

Step-by-Step Injection Guide

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.

This guide is a quick reference to aid the injection process. Please see the full **Instructions for Use** for complete information before reconstituting and administering MIMRYLO.

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

Overview

Keep this guide in front of you as you prepare and inject your medication. It helps reinforce the injection training your healthcare team provided. You can find an additional refresher on the injection process by watching the [Injection Training Video](#) at [MIMRYLO.com/injection-video](https://mimrylo.com/injection-video).

Do not inject yourself or someone else until a healthcare team member has shown you how to inject MIMRYLO.

What to expect when preparing and injecting MIMRYLO

1. Prepare

- Setting up

2. Mix

- Attaching the vial adapter
- Attaching the diluent syringe
- Mixing the medicine

3. Draw syringe

- Drawing the medicine
- Removing the empty vial from the syringe

4. Inject

- Getting ready to inject the medicine
- Choosing and cleaning the injection site(s)
- Preparing the needle
- Giving the injection
- After injecting the medicine

5. Dispose

- Disposal

Troubleshooting

**Important
Safety Information**

What you will need

Provided in the MIMRYLO Drug Kit:

- 1 MIMRYLO vial (single-dose powder)
- 2 Prefilled syringe

Provided in a separate kit:

- 3 Vial adapter (single-use)
- 4 Needle (single-use) with needle shield and cap

Additional supplies you can get from a pharmacy:

- 5 Alcohol swabs
- 6 Cotton ball, gauze, adhesive bandage
- 7 Sharps container





Setting up

Use the MIMRYLO injection placemat

After washing your hands, place the items from the MIMRYLO carton and additional supplies on the placemat. This ensures you have everything you need before you begin.

- Do not remove the prefilled syringe from the carton by its plunger rod or syringe cap
- Do not use if any of the supplies are opened, damaged or missing

Double-check the prescription strength and expiration date on the MIMRYLO carton. Do not use MIMRYLO if the expiration date has passed, and contact your healthcare provider.

Attaching the vial adapter

Remove the cap and clean the medicine vial

Take off the cap from the medicine vial and clean the top with a new alcohol swab. Open the vial adapter packaging.

- Do not touch the top of the vial after cleaning
- Do not let the vial adapter spike touch your hands or any surface
- Do not remove the vial adapter from its plastic packaging



Actor portrayal.

Attaching the vial adapter (continued)



Attaching the vial adapter (continued)

Attach the vial adapter to the medicine vial

Push the adapter straight down until it snaps and is fully attached.

- Do not let the vial adapter spike touch your hands or any surface
- Do not remove the vial adapter from its plastic packaging
- Do not attach the vial adapter at an angle
- Do not remove the vial adapter from the medicine vial after it is attached



Actor portrayal.

Attaching the
diluent syringe





Actor portrayal.

Attaching the diluent syringe

Attach the prefilled syringe to the vial adapter

Twist off the syringe cap, and attach the syringe to the vial adapter by turning it clockwise until snug.

- Do not tighten too much
- Do not push the plunger as it may spill the diluent



Attaching the vial adapter

Mixing the medicine





Actor portrayal.

Mixing the medicine

Inject the diluent and gently swirl to mix

Inject all of the diluent into the medicine vial by slowly pushing down on the plunger rod.

Once they are combined, mix the diluent and medicine together by slowly and gently swirling until the powder is fully dissolved. This may take about 2 minutes.

Let the mixed medicine sit for about a minute and then check the liquid to be sure it's clear with very little foam.

- Do not remove the prefilled syringe from the medicine vial
- Do not shake the medicine vial
- Do not use the medicine vial if the liquid looks colored or contains particles

← Attaching the diluent syringe

a.



b.



Actor portrayal.

c.



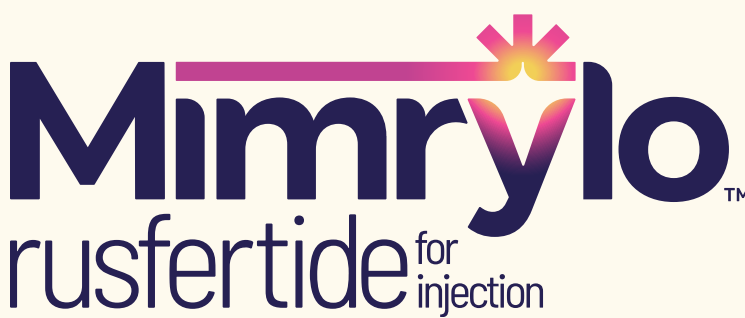
Actor portrayal.

Drawing the medicine

- a. Make sure the syringe plunger rod is pressed down all the way to remove any air.
- b. Turn the syringe upside down so the medicine vial is on top.
- c. Slowly pull the syringe plunger rod down to fill the syringe with the mixed medicine.

Note:
It is normal to have an air gap or bubbles in the syringe after drawing liquid.

Removing the empty vial from the syringe →





Removing the empty vial from the syringe

- Hold the syringe by the body with one hand. With the other hand, grasp the vial adapter and turn it counter-clockwise to remove it from the syringe.
- Dispose of the empty medicine vial into an FDA-cleared sharps disposal container.
 - Do not touch the syringe tip or allow it to touch any surface
 - Do not touch or push the plunger rod until you are ready to inject



**Drawing the
medicine**

Getting ready to inject the medicine

Attach the needle to the syringe

Hold the syringe by the body with one hand, and with the other hand, attach the needle onto the syringe by turning to the right (clockwise) until it is snug.

- Do not touch the open end of the needle



Actor portrayal.

Choosing and cleaning the injection site(s) →

Choosing and cleaning the injection site(s)

Recommended sites: stomach (at least 2 inches from belly button), front of thigh, back of upper arm (administered with the assistance of a caregiver).

Change (rotate) sites for each injection.

Clean the chosen injection site with an alcohol swab and let it air dry.

- Do not inject the same spot twice in a row
- Do not inject where skin is tender, bruised, red, irritated, hard, or broken
- Do not touch the cleaned area again before injecting
- Do not fan or blow on the clean site



Actor portrayals.

← Getting ready to inject the medicine

Preparing the needle →



Preparing the needle

- Hold the syringe by the body with the needle pointing up and firmly pull the needle cap straight off.
- Tap the syringe with your finger to move any air or bubbles to the syringe tip.
- Then, slowly and carefully push the syringe plunger rod to remove air gaps or bubbles.

It is ok if a small air gap or bubbles are left in the syringe.

- 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

← **Choosing and cleaning the injection site(s)**

Giving the injection →

Giving the injection

Use 1 hand to pinch the skin, then insert the needle into the pinched skin at a 45° to 90° angle and slowly push the plunger rod to inject all the medicine.

After all of the medicine is injected, pull the needle and syringe out of the skin at the same angle you inserted it.



Actor portrayals.



Preparing
the needle

After injecting
the medicine



After injecting the medicine

If there is bleeding at the injection site

Gently press a cotton ball or gauze pad on the site and hold it there for 10 seconds.

Cover with an adhesive bandage if needed.

- Do not rub the injection site
- If your dosage requires 2 injections on the same day, repeat the above steps



Actor portrayals.



Giving the injection

Disposal

Dispose of the needle and syringe

Right after injecting, put the needle shield on a hard surface and carefully push the needle shield over the needle until it snaps into place. Throw away the used syringe with the needle attached into an FDA-cleared sharps disposal container.

- Do not try to remove the needle from the syringe
- Do not recap or touch the needle
- Do not throw away the needle or syringe in your household trash
- Do not throw away your used sharps disposal container in your household trash unless your community guidelines permit this

See the [Dosing & Administration Guide](#) and the full [Instructions for Use](#) for more information about appropriate disposal.



Actor portrayal.

Troubleshooting MIMRYLO injection issues

Syringe, needle, and vial issues

Issue	Action
The vial was dropped	If the vial is dropped before anything is attached, check for cracks or leaks . If the vial adapter has been attached or medicine has been mixed and the vial is dropped, it cannot be used .
The adapter doesn't snap	Ensure that you are pushing the adapter straight down onto the top of the medicine vial, with the vial held firmly on a flat surface.
Syringe dropped	If the syringe is dropped without the needle cap on, do not use it. Contact us at 1-844-817-6468 for a replacement.*
Needle is bent or damaged	If the needle looks bent or damaged, do not use it. Contact us at 1-844-817-6468 for a replacement.*
Unable to attach needle	Ensure that you are turning the needle to the right, in a clockwise direction with one hand until it is snug , while holding the syringe still in the other hand.

Reconstitution (mixing liquid and powder) issues

Issue	Action
Medicine is leaking from the device	Do not use. Contact us at 1-844-817-6468 for a replacement.*
The powder is not dissolving	Continue to swirl the mixture. Do not shake it. If the powder does not dissolve after swirling, set it aside and use a different vial. Contact us at 1-844-817-6468 for a replacement.*
The solution looks cloudy, colored, or has particles in it	Do not use. Contact us at 1-844-817-6468 for a replacement.*
Air bubbles in the syringe	It is normal to have an air gap or bubbles in the syringe after drawing the liquid. These bubbles are removed by tapping the syringe and carefully pushing the syringe plunger rod . It is ok if a small air gap remains. Be careful not to lose any drops of medicine.

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

If you're having trouble assembling your injection or mixing your medicine, please contact your doctor or reach out to **MIMRYLO Patient Support—we're Here2Assist®**.



1. Prepare

2. Mix

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4. Inject

5. Dispose

Troubleshooting

Important Safety Information

Troubleshooting MIMRYLO injection issues

Injection concerns

Issue	Action
Mild bleeding	For 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. If this doesn't stop the bleeding, call your doctor.
Redness, itching, or pain at the injection site	These were common side effects of MIMRYLO in clinical trials. If you have any concerns about side effects, contact your doctor.

Dosing questions

Issue	Action
Missed dose	If you miss a dose, the action and timing depend on your injection schedule and how many days after your missed dose you are able to do the injection. Follow the instructions for missed doses in the Dosing & Administration Guide. Do not double your dose. If you are ever unsure about what to do, call your doctor.
Unsure if 2 injections are needed	If you are certain of the dose, refer to the Dosing & Administration Guide to see which doses require 2 injections, and on what schedule (either both the same day or several days apart). If you are not certain of the correct dose, call your doctor.

If you have other questions or concerns, please reach out to your doctor or pharmacist.



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Troubleshooting

Important Safety
Information

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.

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

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.**



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Troubleshooting

Important Safety Information

Call your doctor if you...

- Miss your injection
- Are unsure of your current dose or schedule of MIMRYLO
- Take the wrong dose
- Are experiencing worrisome symptoms, regardless of whether you think they're caused by your condition, your treatment, or something else

Go to the emergency room if you are experiencing a medical emergency.



Hypothetical patient.

We're Here2Assist®

Sign up for MIMRYLO
Patient Support