



Cuvitru
[Immune Globulin Subcutaneous (Human)] 20%

Help them reconnect.

Your guide to CUVITRU® and caring for someone with PI.

People with primary immunodeficiency (PI) who infuse CUVITRU [Immune Globulin Subcutaneous (Human)] 20% Solution weekly or every other week may be able to experience more of these moments.

What is CUVITRU?

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

Please see additional Important Safety Information throughout, click for [Information For Patients](#), and discuss with your HCP.

It all starts here.



You're going to do great.

Your significant other, your friend, your Gran—whichever you're helping, they're surely glad to have a partner like you. In this guide, you'll find all sorts of information that can help you as you help them.

So, what would you like to know?

Still learning about PI? There's a summary on the **next page**.

Why CUVITRU? **Page 6** shows what sets CUVITRU apart.

What's the infusion experience like? Visit **page 10**.

A trip to the doctor is coming up? Find materials to prep for the visit on **page 13**.

Need more resources and support? **Page 14** has that covered.

Is there a term you don't know? There's a glossary on **page 17** to help.

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.

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

Let's start with the basics.



So, what is primary immunodeficiency (PI)?

PI is a term used to describe a group of disorders that cause the immune system to not work correctly, making it harder for your body to fight infections. There are a lot of types of PI—more than 400! PI can be genetic, which means it may run in families.

PI is treated with immune globulin (IG) infusions, which contain antibodies, the infection fighters in the body.

What the person you're caring for may be feeling.

Managing a chronic, lifelong condition can have an emotional toll. There will be good days and bad days throughout their journey, and for you too.

Like any disorder, symptoms will vary for each person. Have they been missing a lot of school because they are too sick? Have they been taken to the hospital over and over again to clear out an infection that just wouldn't go away? PI may be the cause.

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.
- 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.

Here are some ways you can help.

Whether they are your spouse, child, friend, or neighbor, the person you are close to is about to begin their CUVITRU treatment. They are learning a lot right now, and you're going to be cheering them on.

Here are some things you can do for them throughout their treatment:

- Keep them company during infusions
- Help get them to and from infusions if infusing at a center
- Make sure they have everything they need for infusions, like the Patient Starter Kit from the specialty pharmacy
- Help them keep track of their infusions and symptoms in their Wellness Journal, found in the Patient Starter Kit
- Join an online community like MyIgSource to hear from others like you about what they do to help
- Visit [CUVITRU.com](https://www.cuvitru.com) to learn more

There's a lot to PI.

Luckily, you can scan this code or [click here](#) to keep learning.



IMPORTANT SAFETY INFORMATION (continued)

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

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:

- 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 sign of an infection.

Please see additional Important Safety Information throughout, click for [Information For Patients](#), including [Warning about Blood Clots](#), and discuss with your HCP.

What sets us apart.



People get choices on how they infuse.

This means people have flexible options, and they can work with their doctor to pick their preferred way to infuse. Together, they can choose things like: how many infusion sites, how much CUVITRU to infuse at each site, how fast to infuse it, and even how often to infuse.

CUVITRU has*:



the fastest rates



and highest volumes



with the fewest infusion sites of any subQ IG

*CUVITRU was studied in 77 people with primary immunodeficiency (PI) ≥ 2 years of age. The average infusion time was 0.95 hours (range, 0.2-6.4 hours). In the study, most (84.9%) used 1 to 2 needlesticks. CUVITRU can be infused at the fastest rates of any subQ (up to 60 mL/hour/site as tolerated). You'll infuse your first 2 infusions at 10 to 20 mL/hour/site. After that, you'll be able to increase your rate to 60 mL/hour/site, as tolerated. Infuse at up to 4 sites simultaneously.

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
- Diarrhea
- Nausea
- Vomiting
- Fatigue

Please see additional Important Safety Information throughout, click for [Information For Patients](#), and discuss with your HCP.

Reliable protection against infection in a clinical trial.

In a clinical trial, CUVITRU was studied in 77 people ≥ 2 years of age with PI 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 like pneumonia that need immediate medical care. ASBIs were evaluated in 74 people taking CUVITRU for an average of 380.5 days (range, 30-629 days).

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 1/2 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

*One ASBI that occurred during the study was a case of pneumonia in a 78-year-old person.

IMPORTANT SAFETY INFORMATION

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Here's how infusions were tolerated in a clinical study.



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What the data tells 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 $\geq 5\%$ 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)

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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Interested in the full clinical trial results? Scan the code or [click here](#).



IMPORTANT SAFETY INFORMATION (continued)

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- 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.

Finding time to reconnect.

People with primary immunodeficiency (PI) who infuse CUVITRU weekly or every other week may be able to experience more of these moments.



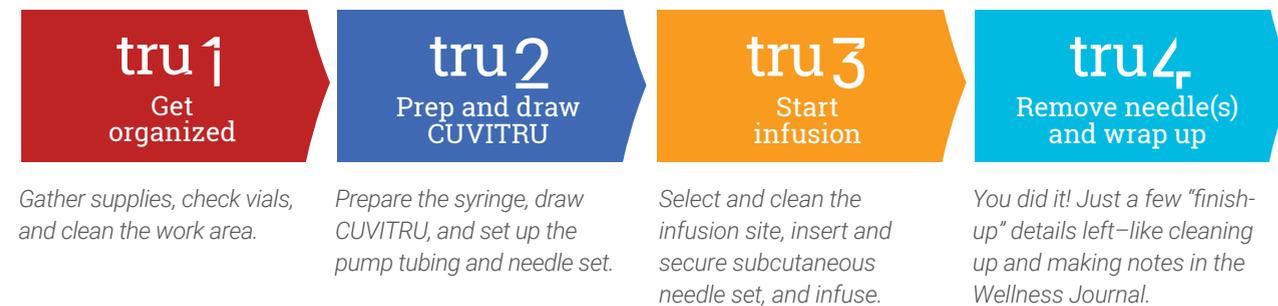
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CUVITRU can give them flexibility in their infusion schedules.

CUVITRU can be infused at a center or at home (after proper training from a nurse). This means CUVITRU can work with their schedule, not against it.

Save time on infusion day by learning the tru4.

We've broken the infusion process up into 4 sections to make the process easier to remember.



Please see the Prescribing Information for Instructions for Administration.

IMPORTANT SAFETY INFORMATION (continued)

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

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 100°F. This could be sign of an infection.

Do you have a child infusing?

We know that it's hard for kids to sit still, so here are some ideas to help settle them down for their infusion:

- Host a video call with family or friends
- Read a book or magazine
- Play board or video games

If you're infusing at home, you can also make a designated space for infusions. Decorate it with them! Stuffed animals, blankets, toys, anything that they love. Creating a routine like this can help them get ready for the infusion.

Want more information on infusing?
[Click here](#) to check out our infusion video or [download](#) the step-by-step infusion brochure.



IMPORTANT SAFETY INFORMATION (continued)

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

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Keep the conversation going!



Does the doctor know how your loved one feels about their treatment?

An ongoing conversation with their doctor is incredibly important to the success of their therapy, so helping them have those conversations is a great way to support them. We understand that it may be hard to know what to ask or what to say. Here are a few documents to help you both with these conversations.



Wellness Journal: Found in the Patient Starter Kit or downloaded from CUVITRU.com, this is a great place for people to track infusions and how they feel day to day. Keeping track can help you communicate what is and isn't working with the healthcare provider.



Doctor Discussion Guide: A handy set of questions to make talking to the doctor easier. It can be filled out online and brought to an appointment to help talk through issues with the treatment and routine. You can find it through this code, or [click here](#).



IMPORTANT SAFETY INFORMATION (continued)

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

The most common side effects that may occur are:

- Headache
- Nausea
- Fatigue
- Diarrhea
- Vomiting

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We're here for you along the way.



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There are resources available that can support you while you're providing support.



Patient Starter Kits are sent by a specialty pharmacy and are designed to help educate about infusing. The kit does not replace adequate training. We have a video to walk you through what's in the kit—watch it by scanning the code, or [click here](#).



A free trial with HelloCuvitru! Does the person you're caring for want to see if CUVITRU may be right for them? If they're eligible, the entire cost of the first 3 infusions can be covered.



With Takeda Patient Support, help is just a tap or call away—from co-pay assistance to PI education. Call Takeda Patient Support or [check out our website](#) for the answers to your questions.



MylgSource 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.



Want to see more resources and programs? Scan or [click here](#) to delve deeper.



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Connect
with common
words and
phrases.



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You'll see these often as you learn about PI.

ASBI: Acute serious bacterial infection, a short-term but serious infection that requires immediate medical care.

IG: Immune globulin, which contains the antibodies that are delivered during infusions.

Local side effects: Occur on the body where the medicine is given; these generally go away within a few hours and are less likely after the first few infusions.

Patient-year: Used to describe what patients 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.

subQ: Shortened form of "subcutaneous," which means "beneath the skin," not in a vein like intravenous (IV) therapies.

Systemic side effects: Happen throughout the body, such as a headache or feeling tired.

Is this list missing something? Visit the full glossary by scanning the code or [clicking here](#).



IMPORTANT SAFETY INFORMATION (continued)

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You can help them through this.

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Find useful information inside:

- The basics of PI
- What sets CUVITRU apart
- An intro to infusing
- Support for talking to a doctor

Want to stay up-to-date with CUVITRU? Scan the code or [click here](#) to sign up for our email list.



If you need more information, visit [CUVITRU.com](https://www.cuvitru.com).

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