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# Reconnect with

People with PI* who infuse CUVITRU may be able to experience more of these moments with weekly or every-other-week infusions. Scroll down to see moments to reconnect with!

*PI=primary immunodeficiency.

## What is CUVITRU® [Immune Globulin Subcutaneous (Human)] 20% Solution?

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

## IMPORTANT SAFETY INFORMATION

**What is the most important information I need to know about CUVITRU?**

CUVITRU 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

***Please see additional Important Safety Information throughout, click for Information for Patients, and discuss with your HCP.***

game night
class time
yoga Tuesdays
hanging out
volunteer work

Keep reading to learn more.

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Let’s start with the basics.

# What is primary immunodeficiency (PI)?

PI is a term used to describe a group of disorders (hundreds!), and unfortunately, they all cause the immune system to not work right, making it harder for your body to fight infections.

## Your genes tell a story.

PI is usually genetic, which means there is a defect in one or more of your genes. This also means that PI diseases can run in families. However, PI isn’t contagious, so you can’t catch it from someone like you would a cold or the flu.

### Common types of PI.

While there are many types of PI (some inherited, some not), some types are more common than others. These include selective IgA deficiency, common variable immune deficiency (CVID), X-linked agammaglobulinemia (XLA), and severe combined immunodeficiency (SCID).

### There’s a treatment for PI: immune globulin, or IG.

IG is a term you’ll hear and read about often. IG contains antibodies you can think of as warriors, helping your body fight infections by replacing the antibodies that are missing from your immune system or not working properly.

How is CUVITRU given?

# You receive IG through an infusion.

CUVITRU is a subcutaneous immune globulin (subQ IG) medicine to treat primary immunodeficiency (PI) in people 2 years and older. It is given under the skin instead of into a vein (called IVIG) like other PI therapies.

## IMPORTANT SAFETY INFORMATION (continued)

**Who should not use CUVITRU?**

Do not use CUVITRU 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 CUVITRU?**

- CUVITRU 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 CUVITRU.
- Tell your HCP if you are pregnant, or plan to become pregnant, or if you are nursing.



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## How do IVIG and a subQ IG like CUVITRU differ?

**IVIG is given directly into a vein and is often done by a nurse at an infusion center.**

**SubQ IG is given under the skin and can be done at home after proper training by a nurse.**

### CUVITRU could mean no more infusion center visits.

You can do your infusion on your own after proper training with a nurse. So, if doing subQ IG infusion at home on your own schedule sounds appealing, ask your doctor about CUVITRU.

## IMPORTANT SAFETY INFORMATION (continued)

**What are the possible or reasonably likely side effects of CUVITRU?**

**CUVITRU can cause serious side effects. If any of the following problems occur after starting CUVITRU, 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.

***Please see additional Important Safety Information throughout, click for Information for Patients, including Warning about Blood Clots, and discuss with your HCP.***

How can CUVITRU help you?

# Reliable protection from infection.

**This means more time for things that matter.**

In a clinical trial, CUVITRU was studied in 77 people with PI ≥2 years of age in North America. The main goal of the study was to measure how many acute serious bacterial infections (ASBIs) patients had over the course of 1 year. ASBIs are short-term but serious infections that need immediate medical care, like pneumonia. The FDA standard for efficacy—that is, if an immunoglobulin treatment works—is 1 ASBI per year. ASBIs were evaluated in 74 people taking CUVITRU for an average of 380.5 days (range, 30–629 days).

**In the North American study, those taking CUVITRU experienced (per patient-year*):**

**Less than 1**
**serious infection**
On average, people taking CUVITRU experienced 0.012 ASBIs, which is significantly less than 1†

**Less than 3**
**infections of any kind**
The rate of any kind of infection was 2.41

**Less than ½ of a day**
**in the hospital**
0.06 is the rate of days spent in the hospital due to infections

**About 1 day**
**of missed work or school**
The amount of time they weren't able to perform normal daily activities due to illness or infections was 1.16 days

*A patient-year is a patient experience in a clinical trial over the course of 1 year. One patient-year is equal to, for example, the experience of 2 patients for 6 months, or 12 patients for 1 month each.
†One ASBI that occurred during the study was a case of pneumonia in a 78-year-old person.



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## Here's what the safety results tell us:

**99.8%** **(4,319 of 4,327) of infusions were completed without a reduction, interruption, or discontinuation due to tolerability in the North American clinical study**

- **0 serious adverse reactions (ARs)** related to CUVITRU were reported
- Of the 278 non-serious ARs (excluding infections), 83% were mild, 16% were moderate, and 1% were severe. The severe ARs were not deemed to be causally related to CUVITRU. The most common general reactions were headache, nausea, fatigue, diarrhea, and vomiting

**98.2%** **(4,247 of 4,327) of infusions in the clinical study had no side effects at the infusion site,* like pain, itching, and redness**

- **1.8% of infusions** resulted in infusion site side effects, and they were mild or moderate. A mild side effect causes temporary discomfort that goes away on its own, or with little medical intervention. A moderate side effect causes a slight decline in function that goes away on its own, or with little medical intervention, and has no further consequences
- **2 of every 3 people** (51 of 74) had no infusion site side effects. The most common local ARs reported in ≥5% of patients were pain (20.3%), redness (10.8%), and itching (5.4%)

*Infusion site side effects generally go away within a few hours and are less likely after the first few infusions.

### IMPORTANT SAFETY INFORMATION (continued)

**What is the most important information I need to know about CUVITRU?**

CUVITRU can cause the following serious reactions:

- Severe allergic reactions causing difficulty in breathing or skin rashes
- Decreased kidney function or kidney failure
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# Your time matters.

**That's why your infusion should work with your schedule, not against it.**



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## Patients living with primary immunodeficiency preferred the convenience of CUVITRU to IVIG.

In the North American study of 68 patients, CUVITRU was shown to significantly improve patient quality of life vs IVIG in terms of convenience (TSQM-9*) and treatment interference (LQI*).

### Convenience measured as:

- Ease of using the medication in its current form
- Ease of planning when to use the medication each time
- Convenience in taking the medication as instructed

### Treatment interference measured as:

- Interference with social/family life
- Time waiting
- Treatment is worthwhile
- Dependence on others
- Freedom to take trips or move
- Scheduled according to patient's convenience

*These results came from the LQI (Life Quality Index) and TSQM-9 (Treatment Satisfaction Questionnaire for Medication). Both TSQM-9 and LQI were measured in patients aged 2 to 12 (with a parent observer), and in patients aged ≥13 (with the patient as the observer). TSQM-9, $P<0.001$; LQI, $P=0.008$.

## IMPORTANT SAFETY INFORMATION (continued)

### What are the possible or reasonably likely side effects of CUVITRU?

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

- 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 100ºF. This could be sign of an infection.

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# What makes the infusion experience different?

**Infusions tailored to you.**

CUVITRU gives you and your doctor the freedom to tailor your PI infusions to your lifestyle while providing reliable protection from infection. You and your doctor can decide how often you infuse (up to every other week).



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## You have a say in your infusion schedule.*†

CUVITRU can be infused at the fastest rates and highest volumes with the fewest infusion sites of any subQ IG. This means you have flexible options, and you and your doctor will work together to pick the right way to infuse just for you. Here are some things you and your doctor will consider:

> How much medicine do you need?
>
> How often do you want to infuse—daily, weekly, every 10 days, or every 2 weeks?
>
> Do you want 1 infusion site, or would you use more sites if it could save you time infusing? If you want to spend less time infusing, CUVITRU may deliver a full week's dose in under 15 minutes when you use multiple infusion sites, depending on your dose.
>
> If you're now using a medicine that takes more than 1 infusion site, would you rather have fewer sites, without having to infuse longer, depending on your dose?

*You'll infuse your first 2 infusions at 10 to 20 mL/hr/site. After that, you'll be able to increase your rate, as tolerated.
†CUVITRU was studied in 77 people with PI ≥2 years of age. The average infusion time was 0.95 hours (range, 0.2-6.4 hr).

### IMPORTANT SAFETY INFORMATION (continued)

**What are the possible or reasonably likely side effects of CUVITRU? (continued)**

The following one or more possible side effects may occur at the site of infusion. These generally go away within a few hours, and are less likely after the first few infusions.

- Mild or moderate pain
- Redness
- Itching

The most common side effects that may occur are:

- Headache
- Nausea
- Fatigue
- Diarrhea
- Vomiting

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# More resources are available too.

### There's a free trial program.

The HelloCUVITRU free trial program is a great resource if you want to try CUVITRU. Your doctor can take the first step to enroll you, so be sure to ask.

### Here are the highlights of HelloCUVITRU:

- It allows you and your doctor to determine if CUVITRU is right for you.
- The entire cost of your first four CUVITRU infusions is free, including the pump, supplies, and infusion training.
- Everything will be shipped right to your home.
- Your Specialty Pharmacy Nursing Network (SPNN) nurse will help you infuse your CUVITRU therapy and will work with you to optimize your infusion (in person or virtually).
- Together, you can customize the number of infusion sites, the volume infused per site, and how fast and how often you infuse.

### To be eligible, you must:

- Be 2 years and older with an ICD-10-verified diagnosis of primary immunodeficiency (PI).
- Be a new patient not currently using CUVITRU and haven't been previously enrolled in the HelloCUVITRU program.

Additional terms and conditions apply. Visit **CUVITRU.com** to learn more and **download a brochure** with more info.

This free trial is solely intended to allow new patients to try CUVITRU with the guidance of your doctor. There's no obligation to continue using CUVITRU after the free trial.

### You'll get plenty of training.

After your doctor prescribes CUVITRU, you'll get in-person training with a nurse, access to a video that walks you through the infusion process, and an official starter kit.

## IMPORTANT SAFETY INFORMATION

**What is the most important information I need to know about CUVITRU?**

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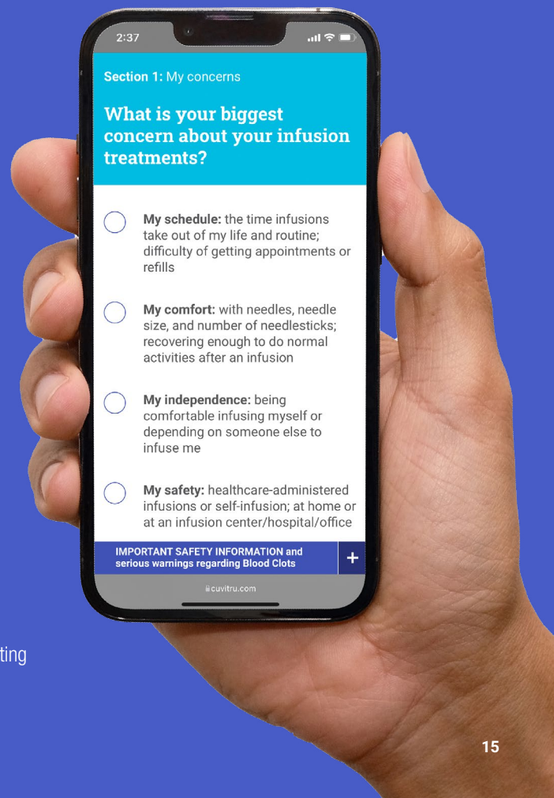
# Ready to reconnect?

Start the conversation with your doctor to find out if CUVITRU may be right for you. At CUVITRU.com, there's an entire section dedicated to helping you talk with your doctor. It includes questions that will help guide your conversation and help you and your doctor figure out what may be best for you, together.

You can download a PDF so you can take the discussion guide to your next appointment. Check out "Talking to Your Doctor."




## IMPORTANT SAFETY INFORMATION (continued)

**What is the most important information I need to know about CUVITRU (continued)?**

CUVITRU 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



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### What are the possible or reasonably likely side effects of CUVITRU? (continued)

- 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.
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- Itching

The most common side effects that may occur are:

- Headache
- Nausea
- Fatigue
- Diarrhea
- Vomiting

**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.**

# Here for you every step of the way.

These resources are opportunities for you to get real, honest, helpful guidance should you ever need it. Plus, the Takeda Patient Support Program* may cover 100% of your co-pay, up to the program maximum.



## my Ig source

This is a whole community committed to helping each other and loved ones manage a life with PI. With more than 52,000 members, this online community helps you and caregivers find information about PI and connect with IG Community Support Team Advocates—people who live with or love someone with PI.

**Want to connect with a nurse advocate?**
**Call 1-855-250-5111 to talk or visit MyIgSource.com to learn more.**

Takeda Patient Support

## 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/enroll** 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.

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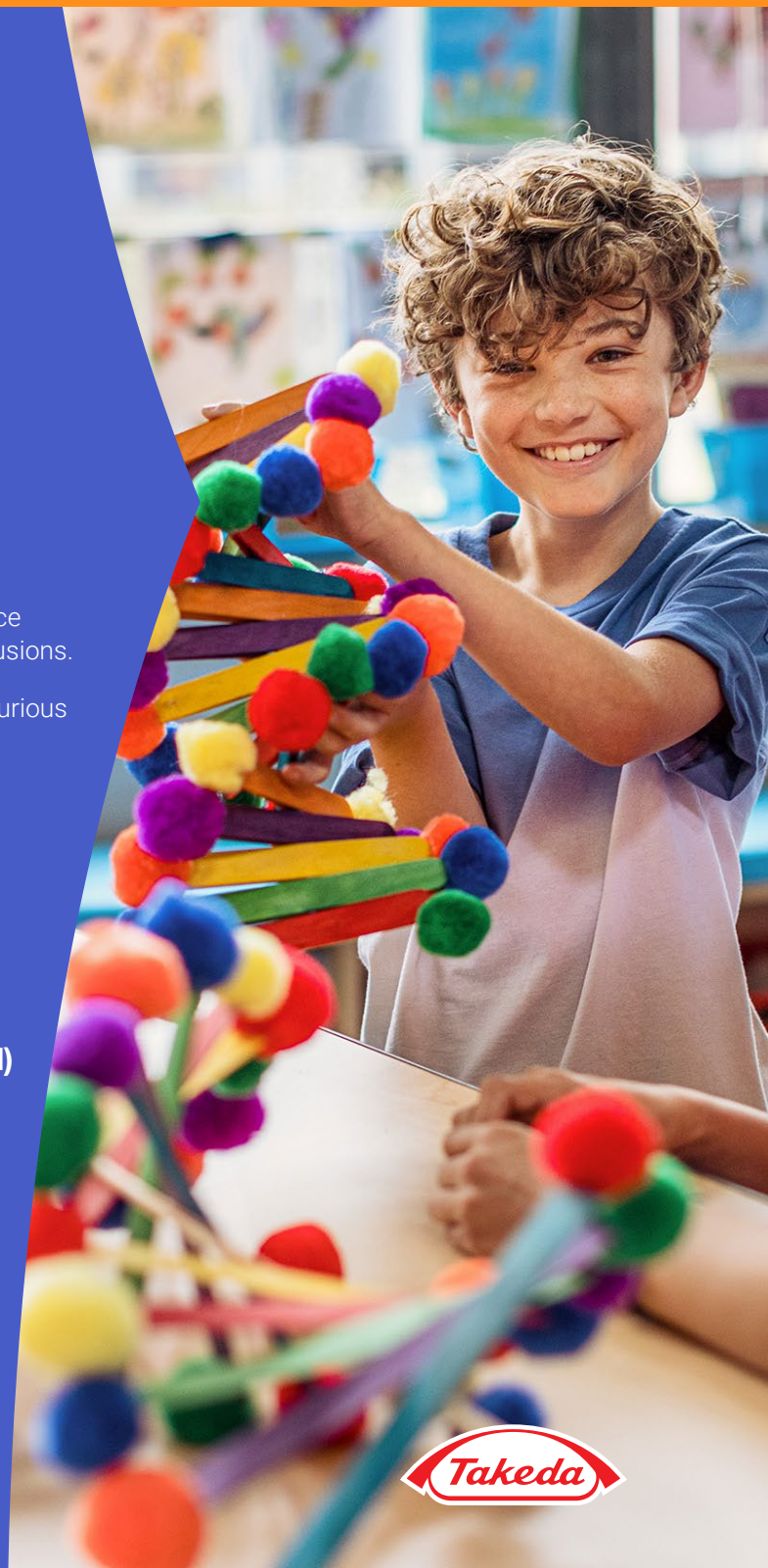
# Reconnect
## with class time.

People with PI who infuse CUVITRU may be able to experience more of these moments with weekly or every-other-week infusions.

We have lots more resources and support for you. If you're curious about CUVITRU, talk to your doctor or visit CUVITRU.com.



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