A new era in PV starts now

Discover how MIMRYLO maintained hematocrit control, reduced reliance on rescue phlebotomies, and delivered relief from fatigue vs placebo

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.

Please see additional Important Safety Information throughout, full Important Safety Information on **page 18**, and **Patient Information** in the MIMRYLO (rusfertide) full **Prescribing Information**.

Mimrylo™
rusfertide for injection

Living with PV may mean ongoing challenges with HCT control and symptoms

Polycythemia vera (polly-sy-THEE-me-uh VEER-uh), or PV, is a rare, chronic blood cancer that affects about 90,000 people in the United States.

In PV, the body makes too many red blood cells, a condition known as erythrocytosis. When this happens, the blood can become thicker than normal.

For some people, living with PV may mean ongoing challenges with keeping hematocrit, or HCT, controlled and managing symptoms that can affect daily life.

Up to

78%

of people with PV

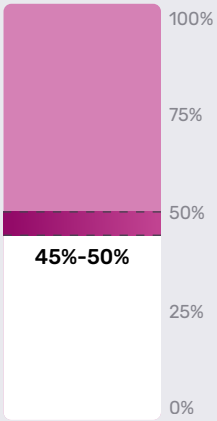
may not be able to keep their HCT below 45%, even with treatment

Hypothetical patient.

Keeping HCT below 45% matters

HCT is the percentage of red blood cells in your blood. In PV, too many red blood cells can cause HCT to rise.

When HCT remains too high, blood may not flow as easily. This can increase the risk of serious complications, such as: **blood clots**, **heart problems**, **and strokes**.



People with HCT levels of **45%-50%** had approximately

~4x higher risk

of serious blood clot-related events or death from heart-related problems compared to those with HCT levels below 45%.

Symptoms can still affect day-to-day life

Even when focusing on HCT control, ongoing symptoms may still take a toll on how you feel day to day.

These symptoms may affect:

- **Physical comfort**
- **Emotional well-being**
- **Everyday routines**

Talking with your doctor about treatment goals

If you are living with PV, talk with your doctor about your treatment goals, including keeping your HCT controlled and managing your symptoms.

MIMRYLO is a first-of-its-kind treatment for adults with PV

MIMRYLO is a type of medicine called a hepcidin mimetic for erythrocytosis in adults with PV. MIMRYLO helps regulate iron in the body to reduce the production of excess red blood cells. MIMRYLO was studied in adults with PV, including people receiving rescue phlebotomies alone or with other PV treatments.

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.

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Fewer rescue phlebotomies:

In a clinical study, 77% of people taking MIMRYLO required fewer rescue phlebotomies during the main study period compared with 33% on placebo.

In the clinical trial, this was called phlebotomy ineligibility.

Maintain hematocrit (HCT) control:

MIMRYLO helped more people (63%) maintain HCT control during the main study period compared with placebo (14%).

Relief from fatigue:

At Month 7 in a clinical study, people taking MIMRYLO reported reduced fatigue compared to placebo.

Self-administered once weekly:

An injection under the skin (subcutaneous), taken at the dose and schedule your doctor prescribes.

During the study, a validated survey was used to capture self-reported fatigue over time. The survey used to measure fatigue was the PROMIS Fatigue Short Form 8a, with lower scores indicating improvement.

Please see full information on the study, its design, and results on pages 8-13.

IMPORTANT SAFETY INFORMATION (cont'd)

Females who are able to become pregnant (cont'd):

- 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.

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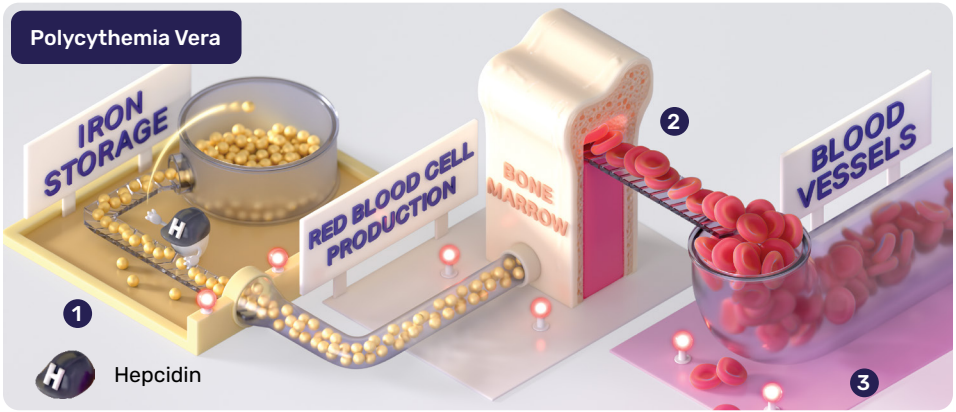
With erythrocytosis in PV, your body produces too many red blood cells

Think of your body's process for making red blood cells like an assembly line in a factory. A key raw material is the mineral iron. Normally, hepcidin (the body's natural iron manager) helps make sure the right amount of iron is released. In people with PV, the body's bone marrow does not allow the iron manager (hepcidin) to control the iron levels. Because of this, your body produces too many red blood cells.

1. In people with PV, it's like there aren't enough managers (hepcidin) for the job, so the iron supply isn't controlled the way it should be...
2. ...and extra iron is sent to the bone marrow, where red blood cells are made. This fuels excess red blood cell production.
3. Overproduction of red blood cells can make blood thicker, and affect how blood flows through the body.



IMPORTANT SAFETY INFORMATION (cont'd)

Before using MIMRYLO, tell your healthcare provider about all of your medical conditions, including if you (cont'd):

- 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.

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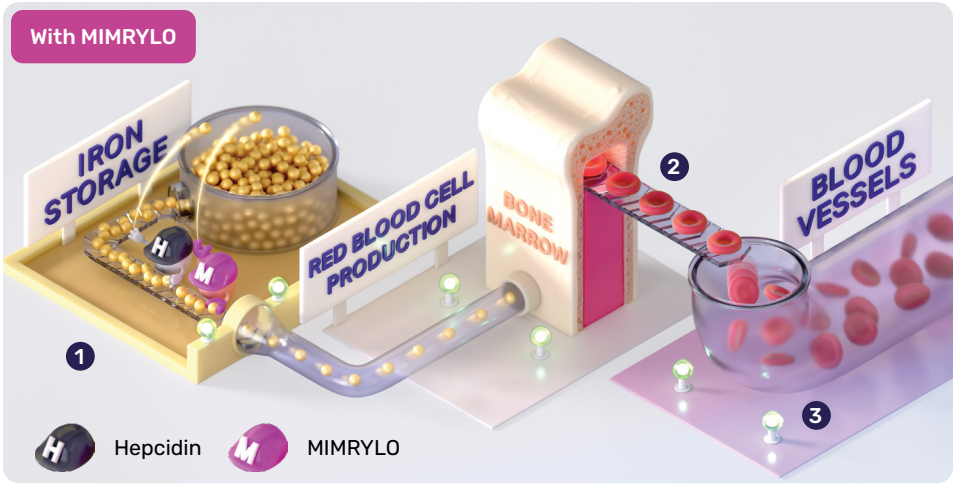
MIMRYLO works with your body to control red blood cell production by managing iron

1. This is where MIMRYLO comes in. MIMRYLO is a therapy that acts like the body's natural iron manager, hepcidin.
2. MIMRYLO helps by limiting how much iron moves down the line to the bone marrow, where red blood cells are made.
3. Less iron in the bone marrow helps to balance red blood cell production, so blood can flow more easily through the body.



IMPORTANT SAFETY INFORMATION (cont'd)

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.

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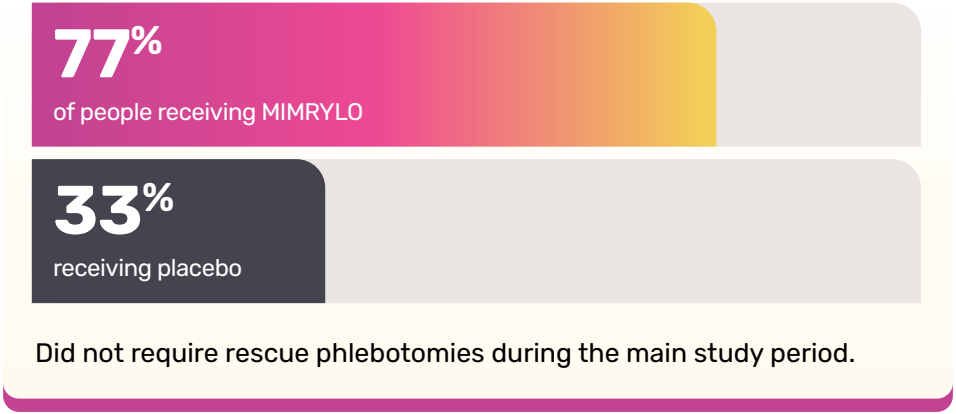
77% of people taking MIMRYLO did not require rescue phlebotomies to keep their HCT controlled



During the study, participants continued the PV treatment they were already receiving. Rescue phlebotomies could be given if needed.

About the study:
MIMRYLO was evaluated in a clinical study called VERIFY in 293 adults with PV who needed frequent rescue phlebotomies before entering the study. During the 7-month main study period, people received either MIMRYLO or placebo, along with the PV treatment they were already receiving. Rescue phlebotomies could be given if needed. Researchers measured how many people avoided rescue phlebotomies while keeping their HCT controlled.

IMPORTANT SAFETY INFORMATION (cont'd)

MIMRYLO may cause serious side effects, including (cont'd):

- **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.

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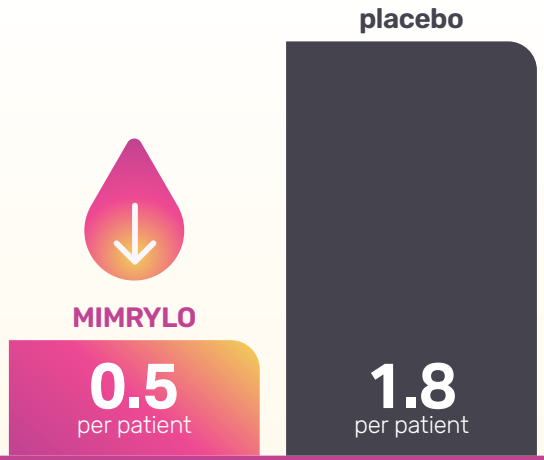
MIMRYLO reduced the need for rescue phlebotomies



People receiving MIMRYLO required over

3x fewer rescue phlebotomies

than people receiving placebo over about 7 months.

Average number of rescue phlebotomies per person

During the study, participants continued the PV treatment they were already receiving. Rescue phlebotomies could be given if needed.

IMPORTANT SAFETY INFORMATION (cont'd)

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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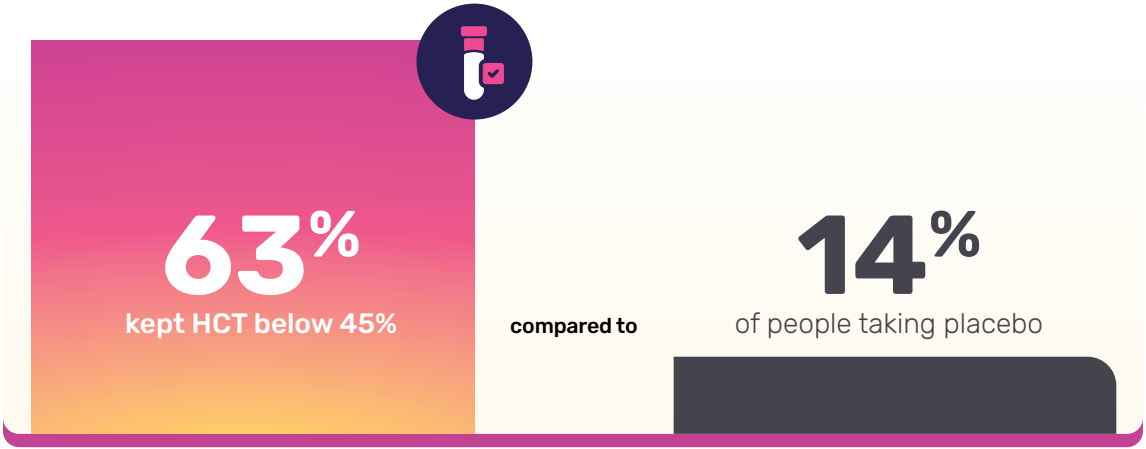
63% of people taking MIMRYLO kept their HCT below 45%*



A reduction in HCT was seen within 4 weeks after switching to MIMRYLO

During the study, participants continued the PV treatment they were already receiving. Rescue phlebotomies could be given if needed.
*A single HCT fluctuation ≥45% was permitted.

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.

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Mimrylo™ rusfertide for injection

MIMRYLO provided relief from fatigue

In the VERIFY study, people taking MIMRYLO reported reduced fatigue compared to placebo at Month 7

During the study, a validated survey was used to capture self-reported fatigue over time.*

Hypothetical patient.

*The survey used to measure fatigue was the PROMIS Fatigue Short Form 8a, with lower scores indicating improvement.

IMPORTANT SAFETY INFORMATION (cont'd)

Females who are able to become pregnant (cont'd):

- 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.

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Mimrylo™ rusfertide for injection

MIMRYLO has a favorable safety profile

Certain side effects were seen in people taking MIMRYLO. In the 7-month clinical study, the most common side effects were:

Injection site reactions

Redness, itching, pain, swelling, bruising, hardening (at the injection site), and irritation.

99% of injection site reactions were mild to moderate.

Low red blood cell count

(also known as anemia)

All cases of anemia were mild to moderate.

Your doctor will monitor your blood counts during treatment and can help you manage side effects if they occur.

The side effects seen with MIMRYLO were similar in additional follow-up studies.

In the 7-month clinical study, serious side effects were rare. Anemia was the only one, occurring in less than 1% (0.4%) of people taking MIMRYLO. A small number of people stopped treatment due to side effects like injection site reactions (0.7%), increased platelets (0.7%), or anemia (0.4%).

IMPORTANT SAFETY INFORMATION (cont'd)

Before using MIMRYLO, tell your healthcare provider about all of your medical conditions, including if you (cont'd):

- 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.

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Mimrylo™ rusfertide for injection

Additional safety information

94%

remained on therapy into the long-term portion of the study.

Injection site reactions became

less common over time.

Among people taking MIMRYLO who experienced injection site reactions, these reactions were reported less often later in treatment than earlier in treatment.

IMPORTANT SAFETY INFORMATION (cont'd)

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.

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Mimrylo™ rusfertide for injection

What to expect when starting MIMRYLO

Start

Treatment begins with 19 mg once weekly. You will receive your first injection and training by your healthcare provider.

Adjust

After treatment begins, your healthcare provider may adjust your dose based on how your body responds, HCT levels, and any side effects. Blood tests will be checked regularly, especially during dose adjustments.

Maintain

Once your HCT is under control, you will continue taking your prescribed dose once weekly, or as directed by your healthcare provider.

IMPORTANT SAFETY INFORMATION (cont'd)

MIMRYLO may cause serious side effects, including (cont'd):

- **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.

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Resources to help you get started on MIMRYLO

Your Welcome Kit and educational resources can help you learn about dosing, injection steps, and what to expect with treatment.

Welcome Kit

Includes helpful materials such as injection training resources, printed dosing guidance, important safety information, and contact information for support services.

Watch and learn

Access helpful resources, including:

- Dosing & Administration Guide
- Step-by-Step Injection Video
- Patient Information

View resources

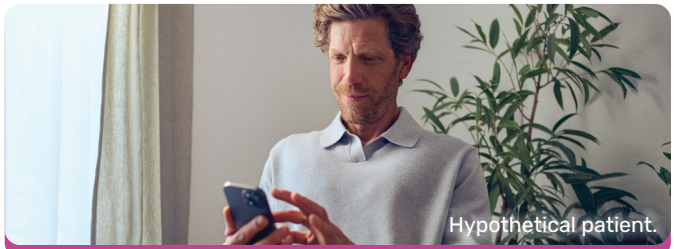
Support groups, communities, and organizations

Living with PV can bring questions over time. Community organizations and educational resources may help you stay informed, connected, and supported.

Connect with your community

Patient advocacy groups may offer education, community connection, and support for people living with PV.

Explore patient advocacy groups



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Mimrylo™ rusfertide for injection

MIMRYLO Patient Support overview

We're Here2Assist®

MIMRYLO Patient Support is a comprehensive patient support program that includes:

Access support

- Working with your insurance company to help you get started on your Takeda medication
- Helping to fill and ship your prescriptions through a network of specialty pharmacies*

Financial assistance

- Identifying available financial assistance that may be right for you, including co-payment assistance

Nursing support

- Providing one-on-one nurse-led self-injection trainings where patients who have been prescribed MIMRYLO™ (rusfertide) can receive expert guidance and support from one of our Nurse Navigators

Helpful resources

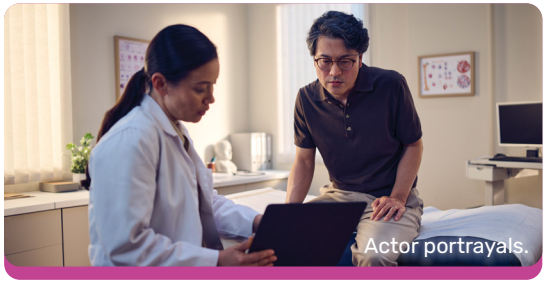
- Conducting regular follow-ups for support along the way
- Sending you status updates and reminders via text message†
- Connecting you to additional support services and resources

*A specialty pharmacy manages medications for complex conditions that require specialized handling, storage, or administration.
†Patients will need to enroll in the texting program to receive text messages.

Mimrylo™ rusfertide for injection

Enroll in MIMRYLO Patient Support

Support through your MIMRYLO journey



Starting a new treatment can be overwhelming—navigating insurance, administration, and questions. When you start MIMRYLO, you can enroll in MIMRYLO Patient Support, which offers personalized support to help you every step of the way. We also have additional services like nursing support and Welcome Kits to help support you.

Together, we got this:

Financial assistance

If you need assistance affording your medication, **MIMRYLO Patient Support** can help identify financial assistance programs that may be able to help you with the cost of your treatment.

Welcome Kit

Starting a new treatment can be tricky, but we've put together a kit that will help you feel comfortable and confident as you get started with MIMRYLO.

Nursing support

Do you have questions on how to use MIMRYLO? Do you need help with your injections? Over the course of your injection education training session, your Nurse Navigators can help you learn more about the self-administration process.

Learn more about financial assistance programs, request a Welcome Kit, or connect with a Nurse Navigator.

Enroll in MIMRYLO Patient Support

Mimrylo™ rusfertide for injection

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

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- 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.
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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

MIMRYLO: a different kind of treatment for erythrocytosis in adults living with PV.

While on MIMRYLO, you may experience:

- Fewer rescue phlebotomies vs placebo
- Consistent HCT control
- Reduced fatigue vs placebo
- A once-weekly self-administered treatment, as prescribed by your doctor

If you are living with PV and continue to require frequent rescue phlebotomies or other PV medications, talk to your doctor about whether MIMRYLO may be right for you.

To learn more, visit MIMRYLO.com

IMPORTANT SAFETY INFORMATION (cont'd)

The most common side effects of MIMRYLO are:

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

Please see additional Important Safety Information throughout, full Important Safety Information on **page 18**, and **Patient Information** in the MIMRYLO (rusfertide) full **Prescribing Information**.

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