHEMIA VERA

Dosing & Administration Guide

Getting comfortable with MIMRYLO™ (rusfertide) dosing and administration

This guide will help you learn the correct way to prepare and inject your medication.

What is MIMRYLO (rusfertide)?

MIMRYLO is a prescription medicine that is used to treat erythrocytosis (high red blood cell count) in adults with polycythemia vera. It is not known if MIMRYLO is safe and effective in children.

IMPORTANT SAFETY INFORMATION

Before using MIMRYLO, tell your healthcare provider about all of your medical conditions, including if you:

- are pregnant or plan to become pregnant. MIMRYLO may harm your unborn baby.

Females who are able to become pregnant:

- Your healthcare provider may do a pregnancy test before you start treatment with MIMRYLO.
 - Use effective birth control (contraception) during treatment and for at least 30 days after the final dose of MIMRYLO.
 - Tell your healthcare provider right away if you become pregnant or think that you may be pregnant during treatment with MIMRYLO.
 - Stop taking MIMRYLO if you become pregnant.
- are breastfeeding or plan to breastfeed. It is not known if MIMRYLO passes into your breast milk. Do not breastfeed during treatment with MIMRYLO and for 30 days after the final dose of MIMRYLO. Talk to your healthcare provider about the best way to feed your baby during this time.

Please see full Important Safety Information on **page 19**, and MIMRYLO (rusfertide) full **Prescribing Information**, including Patient Information, and full **Instructions for Use**.



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Actor portrayals.

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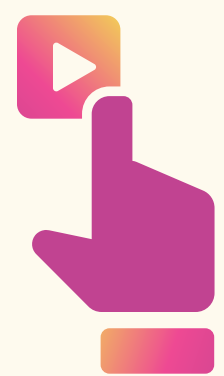
Please see full Important Safety Information on **page 19**, and MIMRYLO (rusfertide) full **Prescribing Information**, including Patient Information, and full **Instructions for Use**.

Getting started with MIMRYLO

What is MIMRYLO?

MIMRYLO is a type of medicine used to treat erythrocytosis (high red blood cell count) in adults with polycythemia vera. Erythrocytosis is a condition that causes the body to make too many red blood cells. MIMRYLO mimics hepcidin, a natural hormone in your body that helps keep iron levels under control, which in turn helps control red blood cell production and your hematocrit levels.

Helping you get comfortable with MIMRYLO



This guide will give you an overview of how to get started with MIMRYLO, and what to expect from the injection process. Review before starting treatment, then revisit this guide after starting MIMRYLO to help keep you on track.



This guide will walk you through dosing, and how your dose may be adjusted when starting MIMRYLO. You will work hand-in-hand with your doctor and care team to make sure that you find the right dose for your treatment.



We're Here2Assist®

This guide does not stand alone. The expertise of your healthcare team, support from MIMRYLO Patient Support, and the additional materials in the Welcome Kit will ensure that you have the support needed to start MIMRYLO with confidence.

Please see full Important Safety Information on **page 19**, and MIMRYLO (rusfertide) full **Prescribing Information**, including Patient Information, and full **Instructions for Use**.

1.

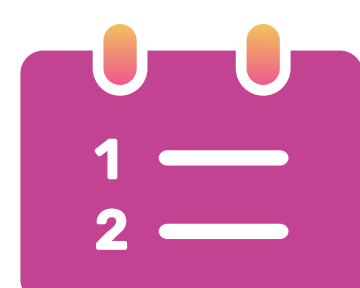
Before your first dose

Please see the full [Instructions for Use](#) for complete information about reconstituting and administering MIMRYLO.

Before your first injection, it is important to understand how your treatment works and how it is prepared and administered. It's natural to feel some concerns about self-injecting correctly, but don't worry. Your healthcare team will ensure that you know what to do. In addition, we've designed this guide and the materials below to help make things as clear as possible:



When you are preparing for the injection, you can use the [Injection Placemat](#) to ensure that you have all the materials necessary. The MIMRYLO carton does not contain all the items you'll need to prepare and inject; you can get these separately from the pharmacy.



When all the materials are arranged on the [Injection Placemat](#), have the [Step-by-Step Injection Guide](#) in front of you as well. This will help you administer MIMRYLO as recommended.



If you are new to treatment, your healthcare team will walk you through the injection process. To revisit this process from home, you can review the [Injection Training Video](#).

If you have questions, we're Here2Assist®. Sign up for MIMRYLO Patient Support at [MIMRYLO.com/enrollment](https://mimrylo.com/enrollment). If you have concerns or further questions, call your doctor. Please see the end of the guide for a more complete list of resources and support.

Hypothetical patient.

Please see full Important Safety Information on [page 19](#), and MIMRYLO (rusfertide) full [Prescribing Information](#), including Patient Information, and full [Instructions for Use](#).

Mimrylo
rusfertide_{for injection}

Reminders

Some important general reminders about administering MIMRYLO:

- MIMRYLO must be **stored at room temperature** between 20 °C to 25 °C (68 °F to 77 °F) in its original carton (to protect it from light). **Do not** refrigerate or freeze it
- **MIMRYLO is for injection under the skin (subcutaneous) only**
- MIMRYLO is available in more than 1 strength. **Check your prescribed dose as it may require more than one injection**
- **If you have any questions on the administration of MIMRYLO**, contact your healthcare provider
- **Your prescribed dose may require more than one injection**
 - **Do not** administer more than 2 injections daily
 - If your weekly dosage is greater than 82 mg, administer your first injection on Day 1 and your second injection on Day 4 or 5
- The supplies included in the MIMRYLO carton, and the vial adapter, needle, and alcohol swabs are for **single use** only. **Do not** reuse any of these supplies
- **Do not** use if any of the supplies are opened, damaged, or missing
- **Do not** use if MIMRYLO is expired
- MIMRYLO is supplied as a **single-dose vial** of powder for mixing (reconstitution). Before you inject MIMRYLO, you must mix MIMRYLO with the liquid that comes in the syringe
- **Do not** prepare MIMRYLO for injection until you are ready to inject. **Keep the medicine at room temperature after mixing and inject within 4 hours of mixing.** Throw away the mixed MIMRYLO if not used within 4 hours
- **Do not** touch the gray rubber stopper on the top of the vial
- **Do not** let the vial adapter tip or spike touch your hands or any surface
- **Do not** let the syringe tip or needle touch your hands or any surface
- **Do not** throw away the needle or syringe in your household trash
- MIMRYLO does not contain natural rubber latex
- **Keep MIMRYLO and all medicines out of the reach of children**

Please see full Important Safety Information on **page 19**, and MIMRYLO (rusfertide) full **Prescribing Information**, including Patient Information, and full **Instructions for Use**.

2.

Finding your dose

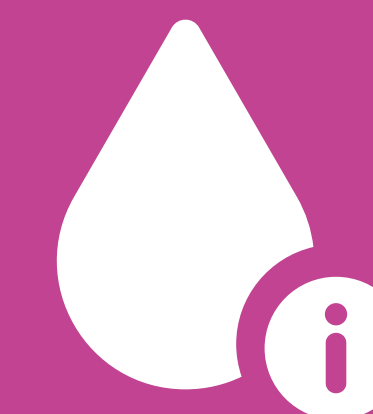
Your doctor will tell you your dose and help you plan your injection schedule. Throughout treatment with MIMRYLO, you will have regular blood tests to monitor your polycythemia vera and to check for side effects. Do not change your dose or stop taking MIMRYLO unless your doctor tells you to.

The recommended starting dose of MIMRYLO is 19 mg once weekly by **injection under the skin**. You will receive your first injection and training by your healthcare provider. Based on side effects and how your body responds to MIMRYLO, your doctor may adjust your dose.

To find the best dose for you, your doctor will initially ask that you get blood tests to measure your hematocrit every 2 to 4 weeks while taking MIMRYLO. Based on the results, **your doctor will decide** if the dose needs to be adjusted. You'll be on each dose for at least 2 weeks before any change is made. Again, your role in the process is to **take the prescribed dose** and **get blood tests done** as recommended by your doctor.

Hypothetical patient.

Lab work is
important.



Remember, the information provided by blood tests is necessary for your doctor to monitor your health and prescribe the right dose of MIMRYLO for you.

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Mimrylo
rusfertide_{for injection}



Doses of **54 mg** and lower are taken as a **single weekly injection**



Doses of **69 mg** or **82 mg** are taken as **two injections on the same day, once weekly**



Doses of **95 mg** or **108 mg** are taken as **two injections on different days** (Day 1 and Day 4 or 5) each week

Dosing schedule example					
Week 1	Week 2	Week 3	Week 4	Week 5	Later Weeks
Starting dose (19 mg)	Starting dose (19 mg)	19 mg or 28 mg	19 mg or 28 mg	Current dose or adjustment	Current dose (at least 2 wks) or adjustment
Blood tests done every 2 to 4 weeks					

After starting at 19 mg once weekly, your healthcare provider may adjust your dose based on how treatment is working and for side effects, such as anemia (low red blood cell count).

Once your hematocrit is under control, you will continue taking your prescribed dose once weekly, or as directed by your doctor.

Reminder—some dosages require more than 1 injection, and your dose and schedule may change during the course of treatment

- Do not administer more than 2 injections in a day
- If your weekly dose is more than 82 mg, administer the first injection on Day 1 and the second injection on Day 4 or 5
- MIMRYLO is available in 5 different strengths, each with a different colored cap. **Always double-check the dosage strength of the vial against what your doctor prescribed**

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3.

Preparing MIMRYLO

Preparing your space

Have the **Step-by-Step Injection Guide** (provided with your Welcome Kit) in front of you for reference when you're ready to mix MIMRYLO. The following information will give you an overview of preparation and injection, but the **Step-by-Step Injection Guide** and **Instructions for Use** have reminders and details that may help during the process.

After washing your hands and organizing all materials on the **Injection Placemat**, the first step is to mix the liquid in the syringe with the powder in the vial using the **vial adapter**. Follow the instructions for opening, sterilizing, and attaching the items.

Important things to keep in mind when preparing your MIMRYLO dose

- Once you inject the liquid from the prefilled syringe into the vial containing the powdered medicine, gently swirl the vial to dissolve your medicine. If there is powdered medicine stuck to the inside of the vial wall, continue to gently swirl until it is removed. **Do not shake**
- Inspect the mixed solution to ensure that it is colorless and contains no particles. If your medicine looks colored or contains particles, do not use it
- Always mix and inject your medicine in a clean area with clean hands to reduce the risk of contamination and infection

Actor portrayal.

Please see full Important Safety Information on **page 19**, and MIMRYLO (rusfertide) full **Prescribing Information**, including Patient Information, and full **Instructions for Use**.

Mixing MIMRYLO

Mixing MIMRYLO powder with the supplied liquid (a process called reconstitution) makes it into a solution that can be injected. The **Step-by-Step Injection Guide** will give you specific instructions on the correct way to mix MIMRYLO.



[Watch a video showing how to mix and inject MIMRYLO](#)



Inject the liquid within the prefilled syringe into the vial containing the powdered medicine



Gently swirl until the powder is dissolved



Let the liquid settle



Inspect the liquid to be sure the powder has dissolved



Draw the mixed liquid into the syringe and **inject within 4 hours**

These are not the full instructions. Please see the **Step-by-Step Injection Guide** or **Instructions for Use** when preparing your MIMRYLO.

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4.

Injecting MIMRYLO

Have the **Step-by-Step Injection Guide** in front of you when you're ready to inject MIMRYLO.

Once the mixed medicine is in the syringe, you will need to **attach the needle** and prepare it for injection, including **removing the needle cap and any air from the syringe**.

The guide steps, including removing air from the syringe, **holding the needle at the correct angle** (45° to 90°), and **choosing an appropriate injection site** for each injection, are in place for your **safety** and for **correct delivery** of MIMRYLO. When the medication is administered correctly, your doctor can accurately observe its effectiveness, any potential side effects, and the need (if any) for dose adjustments.

If your dosing schedule requires 2 injections on the same day, repeat the injection steps for the second injection to reach the full prescribed dose.

Use a different injection site for the second injection.

We recommend making note of which injection site(s) you use on a treatment tracker or calendar. Speak with your healthcare team if you'd like help setting up a treatment tracker.

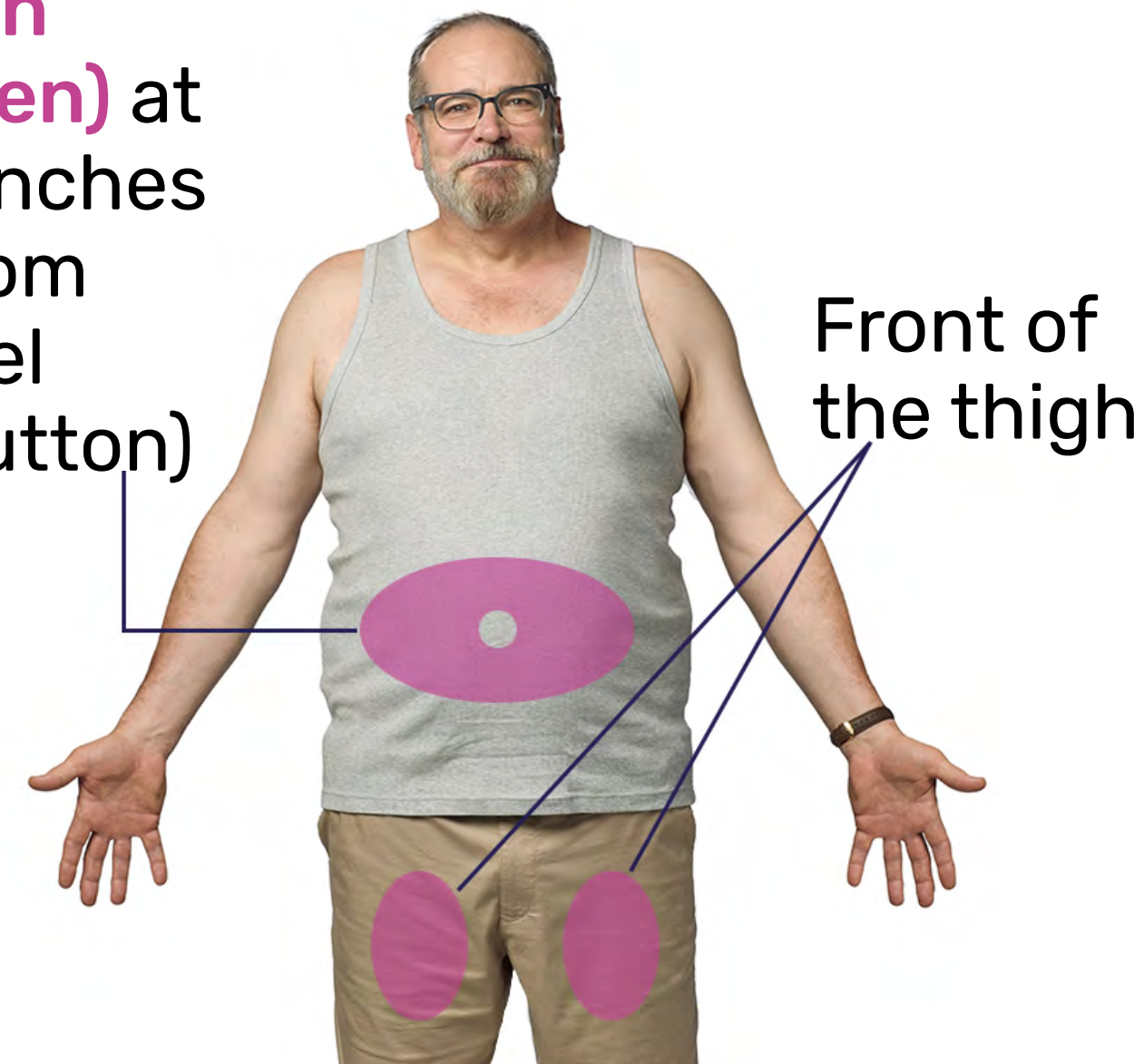
Actor portrayal.

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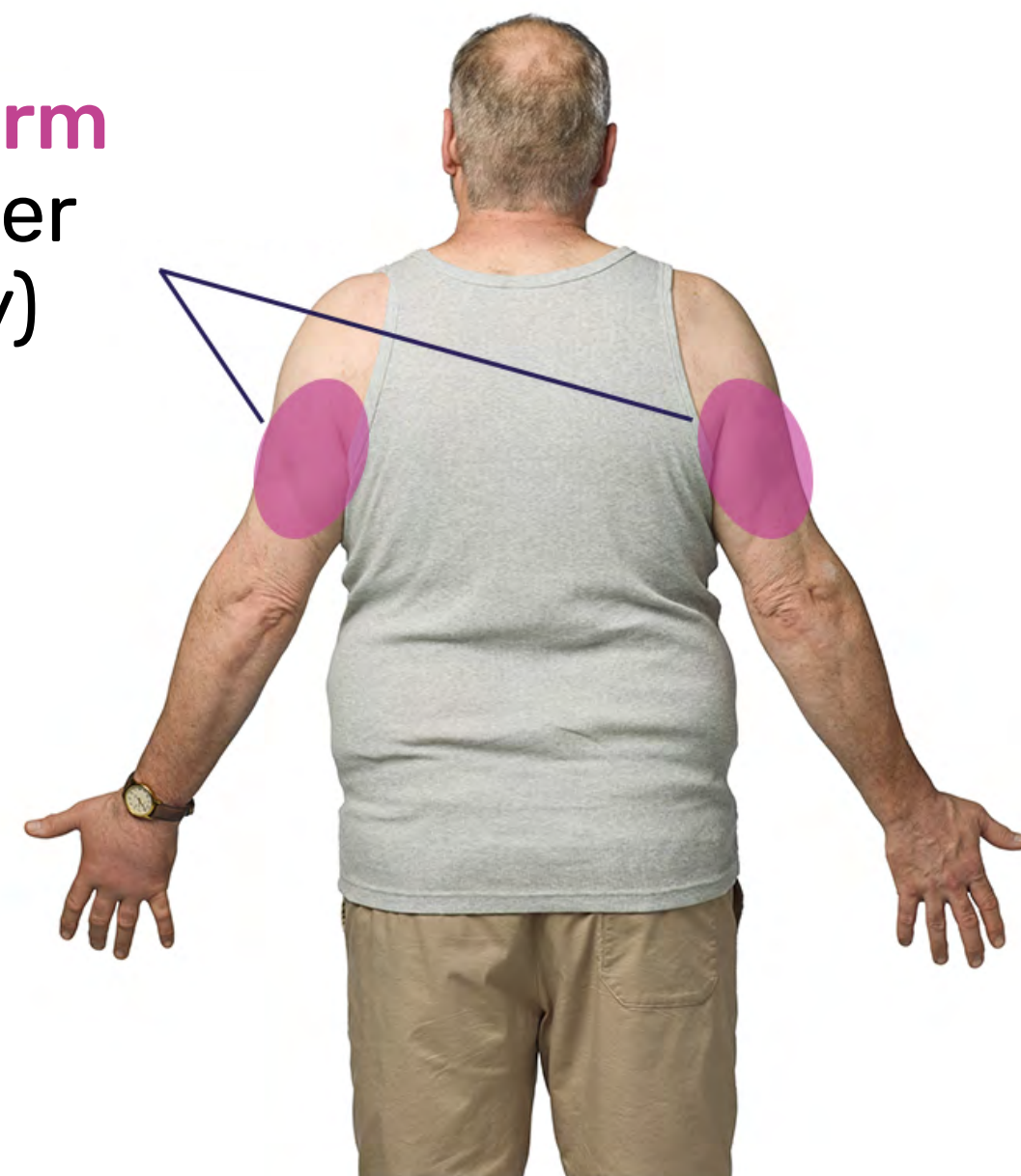
Mimrylo
rusfertide_{for injection}

Choose an injection site

Stomach (abdomen) at least 2 inches away from the navel (belly button)



Upper arm (caregiver use only)



Needle don'ts

- **Do not** remove the needle shield from the needle
- **Do not** touch the plunger rod while taking off the needle cap
- **Do not** use if the needle looks damaged or bent
- **Do not** let the needle touch your hands or any surface
- **Do not** use if the syringe is dropped without the needle cap on
- **Do not** try to remove the needle from the syringe
- **Do not** recap or touch the needle



Injection site don'ts

- **Do not** select a site where the skin is tender, bruised, red, irritated, hard, or broken
- **Do not** inject into the same spot twice in a row. Change (rotate) sites between injections
- **Do not** touch the cleaned area again before injecting (after cleaning it with a new alcohol swab)
- **Do not** fan or blow on the clean site
- **Do not** rub the injection site

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5.

After injection

Treating the injection site

If there is bleeding at the injection site, gently press a cotton ball or gauze pad over the site and hold it there for 10 seconds. Cover it with an adhesive bandage if needed.

Do not rub the injection site.



Safe handling and proper disposal

Right after injection of the medicine, place the needle shield on a hard surface and carefully push the needle shield over the needle until it snaps into place and covers the needle.



- **Do not** try to remove the needle from the syringe
- **Do not** recap or touch the needle

The MIMRYLO needle and syringe are single use and must be disposed of properly after use. Throw away the **used syringe with the needle attached** in a **sharps disposal container**. **Do not** throw away the needle or syringe in your household trash.

Actor portrayal.

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Disposing of your injection materials

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
- ✓ Sits upright and is stable during use
- ✓ Is leak-resistant
- ✓ Is properly labeled to warn of hazardous waste inside the container

When your sharps disposal container is almost full, you will need to follow community guidelines, as well as state or local laws, for the right way to dispose of it.

Do not recycle your sharps disposal container.

Keep the sharps disposal container out of the reach of children.



Disposal don'ts

- **Do not** throw away (dispose of) your used sharps disposal container in your household trash unless your community guidelines permit this
- **Do not** recycle your used sharps disposal container

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6.

Missed injection

See the diagram for instructions on what to do if you miss an injection. The action and timing depend on your injection schedule and how many days after your missed dose you are able to inject. Follow the instructions—**do not double your dose**. If you are ever unsure about what to do, call your doctor.



Missed dose example for a once-weekly injection

Maria usually injects once weekly, on Mondays. She realizes on Saturday that she missed her dose (by 5 days). Following the “Missed by more than 4 days” instructions, she injects her missed dose immediately on Saturday, and then takes her next injection 3 days later, on Tuesday. Moving forward, she resumes her regular schedule, injecting once weekly on Mondays.

Be sure to confirm any change in your dosing schedule with your healthcare provider.

Hypothetical patient.

Please see full Important Safety Information on [page 19](#), and MIMRYLO (rusfertide) full [Prescribing Information](#), including Patient Information, and full [Instructions for Use](#).

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What if an injection is missed?

If you inject **once** a week

Missed by
1 to 4 days



Inject missed dose
immediately



Resume regular
schedule*

Missed by
more than 4 days



Inject missed dose
immediately



Take next injection
3 days later



Resume regular
schedule*

If you inject **twice** a week

Missed by
1 to 2 days



Inject missed dose
immediately



Take next injection
3 days later



Resume regular
schedule*

Missed by
more than 2 days



Skip missed
injection



Resume regular
schedule*

*Confirm any change in your dosing schedule with your healthcare provider.

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7.

Frequently asked questions

1. What should I do if the mixture looks foamy?

Even gentle swirling can introduce air that causes foam. For this reason, it's important to let the mixture **sit for about 1 minute** after mixing (reconstitution), to allow the foam to settle. A very small amount of foam may remain. When your healthcare team trains you on administration, they will let you know what the mixture should look like.

2. What should I do if there are air bubbles in the syringe?

It is normal to have an air gap or bubbles **in the syringe after drawing liquid**. These bubbles are removed by tapping the syringe and carefully pushing the syringe plunger rod.

3. What should I do if the mixture looks colored, not clear?

Do not use the medicine vial if the liquid looks colored. Contact us at 1-844-817-6468 for a replacement.*

4. What should I do if I see particles in the mixture?

Do not use the medicine vial if the liquid contains particles. Reconstitute a different vial of the same dose and contact us at 1-844-817-6468 for a replacement.*

5. What should I do if I drop the syringe?

If the syringe is dropped without the needle cap on, or if it is damaged from the fall, **do not use it**. Reconstitute a different vial of the same dose, and prepare a new syringe. Contact us at 1-844-817-6468 for a replacement.*

Hypothetical patient.

*Ensure you keep the original packaging to help with investigating any quality issues.

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rusfertide_{for injection}

6. What should I do if the needle is bent?

If the needle looks bent or damaged, **do not use it**. Contact us at 1-844-817-6468 for a replacement.*

7. What should I do if any supplies are opened, damaged, missing, or MIMRYLO is expired?

If anything in the carton is opened, damaged, missing, or MIMRYLO is expired, **do not use it**. Contact us at 1-844-817-6468 for a replacement.*

8. Can I use the same syringe again if I'm the only one using it?

No. All MIMRYLO supplies, including needles and syringes, are **single use only** and cannot be reused.

9. What if I reconstitute the mixture but can't do the injection until later?

Do not prepare MIMRYLO for injection until you are ready to inject. Keep the medicine at room temperature after mixing and inject **within 4 hours**. If the mixture sits for more than 4 hours, it cannot be used.

10. What should I do if I forget or cannot get to my lab appointment?

Call the lab to reschedule for the soonest available appointment. **Let your doctor's office know** about the new date or if there are any issues with prompt rescheduling.

We're Here2Assist®

Get more answers

See "Troubleshooting MIMRYLO injection issues" in the **Step-by-Step Injection Guide** (included in this Welcome Kit) for additional guidance. If you have other questions or concerns, **reach out to your doctor, visit [MIMRYLO.com](https://mimrylo.com), or sign up for MIMRYLO Patient Support**, a Takeda program that offers financial assistance, nurse support, and educational resources.

*Ensure you keep the original packaging to help with investigating any quality issues.

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8.

Resources and support

Watch a MIMRYLO injection video

Your healthcare team will train you on how to administer MIMRYLO. However, if you want a refresher, you can watch an [injection training video](#).

Call us

You can reach Takeda at 1-877-TAKEDA-7 (1-877-825-3327) if you have questions or concerns about MIMRYLO.

Visit the website

Learn about the safety profile and effectiveness of MIMRYLO, how it works, and other important information at [MIMRYLO.com](https://mimrylo.com).

We're Here2Assist®

Sign up for MIMRYLO Patient Support

[MIMRYLO Patient Support](#) is a Takeda program that includes educational resources, financial assistance, text message reminders, and other services. The program connects patients with a case manager, and offers translators who cover more than 200 languages.

The MIMRYLO Patient Support team is available to answer questions at 1-844-817-6468 Monday-Friday, 8 AM-8 PM ET.

See the full [Instructions for Use](#) for complete information about storing, mixing, and administering MIMRYLO.

Hypothetical patient.

Please see full Important Safety Information on [page 19](#), and MIMRYLO (rusfertide) full [Prescribing Information](#), including Patient Information, and full [Instructions for Use](#).

Mimrylo
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Indication & Important Safety Information

What is MIMRYLO (rusfertide)?

MIMRYLO is a prescription medicine that is used to treat erythrocytosis (high red blood cell count) in adults with polycythemia vera.

It is not known if MIMRYLO is safe and effective in children.

IMPORTANT SAFETY INFORMATION

Before using MIMRYLO, tell your healthcare provider about all of your medical conditions, including if you:

- are pregnant or plan to become pregnant. MIMRYLO may harm your unborn baby.

Females who are able to become pregnant:

- Your healthcare provider may do a pregnancy test before you start treatment with MIMRYLO.
- Use effective birth control (contraception) during treatment and for at least 30 days after the final dose of MIMRYLO.
- Tell your healthcare provider right away if you become pregnant or think that you may be pregnant during treatment with MIMRYLO.
- Stop taking MIMRYLO if you become pregnant.
- are breastfeeding or plan to breastfeed. It is not known if MIMRYLO passes into your breast milk. Do not breastfeed during treatment with MIMRYLO and for 30 days after the final dose of MIMRYLO. Talk to your healthcare provider about the best way to feed your baby during this time.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What are the possible side effects of MIMRYLO?

MIMRYLO may cause serious side effects, including:

- **New or worsening increased blood platelets (thrombocytosis).** MIMRYLO may increase blood platelet counts. Your healthcare provider will do blood tests when you start and during treatment with MIMRYLO to check your platelet counts.
- **Injection site reactions.** MIMRYLO may cause injection-site reactions such as redness, itching, pain, swelling, bruising, hardening at the injection site, and irritation. If you get an injection site reaction, apply ice packs, steroid cream, or take medicines as needed to treat injection site pain and swelling.

Your healthcare provider may change your dose or stop treatment with MIMRYLO if you have side effects.

The most common side effects of MIMRYLO are:

- injection site reactions
- low red blood cell count (anemia)

These are not all of the possible side effects of MIMRYLO. Call your doctor for medical advice about side effects. **You may report side effects to Takeda at 1-844-662-8532 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**

Please see Patient Information in the MIMRYLO (rusfertide) full Prescribing Information.



Mimrylo™

rusfertide^{for}
injection

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