



# Help **Take Control Of** Your Polycythemia Vera (PV) With **BESREMi**

What you need to know if you're considering or starting BESREMi



## **What is BESREMi?**

BESREMi is a prescription medicine that is used to treat adults with polycythemia vera.

## **IMPORTANT SAFETY INFORMATION**

### **What is the most important information I should know about BESREMi?**

**BESREMi can cause serious side effects that may cause death or may worsen certain serious diseases that you may already have. Tell your healthcare provider right away if you have any serious side effects during treatment with BESREMi. If symptoms get worse, or become severe and continue, your healthcare provider may tell you to stop taking BESREMi. These symptoms may go away in some people after they stop taking BESREMi.**

**Please see additional Important Safety Information throughout and full [Prescribing Information](#), including [Boxed Warning](#) and [Medication Guide](#).**



# What is PV?

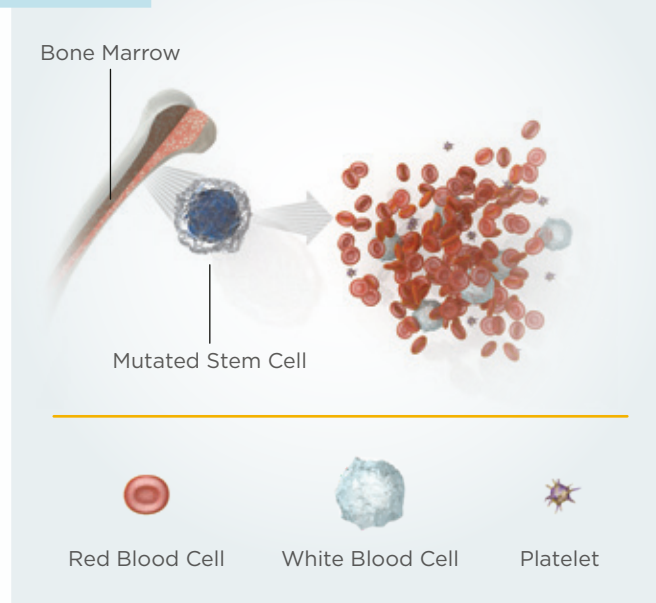
**Polycythemia vera (PAH-lee-sy-THEE-mee-uh VAYR-uh) is a rare and chronic blood cancer. It's part of a group of blood cancers called myeloproliferative neoplasms (MY-eh-loh-proh-LIH-feh-ruh-tiv NEE-oh-PLA-zums), or MPNs. It's possible to have PV for years before a diagnosis is made.**

Stem cells in the bone marrow make all the blood cells in your body: red blood cells, white blood cells, and platelets. Normally, your body keeps these blood cells in balance.

PV occurs when a hematopoietic (hee-MA-toh-poy-ET-tik) stem cell in the bone marrow develops a mutation (or DNA change) and starts to make too many blood cells. Too many blood cells can cause the blood to thicken and not flow properly. For most people, this DNA change is caused by something called a *JAK2* mutation. In PV, 1 or more types of blood cells may be overproduced.

**It starts in the bone marrow**

## PV blood cell production

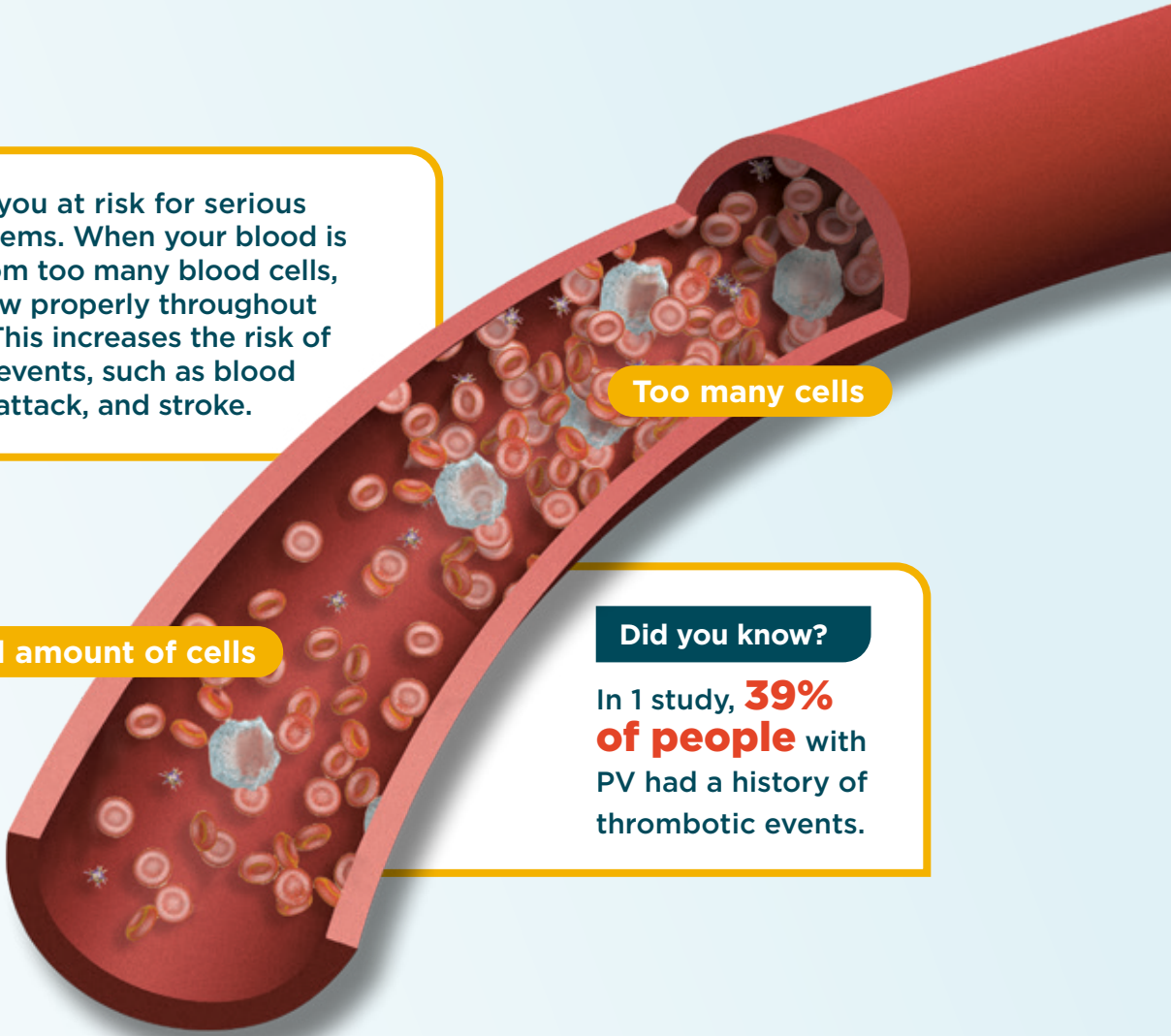


# Treating PV for the long term

When managing PV, keeping all blood cell counts—red blood cells, white blood cells, and platelets—under control is critical.

To effectively monitor PV, it's important for your doctor to measure your complete hematologic response. When measuring this, your doctor should focus on:

- All blood cell counts (red, white, platelets)
  - Hematocrit (red blood cell) level should be less than 45%
  - White blood cell count should be less than or equal to  $10 \times 10^9/L$
  - Platelet count should be less than or equal to  $400 \times 10^9/L$
- Time since last phlebotomy



PV can put you at risk for serious health problems. When your blood is too thick from too many blood cells, it cannot flow properly throughout your body. This increases the risk of thrombotic events, such as blood clots, heart attack, and stroke.

Too many cells

Normal amount of cells

Did you know?

In 1 study, **39%** of people with PV had a history of thrombotic events.

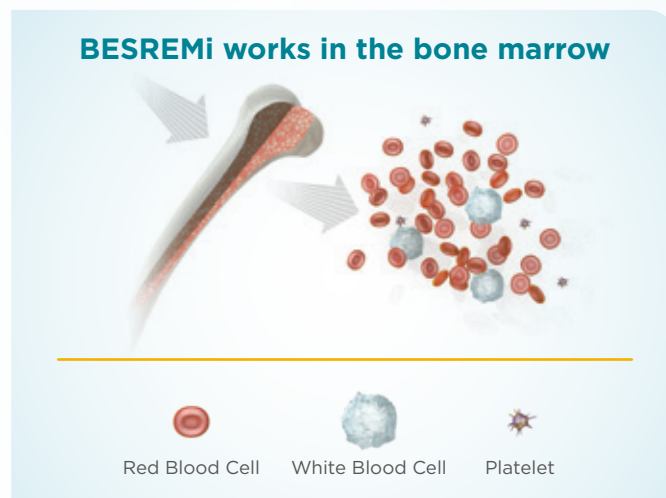
## How BESREMi works

### An innovative approach for your PV

BESREMi (bez-REH-me) is different from many other therapies for PV.

- BESREMi is not a chemotherapy—it's an innovative biologic interferon specifically designed to target PV at its source
- Interferons are natural proteins that tell your immune system when cancer cells are present in your body and trigger immune cells to fight them

### BESREMi works at the source of PV in the bone marrow



### IMPORTANT SAFETY INFORMATION (continued)

#### What is the most important information I should know about BESREMi? (continued)

- Mental health problems, including suicide: BESREMi may cause you to develop mood or behavior problems that may get worse during treatment with BESREMi or after your last dose, including 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, or thoughts of hurting yourself or others, or thoughts of suicide. If you develop any of these symptoms, you, your caregiver, or family member should call your healthcare provider immediately. Your healthcare provider should carefully monitor you during treatment with BESREMi.
- New or worsening autoimmune problems: BESREMi may cause autoimmune problems (a condition where the body's immune cells attack other cells or organs in the body), including thyroid problems, increased blood sugar (hyperglycemia), and type I diabetes. In some people who already have an autoimmune problem, it may get worse during your treatment with BESREMi. Tell your healthcare provider if you have tiredness, are urinating often, or if you are very thirsty.

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# How BESREMi works (continued)

## BESREMi was studied in a broad range of patients with PV

A clinical study of BESREMi in adults diagnosed with PV looked at efficacy (how much it helped), dosing, and safety.

### Patients were included regardless of:

- History of cardiovascular events
- Prior treatment with hydroxyurea (HU), a type of chemotherapy

Length of study:  
**7.5 years**

### Characteristics of the patients who took BESREMi in the clinical study:



Age range



Treated with HU



Had a previous  
thrombotic event

## IMPORTANT SAFETY INFORMATION (continued)

### What is the most important information I should know about BESREMi? (continued)

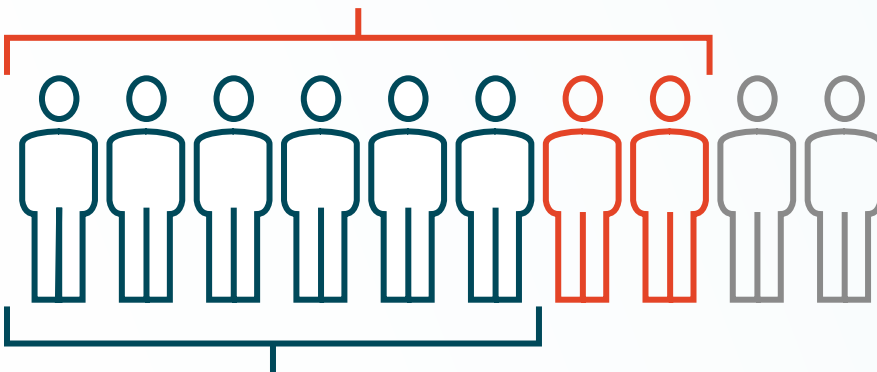
- Heart problems: BESREMi may cause heart problems, including problems with your heart muscle (cardiomyopathy), heart attack, abnormal heart rhythm (atrial fibrillation), and decreased blood flow to your heart. You should not use BESREMi if you have high blood pressure that is not controlled, congestive heart failure, a serious abnormal heart rhythm, narrowing of the arteries to your heart, certain types of chest pain (angina), or a recent stroke or heart attack. If you have a heart problem before you start using BESREMi, your healthcare provider should monitor you closely during treatment with BESREMi.

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## Meaningful outcomes

### 8 out of 10 patients achieved complete hematologic response, which means:

- Blood cell counts (red, white, and platelets) returned to a normal level
  - Hematocrit (red blood cell) level was less than 45%
  - White blood cell count was less than or equal to  $10 \times 10^9/L$
  - Platelet count was less than or equal to  $400 \times 10^9/L$
- No phlebotomy in the past 2 months



As a reminder, complete hematologic response (CHR) is a way to monitor how your treatment is working to control PV.

### 6 out of 10 patients achieved comprehensive disease control, which means:

- Hematocrit (red blood cell) level was less than 45%
- White blood cell count was less than or equal to  $10 \times 10^9/L$
- Platelet count was less than or equal to  $400 \times 10^9/L$
- No phlebotomy in the past 2 months
- No thrombotic events
- Normal spleen size

## IMPORTANT SAFETY INFORMATION (continued)

### Who should not use BESREMi?

Do not use BESREMi if you:

- have or had severe mental health problems, especially severe depression, thoughts of suicide, or attempted suicide
- have or had a serious or untreated autoimmune disease
- have had a serious allergic reaction to another interferon product or to any of the ingredients in BESREMi. Symptoms of a serious allergic reaction may include itching, swelling of your face, tongue, throat, trouble breathing, feeling dizzy or faint, and chest pain
- have certain types of liver problems
- have received a transplant and take immunosuppressive medicines

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# Long-term results

CHR was maintained  
**for more than 7.5 years**

**BESREMi is a biologic interferon that delivers results over time to treat PV.**

- In the clinical study, the median time for patients to achieve comprehensive disease control\* was 7.8 months
- It's important that you keep up with your appointments to monitor your progress with your doctor

\*Comprehensive disease control means red blood cell levels are <45%, white blood cell counts are  $\leq 10 \times 10^9/L$ , platelet counts are  $\leq 400 \times 10^9/L$ , no phlebotomy has occurred in the past 2 months, no thrombotic events have occurred, and the spleen is a normal size.

## IMPORTANT SAFETY INFORMATION (continued)

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

- are being treated for a mental illness or had treatment in the past for any mental illness, including depression and have had thoughts of hurting yourself or others
- have type 1 diabetes
- have or ever had any problems with your heart, including heart attack or high blood pressure
- have or ever had bleeding problems, a blood clot, or low blood cell counts
- have a condition that suppresses your immune system, such as certain cancers
- have hepatitis B or HIV infection
- have kidney or liver problems
- are pregnant or plan to become pregnant. BESREMi may harm your unborn baby and may cause loss of your pregnancy (miscarriage).
  - Before you start using BESREMi your healthcare provider should do a pregnancy test.
  - You should use effective birth control during treatment and for at least 8 weeks after your final dose of BESREMi. Talk to your healthcare provider about birth control choices for you during treatment with BESREMi.
  - BESREMi can affect your menstrual cycles and may cause your menstrual periods to stop.
  - Tell your healthcare provider if you become pregnant during treatment with BESREMi.
- are breastfeeding or plan to breastfeed. It is not known if BESREMi passes into your breast milk. You should not breastfeed during treatment and for 8 weeks after your final dose of BESREMi.

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## What to expect when administering BESREMi

BESREMi is a subcutaneous (just under the skin's surface) injection that you administer at home once every 2 weeks.



**BESREMi syringe (not actual size)**  
The needle is as thin as a strand of hair, much smaller compared to needles used in phlebotomies or flu shots.



[See how patients like you are taking charge of their PV treatment—and more.](#)

- You'll start by taking BESREMi every 2 weeks
- In order to reach stable blood counts,\* your BESREMi dose may need to be increased over time. Your doctor will work with you to increase your dose. Don't modify or stop your dose without talking to your doctor  
\*Hematocrit is <45%, leukocytes are  $\leq 10 \times 10^9/L$ , and platelet count is  $\leq 400 \times 10^9/L$ .
- If you achieve stable blood counts on BESREMi for 1 year, your doctor may reduce your injections to once a month

**You can reach out to your doctor or call PharmaEssentia SOURCE™ at 800-700-5053 for one-on-one injection training.**

### IMPORTANT SAFETY INFORMATION (continued)

#### What are the possible side effects of BESREMi?

BESREMi can cause serious side effects including:

- **Decreased blood cell counts:** Your healthcare provider should check your blood cell counts before you start and during treatment with BESREMi. If your blood cell counts are too low you can develop anemia, infections or have problems with bleeding or bruising. Call your healthcare provider right away if you develop weakness and tiredness, bruising easily, nose bleeds often, fever, chills, burning and painful urination, urinating often, or coughing up yellow or pink mucus (phlegm).

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## Discover patient perspectives



**“At first, the self-injection process felt scary, but I felt pretty comfortable doing it after going on BESREMi’s website and reviewing the video.”**

-Cheri, patient with PV

**“BESREMi is supposed to be taken every 2 weeks. I was able to pick the day that works for me.”**

-Kevin, patient with PV



### **IMPORTANT SAFETY INFORMATION** (continued)

#### **What are the possible side effects of BESREMi?** (continued)

- 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 the face, eyes, lips, tongue or throat; trouble breathing; chest pain; or feeling faint
- Eye problems: BESREMi can cause severe eye problems with your retinas that can lead to vision loss or blindness. You should have an eye exam before and during treatment with BESREMi if you have diabetes or high blood pressure and also have retinal problems. Your healthcare provider may stop BESREMi if you develop new or worse eye problems during treatment with BESREMi.
- Liver problems: BESREMi can cause increases in liver enzymes and liver damage. Your healthcare provider should do blood tests to monitor your liver enzymes and liver function before you start and during treatment with BESREMi.

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## Practical tips to help as you start therapy

Every person may have a different experience taking BESREMi. Since BESREMi is a biologic interferon, it triggers your immune system to start working, which may make you more likely to experience some side effects when you first start taking it. In clinical trials for BESREMi, some of these side effects lessened over time.

Here are some suggestions for how to manage the most common side effects of BESREMi:

### **Flu-like symptoms (such as tiredness, weakness, fever, chills, muscle aches, and joint pain)**

*For many patients, these symptoms diminish over a matter of hours after BESREMi injection.*

- Start injections on a day and time that is convenient for your schedule
- Talk with your doctor about taking acetaminophen to help reduce fever symptoms or ibuprofen to help reduce aches and pains
- Alternate periods of rest and activity
- Stay hydrated

### **Itching**

- Avoid hot showers
- Use unscented body products
- Ask your doctor about taking an antihistamine

### **Sore throat**

- Drink hot tea or hot soup
- Try sucking on lozenges, hard candies, or ice chips
- Gargle salt water

### **Injection site reactions**

- Apply ice to the injection site
- Rotate your injection site



**Talk with your doctor about managing any side effects you might experience.**



**“I did experience influenza-like side effects at first... but I’m not experiencing any now. I really encourage you to reach out to your doctor to gather information about managing side effects knowing that everyone’s experience is different.”**

–Susan, patient with PV

# What happens after your doctor prescribes BESREMi

It's important to understand what to expect before you start BESREMi. There are certain steps that need to be completed before you receive your treatment, and it's normal for these steps to take some time.

After your doctor writes you a prescription for BESREMi, your health plan will follow a review process to determine your coverage before you can receive BESREMi.

Once your coverage is determined, your pharmacy will work with you to deliver your BESREMi.



**Tip:**

**If your pharmacy calls you, save the number in your phone so you know who's calling.**

## PharmaEssentia SOURCE™ is an additional tool to help you navigate your treatment with BESREMi

- BESREMi treatment support and education
- Insurance and financial support options

PharmaEssentia  
**SOURCE™**  
Your resource for patient support & education

Enroll now at [pharmaessentiasource.com](https://pharmaessentiasource.com)  
or call 800-700-5053.

## IMPORTANT SAFETY INFORMATION (continued)

### What are the possible side effects of BESREMi? (continued)

- **Kidney problems:** Your healthcare provider will do blood tests to check your kidney function before starting and during treatment with BESREMi. Tell your healthcare provider right away if you develop any symptoms of a kidney problem, including changes in the amount or color of your urine, blood in your urine, swelling in your ankles, or loss of appetite. Your healthcare provider may stop BESREMi if you develop severe kidney problems.

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# Help **take control** of your PV with **BESREMi**. Visit **BESREMi.com** for more information.

## IMPORTANT SAFETY INFORMATION (continued)

### What are the possible side effects of BESREMi? (continued)

- Tooth and gum (periodontal) problems: BESREMi can cause tooth and gum problems which can lead to tooth loss. BESREMi can also cause problems with dry mouth that can damage your teeth and the lining of the mouth during long-term treatment with BESREMi. It is important for you to brush your teeth well, two times each day and have regular dental examinations during treatment with BESREMi.
- Skin problems: BESREMi can cause skin problems. Signs and symptoms of a skin problem with BESREMi include itching, hair loss, rash, redness, psoriasis, acne, thickening of the skin, or excessive sweating. Call your healthcare provider if you develop a rash that is bothersome or covers a large skin area.

The most common side effects of BESREMi include:

- flu like symptoms including tiredness, weakness, fever, chills, muscle aches, and joint pain
- itching
- sore throat

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