

Your trusted partner in treating PI

YOUR GUIDE TO GAMMAGARD LIQUID



FOR 15 YEARS—
the most prescribed immune globulin (IG)*

*Based on combined data: internal calculations by Takeda based on Marketing Research Bureau (MRB) database of total Ig Units prescribed over a combined 15+ years (2005-2022).

What is GAMMAGARD LIQUID® [Immune Globulin Infusion (Human)] 10% Solution?

GAMMAGARD LIQUID is a ready-to-use liquid medicine that is given in a vein (intravenously) or under the skin (subcutaneously) to treat primary immunodeficiency (PI) in people 2 years and older.

Important Safety Information

What is the most important information that I should know about GAMMAGARD LIQUID?

GAMMAGARD LIQUID can cause the following serious reactions:

- Severe allergic reactions causing difficulty in breathing or skin rashes
- Decreased kidney function or kidney failure
- Blood clots in the heart, brain, lungs or elsewhere in the body

For additional safety information, click for [Information For Patients](#) and discuss with your HCP.

Welcome

TO GAMMAGARD LIQUID

Whether you've just been diagnosed with primary immunodeficiency (PI), have been prescribed GAMMAGARD LIQUID, or just want to learn more, this brochure is here to help.

Throughout the guide you'll find QR codes that will take you to our website for more information.

GAMMAGARD LIQUID
[Immune Globulin Infusion (Human)] 10%

What's inside?

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Important Safety Information (continued)

What is the most important information that I should know about GAMMAGARD LIQUID? (continued)

GAMMAGARD LIQUID can cause the following serious reactions:

- Severe headache, drowsiness, fever, painful eye movements, or nausea and vomiting
- Dark colored urine, swelling, fatigue, or difficulty breathing

Who should not use GAMMAGARD LIQUID?

Do not use GAMMAGARD LIQUID if you:

- Have had a severe allergic reaction to immune globulin or other blood products.
- Have a condition called selective (or severe) immunoglobulin A (IgA) deficiency.

For additional safety information, including Warning about Blood Clots, Decreased Kidney Function, and Kidney Failure, click for [Information For Patients](#) and discuss with your HCP.

Get to know PI

What is PI?

PI is a term used to describe a group of disorders that cause the immune system to not work correctly.

The immune system protects your body from germs, like bacteria and viruses. When the immune system doesn't work the way it's supposed to, you're more likely to:

- Get infections more often
- Get more serious infections
- Take longer to get better

Although PI was once considered rare, more people are getting diagnosed because doctors are more aware of what to look out for.

How do you know if you have PI?

Your doctor will do PI testing. PI can sometimes be difficult to diagnose, so make sure to have honest, open conversations with your doctor(s) — ask questions and talk about any symptoms you may be experiencing.

How is PI treated?

The most common way to treat PI is with immune globulin, or IG. IG contains antibodies that help your body fight infections.

250,000

Americans are estimated to have been diagnosed with PI

500,000

more Americans are suspected to have PI but haven't been diagnosed yet

1 in 1,200

people are thought to be affected by PI



Want to learn more about PI?
Scan the QR code or [click here](#).

YOUR INTRODUCTION TO GAMMAGARD LIQUID

Made with your needs in mind

A trusted PI treatment

GAMMAGARD LIQUID has been trusted by doctors and people living with PI since 2005. It is a treatment that gives you the antibodies you need that are either missing or not working properly because of your PI. It may be given in a vein (intravenous, or IV) or under the skin (subcutaneous, or SubQ).

Not all IG therapies are the same. GAMMAGARD LIQUID is made differently.



Free from sucrose or added sugars



Free from glucose or proline stabilizers



Free from added sodium



Free from added preservatives

GAMMAGARD LIQUID is stabilized and buffered with glycine.



Get the latest information about GAMMAGARD LIQUID. Scan the QR or [click here to sign up for emails.](#)

Important Safety Information (continued)

What should I avoid while taking GAMMAGARD LIQUID?

- GAMMAGARD LIQUID can make vaccines (like measles/mumps/rubella or chickenpox vaccines) not work as well for you. Before you get any vaccines, tell your healthcare provider (HCP) that you take GAMMAGARD LIQUID.
- Tell your HCP if you are pregnant, or plan to become pregnant, or if you are nursing.

For additional safety information, including **Warning about Blood Clots, Decreased Kidney Function, and Kidney Failure**, click for [Information For Patients](#) and discuss with your HCP.



GAMMAGARD LIQUID INTRAVENOUS (IV)

An IV treatment that can work for you

GAMMAGARD LIQUID IV treatment is delivered through a needle into a vein.

If you and your doctor choose to treat your PI with GAMMAGARD LIQUID IV, here are some things you may want to know:

- The infusion is given with a needle directly into a vein
- Infusion frequency is every 3 to 4 weeks
- There will be 1 injection site
- The treatment can be given by a doctor, nurse, or other healthcare professional
- It is administered at a clinic, hospital, or at home by a nurse

GAMMAGARD LIQUID
[Immune Globulin Infusion (Human)] 10%



How effective is it?

In a clinical study of 61 people with PI, GAMMAGARD LIQUID IV was shown to provide protection from infection when given at a dose of 300 to 600 mg/kg every 3 to 4 weeks for 12 months.



No acute serious bacterial infections*



No hospitalizations because of an infection



4 validated other bacterial infections reported†

Not familiar with ASBIs? They're short-term but serious infections caused by bacteria that require immediate medical care. The FDA standard for effectiveness—that is, if an immunoglobulin works—is less than 1 ASBI per year. In the clinical study, people taking GAMMAGARD LIQUID experienced no ASBIs.

*Validated acute serious bacterial infections (ASBIs).
†The validated other bacterial infections were urinary tract infection (1), gastroenteritis (sometimes called "stomach flu") (1), and ear infection (2).

Important Safety Information (continued)

What are the possible or reasonably likely side effects of GAMMAGARD LIQUID?

GAMMAGARD LIQUID can cause serious side effects. If any of the following problems occur after starting GAMMAGARD LIQUID, stop the infusion immediately and contact your HCP or call emergency services:

- Hives, swelling in the mouth or throat, itching, trouble breathing, wheezing, fainting or dizziness. These could be signs of a serious allergic reaction.
- Bad headache with nausea, vomiting, stiff neck, fever, and sensitivity to light. These could be signs of irritation and swelling of the lining around your brain.

For additional safety information, including Warning about Blood Clots, Decreased Kidney Function, and Kidney Failure, click for [Information For Patients](#) and discuss with your HCP.



What you may expect with your infusions

If you're prescribed GAMMAGARD LIQUID IV, you may receive treatment in a clinic, hospital, or at home with a nurse, depending on what you and your healthcare provider decide is best.



Before the infusion

- Bring a book, electronic device (and charger), or activity to occupy yourself during the infusion
- Review and sign the consent form
- The nurse will place the IV catheter into the vein



During the infusion

- Relax and sit comfortably
- Let the staff know if you feel uncomfortable at any time or are having any side effects



After the infusion

- Let the nurse know if you feel uncomfortable at any time
- Write down the date and any notes about your infusion in your treatment journal



Scan or [click here](#) to learn more about the effectiveness and safety of GAMMAGARD LIQUID IV.

What kind of side effects have people experienced?

The most common side effects (seen in $\geq 5\%$ of patients) were headache, fatigue, fever, nausea, chills/shaking chills, pain in the hands or feet, diarrhea, migraine, dizziness, vomiting, cough, hives, asthma, sore throat, rash, joint pain, muscle pain, swelling in the arms or legs, itching, and heart murmur.



95% of the non-serious side effects (400 events) reported in this study were considered mild to moderate; 5% (19 events) were severe

Important Safety Information (continued)

What are the possible or reasonably likely side effects of GAMMAGARD LIQUID? (continued)

GAMMAGARD LIQUID can cause serious side effects. If any of the following problems occur after starting GAMMAGARD LIQUID, stop the infusion immediately and contact your HCP or call emergency services:

- Reduced urination, sudden weight gain, or swelling in your legs. These could be signs of a kidney problem.
- Pain, swelling, warmth, redness, or a lump in your legs or arms. These could be signs of a blood clot.

For additional safety information, including Warning about Blood Clots, Decreased Kidney Function, and Kidney Failure, click for [Information For Patients](#) and discuss with your HCP.



GAMMAGARD LIQUID SUBCUTANEOUS (SubQ)

A SubQ treatment that can work for you

GAMMAGARD LIQUID treatment can also be delivered through a needle just under the skin.

If you and your doctor choose to treat your PI with GAMMAGARD LIQUID SubQ, here are some things you may want to know:

- The infusion is given with a needle under the skin in the fatty tissue of the abdomen, thighs, upper arm, or lower back
- Infusion frequency is once a week
- There will be multiple (up to 8) injection sites
- The treatment can be given by you or a care partner after training
- It can be administered at home after training

GAMMAGARD LIQUID
[Immune Globulin Infusion (Human)] 10%



How effective is it?

In the clinical study of 47 people with PI, GAMMAGARD LIQUID SubQ was shown to provide sustained protection against infection. People in the study were treated for about one year (54 weeks on average, with a range of 8 to 68 weeks overall).



There was <1 (0.067) acute serious bacterial infection* per year†



No hospitalizations because of an infection

*Validated acute serious bacterial infection (ASBI).
†3 patients had pneumonia, which didn't need hospitalization.

Important Safety Information (continued)

What are the possible or reasonably likely side effects of GAMMAGARD LIQUID? (continued)

GAMMAGARD LIQUID can cause serious side effects. If any of the following problems occur after starting GAMMAGARD LIQUID, stop the infusion immediately and contact your HCP or call emergency services:

- Brown or red urine, fast heart rate, yellow skin or eyes. These could be signs of a liver or blood problem.
- Chest pain or trouble breathing, or blue lips or extremities. These could be signs of a serious heart or lung problem.
- Fever over 100°F. This could be a sign of an infection.

For additional safety information, including Warning about Blood Clots, Decreased Kidney Function, and Kidney Failure, click for [Information For Patients](#) and discuss with your HCP.



What you may expect with your infusions

Before you are able to infuse at home, a nurse will show you, or the person at home who is going to help, how to perform the infusions and make sure you are comfortable with the process. You can ask questions at any point if anything is unclear.



Before the infusion

- Choose a quiet spot
- Set up supplies, including your book, TV, or quiet activity you plan on doing during the infusion
- Have your doctor's phone number or someone else nearby in case you experience any side effects



During the infusion

- Relax and sit comfortably
- Care for any side effects based on the instructions from your care team



After the infusion

- Let your doctor or nurse know if you have any side effects
- Write down the date and any notes about your infusion in your treatment journal

What kind of side effects have people experienced?

The most common side effects (seen in $\geq 5\%$ of patients) were infusion site reactions, headache, fatigue, increased heart rate, fever, upper abdominal pain, nausea, vomiting, asthma, increased blood pressure, diarrhea, ear pain, canker sores, migraine, sore throat, and pain in the hands or feet.



98% of the non-serious side effects (348 events) reported in this study were considered mild to moderate; 2% (8 events) were severe



Scan or [click here](#) to learn more about the effectiveness and safety of GAMMAGARD LIQUID SubQ.

Important Safety Information (continued)

What are the possible or reasonably likely side effects of GAMMAGARD LIQUID? (continued)

The following one or more possible reactions may occur at the site of infusion of GAMMAGARD LIQUID for PI, generally go away within a few hours, and are less likely after the first few infusions:

- Mild or moderate pain
- Itching
- Bruising
- Swelling
- Redness
- Warmth




For additional safety information, including [Warning about Blood Clots, Decreased Kidney Function, and Kidney Failure](#), click for [Information For Patients](#) and discuss with your HCP.

Meet a family of IG therapies

GAMMAGARD LIQUID is a part of a larger family of IG therapies from Takeda Pharmaceuticals. Each therapy has its own administration options that you and your doctor may decide are better for you. Whatever changes you may need to make in your treatment journey, Takeda is here with the broadest range of treatments and resources to help you along the way.



How GAMMAGARD LIQUID compares to other Takeda IG therapies

	GAMMAGARD LIQUID IV	SubQ IG with flexible infusion options	Once-a-month* SubQ IG infusion
Administration options	In a vein	Under the skin	Under the skin with hyaluronidase that helps more IG to be absorbed into the bloodstream
Frequency	Every 3 to 4 weeks	Daily to every 2 weeks	Every 3 to 4 weeks
Average infusion time†	~2 hours	~1 to 2 hours	~2 hours
Infusion time range†	~1 to 2 hours	~5 min to 2 hours	~1 to 2 hours
Who administers	Nurse	Yourself or care partner after training by HCP	Nurse or yourself or care partner after training by HCP
Location	Home, healthcare office, hospital, or infusion center	Home, healthcare office, hospital, or infusion center	Home, healthcare office, hospital, or infusion center
Scan to learn more			

*Every 3 or 4 weeks.

†Infusion times may vary based on frequency, dose, volume, number of needles, and tolerability.

Important Safety Information (continued)

What are the possible or reasonably likely side effects of GAMMAGARD LIQUID? (continued)

During the infusion of GAMMAGARD LIQUID for PI, look out for the first signs of the following common side effects:

- Headache
- Migraine
- Fever
- Fatigue

For additional safety information, including Warning about Blood Clots, Decreased Kidney Function, and Kidney Failure, click for [Information For Patients](#) and discuss with your HCP.



Help is just a tap or call away.

When prescribed a Takeda treatment—whether it’s new to you, you’ve been on treatment, or you’re taking care of someone else—Takeda Patient Support is here to help.

The Takeda Patient Support Co-Pay Assistance Program may cover

100%

of your out-of-pocket costs if you’re eligible*

Not enrolled or need assistance?

You can join Takeda Patient Support in a few simple steps. Visit [TakedaPatientSupport.com](https://www.takedapatient.com) or scan this QR code.

Our support specialists are never more than a tap or a call away. Reach us at **1-866-861-1750**, Monday through Friday, 8 AM to 8 PM ET.



A co-pay assistance program

Your dedicated specialist will walk you through the insurance process and help you understand what’s covered.

Help getting your medicine

We can help you receive your treatment by getting your medication when you need it.

Nursing support

This can be arranged if you have questions about your treatment. Our nurses cannot provide medical advice.

Education about your condition

We can help you better understand your condition and treatment, and direct you to support resources and education that you can discuss with your healthcare provider.

Ongoing support

We’re here for you. We’ll share emails and texts with tips and timely info throughout your treatment.

***IMPORTANT NOTICE:** The Takeda Patient Support Co-Pay Assistance Program (the Program) is not valid for prescriptions eligible to be reimbursed, in whole or in part, by Medicaid, Medicare (including Medicare Part D), Tricare, Medigap, VA, DoD, or other federal or state programs (including any medical or state prescription drug assistance programs). No claim for reimbursement of the out-of-pocket expense amount covered by the Program shall be submitted to any third party payer, whether public or private. The Program cannot be combined with any other rebate/coupon, free trial, or similar offer. Copayment assistance under the Program is not transferable. The Program only applies in the United States, including Puerto Rico and other U.S. territories, and does not apply where prohibited by law, taxed, or restricted. This does not constitute health insurance. Void where use is prohibited by your insurance provider. If your insurance situation changes you must notify the Program immediately at 1-866-861-1750. Coverage of certain administration charges will not apply for patients residing in states where it is prohibited by law. Takeda reserves the right to rescind, revoke, or amend the Program at any time without notice.

More helpful information and resources to support you

The following websites provide information and resources for people living with PI:

mylg source

MyIgSource is an online PI community, 52,000 strong. It's a great place to learn ways to manage PI from the people living with it and others like you. Visit [MyIgSource.com](https://www.mylgsource.com) or call 1-855-250-5111.



My Life, My Story.
Community Events.

My Life, My Story is an educational program led by Nurse Speakers and patients living with PI. Here you can sign up for live and virtual events about PI and treatment from those who know PI first-hand. Learn more at [MyLifeMyStory.com](https://www.mylifemystory.com).



IDF Immune
Deficiency
Foundation

IDF* is a national patient organization dedicated to improving the diagnosis, treatment, and quality of life of people living with PI through advocacy, education, and research. Learn more at [primaryimmune.org](https://www.primaryimmune.org).



jm Jeffrey Modell
Foundation

JMF* is dedicated to early and precise diagnosis, meaningful treatments, and, ultimately, cures of the known PI diseases through research, physician education, patient support, advocacy, public awareness, and newborn screening. Learn more at [info4pi.org](https://www.info4pi.org).



AAAAI
American Academy of
Allergy Asthma
& Immunology

AAAAI,* a professional society for clinical immunologists, is a dedicated resource for information about PI. Search for PI under the list of conditions to find links to facts about PI, as well as support organizations and helpful guides. The site also has a tool to search for an allergist/immunologist near you. Learn more at [aaaai.org](https://www.aaaai.org).



*This organization is a third-party resource and not associated with Takeda.



What is GAMMAGARD LIQUID?

GAMMAGARD LIQUID is a ready-to-use liquid medicine that is given in a vein (intravenously) or under the skin (subcutaneously) to treat primary immunodeficiency (PI) in people 2 years and older.

Important Safety Information

What is the most important information that I should know about GAMMAGARD LIQUID?

GAMMAGARD LIQUID can cause the following serious reactions:

- Severe allergic reactions causing difficulty in breathing or skin rashes
- Decreased kidney function or kidney failure
- Blood clots in the heart, brain, lungs or elsewhere in the body
- Severe headache, drowsiness, fever, painful eye movements, or nausea and vomiting
- Dark colored urine, swelling, fatigue, or difficulty breathing

Who should not use GAMMAGARD LIQUID?

Do not use GAMMAGARD LIQUID if you:

- Have had a severe allergic reaction to immune globulin or other blood products.
- Have a condition called selective (or severe) immunoglobulin A (IgA) deficiency.

What should I avoid while taking GAMMAGARD LIQUID?

- GAMMAGARD LIQUID can make vaccines (like measles/mumps/rubella or chickenpox vaccines) not work as well for you. Before you get any vaccines, tell your healthcare provider (HCP) that you take GAMMAGARD LIQUID.
- Tell your HCP if you are pregnant, or plan to become pregnant, or if you are nursing.



What are the possible or reasonably likely side effects of GAMMAGARD LIQUID?

GAMMAGARD LIQUID can cause serious side effects. If any of the following problems occur after starting GAMMAGARD LIQUID, stop the infusion immediately and contact your HCP or call emergency services:

- Hives, swelling in the mouth or throat, itching, trouble breathing, wheezing, fainting or dizziness. These could be signs of a serious allergic reaction.
- Bad headache with nausea, vomiting, stiff neck, fever, and sensitivity to light. These could be signs of irritation and swelling of the lining around your brain.
- Reduced urination, sudden weight gain, or swelling in your legs. These could be signs of a kidney problem.
- Pain, swelling, warmth, redness, or a lump in your legs or arms. These could be signs of a blood clot.
- Brown or red urine, fast heart rate, yellow skin or eyes. These could be signs of a liver or blood problem.
- Chest pain or trouble breathing, or blue lips or extremities. These could be signs of a serious heart or lung problem.
- Fever over 100°F. This could be a sign of an infection.

The following one or more possible reactions may occur at the site of infusion of GAMMAGARD LIQUID for PI, generally go away within a few hours, and are less likely after the first few infusions:

- Mild or moderate pain
- Swelling
- Itching
- Redness
- Bruising
- Warmth

During the infusion of GAMMAGARD LIQUID for PI, look out for the first signs of the following common side effects:

- Headache
- Migraine
- Fever
- Fatigue
- Itching
- Rashes/hives
- Cough
- Chest pain/tightness
- Chills/shaking chills
- Dizziness
- Nausea/vomiting
- Faster heart rate
- Upper abdominal pain
- Increased blood pressure
- Muscle cramps
- Sore throat

These are not all the possible side effects. Talk to your HCP about any side effect that bothers you or that does not go away.

For additional safety information, click for [Information For Patients](#) and discuss with your HCP.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

GAMMAGARD LIQUID

[Immune Globulin Infusion (Human)] 10%

We're here for you on your PI treatment journey

Find useful information inside:

- The basics of PI
- Information on GAMMAGARD LIQUID IV and GAMMAGARD LIQUID SubQ
- What to expect with treatment
- Patient support and resources



Sign up for more information about PI and GAMMAGARD LIQUID—sent directly to your inbox.

Important Safety Information (continued)

Who should not use GAMMAGARD LIQUID?

Do not use GAMMAGARD LIQUID if you:

- Have had a severe allergic reaction to immune globulin or other blood products.
- Have a condition called selective (or severe) immunoglobulin A (IgA) deficiency.

For additional safety information, including *Warning about Blood Clots, Decreased Kidney Function, and Kidney Failure*, click for [Information For Patients](#) and discuss with your HCP.

