

For adults living with  
primary immunodeficiency

SEE WHAT'S  
**POSSIBLE**

WITH  
**QIVIGY®**

**QIVIGY®**  
(Immune Globulin Intravenous  
Human-kthm) 10% Liquid

Hypothetical patient.

## What is QIVIGY®?

QIVIGY (immune globulin intravenous, human-kthm) is an immune globulin (Ig) liquid used to treat adults with primary humoral immunodeficiency.

## IMPORTANT SAFETY INFORMATION

QIVIGY may cause:

- **Blood clots (thrombosis).** Blood clots may occur in people taking Ig intravenous (IGIV) products, including QIVIGY. You may be at greater risk for blood clots if you are older, sit or lie for long periods, have a clotting problem or history of blood clots, take estrogen, have a central catheter, have thick blood, and/or if you have other conditions that put you at risk for cardiovascular disease. Blood clots may occur even if you do not have any of these risk factors. Your healthcare provider will monitor you for signs and symptoms of blood clotting.
- **Impaired kidney function or kidney failure.** IGIV products have been associated with kidney dysfunction and damage, kidney failure, and death. You may be at greater risk for kidney failure if you have kidney disease, diabetes, are over 65, are seriously dehydrated, overweight, have certain infections like sepsis, have a condition that causes abnormal proteins in your blood, or take drugs that may damage your kidneys. Your healthcare provider will monitor your kidney function before and periodically after your first infusion.

Please see full [Important Safety Information](#) and full [Prescribing Information](#) for complete prescribing details, including [Boxed Warning](#).



SEE WHAT'S  
**POSSIBLE**  
WITH  
**QIVIGY<sup>®</sup>**

In a clinical study,  
PEOPLE TAKING  
QIVIGY EXPERIENCED<sup>1,2</sup>:

**Proven protection  
with zero acute serious  
bacterial infections (SBIs)**

**Zero hospitalizations due  
to infection and low rates  
of antibiotic use**

**High treatment  
satisfaction**

Hypothetical patient.

QIVIGY was studied in a clinical trial to measure its safety and effectiveness in adults with primary immunodeficiency.<sup>1</sup>

### **IMPORTANT SAFETY INFORMATION (cont'd)**

#### **Do NOT use QIVIGY if:**

- You have a history of severe hypersensitivity or a history of allergic reactions to human Ig. Tell your healthcare provider if you have had a serious reaction to other medicines that contain human Ig or ask if you are not sure.
- You have an immunoglobulin A (IgA) deficiency, have antibodies to IgA, and have a hypersensitivity or a history of allergic reactions. Tell your healthcare provider if you have an IgA deficiency or ask if you are not sure.

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**Boldfaced underlined** text indicate key terms that are defined in the glossary.

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# What is primary immunodeficiency?



Primary immunodeficiency (PI) is a group of more than 550 rare, chronic conditions in which part of the body's immune system meant to fight infection is missing or does not function correctly.<sup>3</sup>



PI can affect anyone regardless of gender, age, or race.<sup>3</sup>



People with PI rely on immune globulin replacement therapy (IgRT) to help protect against infection.<sup>4</sup>

**Living with a chronic condition can take a toll on your body and overall well-being.<sup>5,6</sup>**

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# Even with treatment, setbacks can happen

IgRT is the standard treatment for people with PI and helps them manage their condition. However, even with treatment, many people with PI still experience frequent health setbacks that disrupt their daily lives.<sup>4,7</sup>

On average, people treated for PI experience<sup>7\*</sup>:



**~8**  
**infections**  
per year



**3 days**  
**in the hospital**  
due to infection  
per year



**~20%**  
of the year  
**on antibiotics**



**9 days**  
**of school/work**  
**missed**  
after diagnosis  
per year

Wherever you are on your treatment journey, you deserve a satisfying level of protection from life-interrupting events like hospitalizations and infections.

**It's time to expect more  
from your PI treatment.**

\*The Jeffrey Modell Foundation, a charity that supports people with PI, conducted a large survey of doctors in 2021 on select outcomes in people of all ages with PI 1 year before and 1 year after diagnosis. These outcomes were compared with data collected in 2018 and 2013. IgRT was used to treat all people with PI.<sup>7</sup>

IgRT, immune globulin replacement therapy; PI, primary immunodeficiency.

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# What is QIVIGY®?

**QIVIGY** (KEE'-vi-jee) is a type of FDA-approved IgRT for adults with PI called **intravenous immune globulin (IVIG)** that replaces **antibodies** that are missing or do not work as they should. The goal of this treatment is to reduce the number, severity, and potential complications of repeated infections in people with PI.<sup>1</sup>

QIVIGY was studied in a **clinical trial** to measure its safety and effectiveness in adults with PI.<sup>1</sup>

The QIVIGY clinical trial <sup>1</sup>	
<b>LENGTH OF TRIAL</b>	<b>12 months</b> Treatment given every 3 or 4 weeks
<b>NUMBER OF PARTICIPANTS</b>	<b>47 people</b> aged 20 to 70 years
<b>MAIN MEASURE OF EFFECTIVENESS</b>	<b>&lt;1 acute serious bacterial infection (SBI)</b> per person per year

IgRT, immune globulin replacement therapy; PI, primary immunodeficiency.

## IMPORTANT SAFETY INFORMATION (cont'd) WARNINGS AND PRECAUTIONS

- Severe allergic reactions may occur. People with IgA deficiency who have antibodies against IgA may be at greater risk of these reactions.

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# How did QIVIGY® perform in its clinical trial?

People receiving QIVIGY experienced on average:

**0** **ZERO ACUTE SBIs**  
per person per year<sup>1,2</sup>



**0** **ZERO DAYS IN THE HOSPITAL DUE TO INFECTION**  
per person per year<sup>1</sup>



The trial also looked at the impact of infections on daily life in people treated with QIVIGY<sup>1</sup>



**2.1**  
**other infections**  
per person per year



**3%**  
**of the year on**  
**antibiotics<sup>†</sup>**



**6 days**  
**lost from**  
**work/school**  
due to infection  
per person per year  
(median)\*

**Expect the quality protection you deserve.**

\*The range of missed days from work/school due to infection was 1-53 days.<sup>1</sup>

<sup>†</sup>The median duration of antibiotic use during the 1-year trial was 10 days. Thirty-six people in the trial used at least 1 antibiotic while taking QIVIGY. Eleven people in the trial did not need antibiotics.<sup>2</sup>

SBI, serious bacterial infection.

## IMPORTANT SAFETY INFORMATION (cont'd)

### WARNINGS AND PRECAUTIONS (cont'd)

- You could experience higher-than-normal levels of protein in your blood, thick blood, or low sodium (salt) in your blood. This may prevent your blood from flowing easily and possibly lead to blood clots.

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# What are the potential side effects of QIVIGY®?

The safety of QIVIGY was studied in a 12-month clinical trial, with the most common side effects listed below.<sup>1</sup>

Be sure to tell your doctor about any side effects you may experience with QIVIGY.

## The most common side effects of QIVIGY seen in less than 5% of infusions were<sup>1</sup>:

- Headache
- Fatigue
- Nausea
- Infusion-related reaction
- Positive **Coombs direct test\***
- Sinusitis
- Dizziness
- Diarrhea

**No one in the clinical trial experienced side effects that were considered serious, life-threatening, or left them unable to complete the trial.<sup>2</sup>**

\*A positive Coombs test indicates the presence of antibodies that may harm red blood cells. No harm to red blood cells were reported during the trial and no laboratory findings that would suggest harm to red blood cells associated with a positive test result were found.<sup>8</sup>

## IMPORTANT SAFETY INFORMATION (cont'd)

### WARNINGS AND PRECAUTIONS (cont'd)

- Brain swelling called aseptic meningitis syndrome may occur with IGIV products, especially if you receive a high dose or a rapid infusion.

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Hypothetical patient.

**93%**

of people in the trial reported satisfaction with QIVIGY<sup>®</sup>

vs 68% who reported satisfaction with their previous IVIG therapy<sup>2\*</sup>



\*Based on a study-specific patient satisfaction questionnaire. This questionnaire was an exploratory endpoint in the trial meant to give more insight about QIVIGY beyond the main goals of the trial. All 47 people in the trial completed the questionnaire at Week 24.<sup>2</sup>

IVIG, intravenous immune globulin.

### IMPORTANT SAFETY INFORMATION (cont'd)

#### WARNINGS AND PRECAUTIONS (cont'd)

- Blood damage called hemolysis and hemolytic anemia can develop after treatment with QIVIGY. Your healthcare provider will monitor you for signs and symptoms.

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# What can you expect while receiving QIVIGY® infusions?

QIVIGY is given through **intravenous (IV) infusion** by a trained healthcare professional in the comfort of your home or at an infusion center every 3 to 4 weeks. Your dose, how often you get infusions, and the duration of your infusions depend on your weight and how well you respond to QIVIGY.<sup>1</sup>

**You will want to dress comfortably for your infusion and you're welcome to pass the time by:**



Listening to music or a podcast



Watching a TV show or movie



Catching up on work



Reading



Playing a game



Relaxing



Remember to drink plenty of water before your infusion with QIVIGY!

Keep track of how you feel after each infusion to help you and your doctor decide if your dose of QIVIGY needs to be adjusted.

## IMPORTANT SAFETY INFORMATION (cont'd)

### WARNINGS AND PRECAUTIONS (cont'd)

- Swelling of the lungs may occur following treatment. Your healthcare provider will monitor you for signs of lung damage.

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# 97.8

out of 100

On a scale from 0 to 100, people in the trial gave QIVIGY®, on average, a **high satisfaction rating**<sup>2\*</sup>



Hypothetical patient.

\*A scale where 0 was not at all recommended and 100 was completely recommended. Based on a study-specific patient questionnaire. Overall, 46 patients in total answered this question and 97.8 was the mean score.<sup>2</sup>

## **IMPORTANT SAFETY INFORMATION (cont'd) WARNINGS AND PRECAUTIONS (cont'd)**

- QIVIGY is made from human blood and may contain infectious agents, eg, viruses and, theoretically, the Creutzfeldt-Jakob disease agent.

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# Get support for the journey ahead

Kedrion Biopharma provides support for eligible people receiving QIVIGY®.

Contact us to learn more about our copay assistance program and how you may qualify.

You may be eligible to receive up to \$10,000 per calendar year to use on out-of-pocket costs for QIVIGY.



Hypothetical patient.

Questions about  
copay assistance?

CALL: **1-888-262-8040**

EMAIL: [reimbursementsupport@medmonk.com](mailto:reimbursementsupport@medmonk.com)

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# Connect with patient advocacy organizations



The Immune Deficiency Foundation (IDF) improves the diagnosis, treatment, and quality of life for every person affected by PI. The IDF fosters a community that is connected, engaged, and empowered through advocacy, education, and research.

[primaryimmune.org](http://primaryimmune.org)



The International Patient Organisation for Primary Immunodeficiencies (IPOPI) is an international nonprofit organization and the leading worldwide advocate for people with PI.

[ipopi.org](http://ipopi.org)



The Jeffrey Modell Foundation is a global nonprofit dedicated to early diagnosis, meaningful treatments and, ultimately, cures through basic and clinical research, physician and patient education, public awareness, government advocacy, patient support, newborn screening, and genetic sequencing.

[info4pi.org](http://info4pi.org)



The Immunoglobulin National Society (IgNS) is a professional organization dedicated to the advancement of Ig therapy practice across clinical indications and areas of practice.

[ig-ns.org](http://ig-ns.org)

Ig, immunoglobulin; PI, primary immunodeficiency.

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# Glossary

## Antibodies

proteins, created by your immune system, that protect you when an unwanted substance, like a bacteria or virus, enters your body

## Clinical trial

a research study that evaluates new interventions, like tests or treatments, and their effect on a person's health

## Coombs direct test

Positive Coombs direct test results suggest the immune system is attacking the body's red blood cells and can cause anemia

## Immune globulin replacement therapy (IgRT)

a **standard of care** treatment for PI that administers antibodies, or immune globulins, to individuals with weakened or compromised immune systems

PI, primary immunodeficiency.

## IMPORTANT SAFETY INFORMATION (cont'd)

### WARNINGS AND PRECAUTIONS (cont'd)

- Be sure to tell your healthcare provider about your recent history of vaccinations. Live vaccines for diseases like measles, mumps, rubella, and varicella may not work as well while receiving QIVIGY. Tell your healthcare provider that you are taking QIVIGY before you receive any vaccination.

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# Glossary

(cont'd)

## Intravenous immune globulin (IVIG) treatment

a type of IgRT that involves an infusion of donated antibodies into an individual's bloodstream to manage immunodeficiency disorders

## Intravenous (IV) infusion

a method of putting fluids, including drugs, into the bloodstream

## Acute serious bacterial infections

infections considered to be serious over 12 months in the QIVIGY® clinical trial, including: bacterial pneumonia, bacteremia/septicemia, osteomyelitis/septic arthritis, visceral abscesses, or bacterial meningitis<sup>1</sup>

## Standard of care

treatment that is accepted and used by healthcare professionals as a proper treatment for a certain type of disease

IgRT, immune globulin replacement therapy.

## **IMPORTANT SAFETY INFORMATION (cont'd)**

### **WARNINGS AND PRECAUTIONS (cont'd)**

- Be sure to tell your healthcare provider about your recent history of vaccinations. Live vaccines for diseases like measles, mumps, rubella, and varicella may not work as well while receiving QIVIGY. Tell your healthcare provider that you are taking QIVIGY before you receive any vaccination.

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# Commonly Asked Questions



**How active can I be while taking QIVIGY®?**

Some people may find it helpful to stay active while taking QIVIGY. Talk to your doctor about how you are feeling so that, together, you can come up with an exercise routine that works best for you.



**Is there anything I should bring to my infusion?**

You should bring water to make sure you stay hydrated before your infusion and dress comfortably.<sup>1</sup>

Since your infusion time may vary, it's important that you have what you need to be comfortable. You can bring something to help you pass the time, whether it's a tablet to watch a show or play a game, headphones to listen to music or a podcast, a book, a laptop to catch up on work, or a cozy pillow and blanket to help you relax.

## IMPORTANT SAFETY INFORMATION (cont'd)

### ADVERSE REACTIONS

The most common side effects of QIVIGY were headache, fatigue, infusion-related reaction, positive direct Coombs test result suggesting the immune system is attacking the body's red blood cells, nausea, sinus inflammation, dizziness, and diarrhea. During treatment with QIVIGY, be sure to tell your healthcare provider about any unusual symptoms you experience, as they may indicate a possible side effect.

To report SUSPECTED ADVERSE REACTIONS, contact Kedrion Biopharma Inc. at 1-855-3KDRION (1-855-353-7466) or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

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# Commonly Asked Questions (cont'd)



**What are the most common side effects of QIVIGY®?**

The most common side effect of QIVIGY is headaches. Other common side effects include fatigue, nausea, infusion-related reaction, positive direct Coombs test result suggesting the immune system is attacking the body's red blood cells, sinus inflammation, dizziness, and diarrhea.<sup>1</sup>



**Is QIVIGY safe for people who are pregnant?**

It is not known whether QIVIGY can cause fetal harm in people who are pregnant as there are no data available to determine the risk. What is known is that immune globulins can cross the placenta through maternal blood circulation. It is advised QIVIGY be given to people who are pregnant only if clearly needed.<sup>1</sup>



**Can children use QIVIGY?**

QIVIGY is approved for adults with PI. Its safety and effectiveness in children has not been established.<sup>1</sup>

PI, primary immunodeficiency.

## IMPORTANT SAFETY INFORMATION (cont'd)

### ADVERSE REACTIONS

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# Indication and Important Safety Information

## What is QIVIGY®?

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## IMPORTANT SAFETY INFORMATION

### QIVIGY may cause:

- **Blood clots (thrombosis).** Blood clots may occur in people taking Ig intravenous (IGIV) products, including QIVIGY. You may be at greater risk for blood clots if you are older, sit or lie for long periods, have a clotting problem or history of blood clots, take estrogen, have a central catheter, have thick blood, and/or if you have other conditions that put you at risk for cardiovascular disease. Blood clots may occur even if you do not have any of these risk factors. Your healthcare provider will monitor you for signs and symptoms of blood clotting.
- **Impaired kidney function or kidney failure.** IGIV products have been associated with kidney dysfunction and damage, kidney failure, and death. You may be at greater risk for kidney failure if you have kidney disease, diabetes, are over 65, are seriously dehydrated, overweight, have certain infections like sepsis, have a condition that causes abnormal proteins in your blood, or take drugs that may damage your kidneys. Your healthcare provider will monitor your kidney function before and periodically after your first infusion.

### Do NOT use QIVIGY if:

- You have a history of severe hypersensitivity or a history of allergic reactions to human Ig. Tell your healthcare provider if you have had a serious reaction to other medicines that contain human Ig or ask if you are not sure.
- You have an immunoglobulin A (IgA) deficiency, have antibodies to IgA, and have a hypersensitivity or a history of allergic reactions. Tell your healthcare provider if you have an IgA deficiency or ask if you are not sure.

## WARNINGS AND PRECAUTIONS

- Severe allergic reactions may occur. People with IgA deficiency who have antibodies against IgA may be at greater risk of these reactions.
- You could experience higher-than-normal levels of protein in your blood, thick blood, or low sodium (salt) in your blood. This may prevent your blood from flowing easily and possibly lead to blood clots.

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# Important Safety Information (cont'd)

- Brain swelling called aseptic meningitis syndrome may occur with IGIV products, especially if you receive a high dose or a rapid infusion.
- Blood damage called hemolysis and hemolytic anemia can develop after treatment with QIVIGY®. Your healthcare provider will monitor you for signs and symptoms.
- Swelling of the lungs may occur following treatment. Your healthcare provider will monitor you for signs of lung damage.
- QIVIGY is made from human blood and may contain infectious agents, eg, viruses and, theoretically, the Creutzfeldt - Jakob disease agent.
- Be sure to tell your healthcare provider about your recent history of vaccinations. Live vaccines for diseases like measles, mumps, rubella, and varicella may not work as well while receiving QIVIGY. Tell your healthcare provider that you are taking QIVIGY before you receive any vaccination.

## ADVERSE REACTIONS

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**REFERENCES:** 1. QIVIGY [prescribing information], Kedrion Biopharma Inc.; 2025. 2. Data on file. REF-01262. Kedrion Biopharma Inc.; 2024. 3. Immune Deficiency Foundation. What is PI? Accessed January 22, 2026. <https://primaryimmune.org/understanding-primary-immunodeficiency/what-is-pi> 4. Immune Deficiency Foundation. Immunoglobulin replacement therapy. Accessed January 22, 2026. <https://primaryimmune.org/understanding-primary-immunodeficiency/treatment/immunoglobulin-replacement-therapy> 5. Data on file. REF-01274. Kedrion Biopharma Inc.; 2025. 6. Cleveland Clinic. Immunocompromised. Content last reviewed on December 17, 2024. Accessed January 22, 2026. <https://my.clevelandclinic.org/health/diseases/immunocompromised> 7. Quinn J, Modell V, Orange JS, Modell F. Growth in diagnosis and treatment of primary immunodeficiency within the global Jeffrey Modell Centers Network. *Allergy Asthma Clin Immunol*. 2022;18(1):19. 8. Cleveland Clinic. Coombs test. Content last reviewed on May 11, 2022. Accessed December 18, 2025. <https://my.clevelandclinic.org/health/diagnostics/22978-coombs-test>

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Hypothetical patient.

## IMPORTANT SAFETY INFORMATION

### ADVERSE REACTIONS

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