



Cuvitru
[Immune Globulin Subcutaneous (Human)] 20%

Look out, PI.

CUVITRU is here.

When you have a child with PI, you want the treatment plan that's best for them.

Learn more about how the fastest-growing subQ therapy on the market in 2018* offers an administration that can be tailored to meet your child's individual needs and allows you to customize their treatment plan with confidence.

PI=primary immunodeficiency. subQ=subcutaneous immune globulin.

*Data based on PI diagnosis codes (ICD 10) from 4 of the 5 largest specialty pharmacies servicing patients with PI in the home in 2018.

What is CUVITRU?

CUVITRU® [Immune Globulin Subcutaneous (Human)] 20% Solution 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 safety information throughout, click for [Information for Patients](#), and discuss with your HCP.

You can do this.

PI can be managed.

Maybe you're still learning about PI—or maybe you're familiar with your child's diagnosis, but you're thinking about changing their current treatment.

Regardless of where you and your family are in your journey with PI, you probably have a lot of questions.

This brochure was made to help guide you as you navigate diagnosis, administration plans, and support programs—so you can manage your child's treatment experience, as well as your own.

What does a PI diagnosis mean?

Most likely, your child with PI has a history of recurrent, stubborn infections due to the fact that part of their immune system is either missing or not working properly. Because their immune system is incomplete in this way, their body doesn't have enough antibodies—also called immune globulin (Ig)—to fight off things like bacteria or viruses, causing infections to be more common.

PI is:

- Incomplete immune function
- Usually, but not always, inherited
- Diagnosed at any age and gender

PI is NOT:

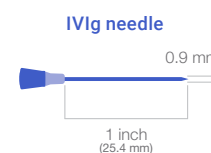
- Secondary immune deficiency (HIV/AIDS) or an autoimmune disease
- Contracted or acquired
- Contagious

How is PI treated?

While your child's PI cannot be cured, regular Ig treatments can provide them with the antibodies they need to help their bodies fight infections. One way of doing this is called "Ig replacement therapy." During Ig replacement therapy, Ig is administered into your child's body in 1 of 2 ways: either intravenously (in a vein) or subcutaneously (under the skin). The method you and your child's doctor choose to use is called the "route of administration."

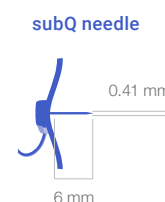
Intravenous (or "IVIg") administration

- Ig enters the body through a vein in the hand or arm, through use of an IV needle
- Healthcare providers (HCPs) administer at an infusion center or physician's office



Subcutaneous (or "subQ") administration

- Ig enters the body through the subQ tissue—which is a layer of tissue between the skin and muscle—through use of a pump and a small, thin subQ needle
- After training, you can administer at home



For illustrative purposes only.

How can you help your child understand PI?

Depending on your child's age, it may be difficult for them to understand PI and why they are getting infusions.

Here's one way to talk about it:

“Inside our bodies, we have something called an ‘immune system,’ and inside that live protectors that keep us from getting sick.

If we don't have enough protectors, or they don't work right, it can be easy to get sick—but we can get more protectors with a medicine called ‘Ig.’

The protectors in Ig can enter our bodies through an ‘infusion,’ and help keep us from getting sick as often.”

What is CUVITRU?

CUVITRU is a subQ replacement therapy consisting of immunoglobulin G (IgG) antibodies collected from human plasma, donated by healthy people.

CUVITRU was studied in 77 people with PI \geq 2 years of age in North America. The main goal of this study was to measure how many acute serious bacterial infections (ASBIs) were experienced over the course of 1 year. ASBIs are short-term but serious infections caused by bacteria that require immediate medical care.

The US Food and Drug Administration (FDA) states that for an immunoglobulin treatment to be considered effective, the rate of ASBIs should be less than 1 per year.

What can CUVITRU offer?



Reliable infection protection and consistent Ig levels

CUVITRU can offer protection and consistent Ig levels to your child, regardless of how frequently they dose—and they can dose daily to biweekly (every 2 weeks) because of its unique infusion profile. In the North American study, people taking CUVITRU experienced:

- 0.012 ASBIs* per year
- A yearly rate of any infections of 2.41 (per patient-year)
- 1.16 days in which they were unable to attend work/school or perform normal daily activities due to illness or infection
- 0.06 days spent in the hospital due to infections

*The 1 ASBI that occurred was in a 78-year-old patient, which means that no children taking CUVITRU experienced an ASBI.



Well tolerated, even at higher volumes and rates

There were no local side effects—that is, reactions that occur at the infusion site—such as pain, redness, and itching in 98.2% of CUVITRU infusions (4247/4327 infusions), even at higher infusion rates and increased volume per site, in the North American study.

- 100% of local side effects 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
- The most common side effects overall were local side effects and systemic side effects—that is, reactions that affect the entire body and can occur within 72 hours (excluding infections)—including headache, nausea, fatigue, diarrhea, and vomiting



Fastest subQ rates and fewest needlesticks

Whether faster infusions or fewer needlesticks are more important to you and your child, CUVITRU allows you and their doctor to customize administration without compromising on tolerability. In the North American study:

- Infusions typically took <1 hour*
- Most infusions (84.9%) used 1-2 infusion sites†

*Average: 0.95 hours (range, 0.2-6.4 hours).

†Your child can use up to 4 sites simultaneously.

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.

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 safety information throughout, click for [Information for Patients](#), including Warning about Blood Clots, and discuss with your HCP.

How can you administer

CUVITRU to your child?

Administering CUVITRU is a 3-stage process, called the “ABCs to infuse.” If you and your child’s doctor decide that CUVITRU is right for them, you’ll receive step-by-step in-person training for at-home administration, as well as a detailed step-by-step guide as a supplement. The guide will help you as you learn to administer CUVITRU to your child on your own. The stages to administer may feel unfamiliar at first, but you’ll become experienced with practice.

Do not use CUVITRU at home until you get instructions and training from your child’s HCP.

A

Assemble

- Check vial(s)
- Gather supplies
- Prepare syringe(s)
- Set up pump and tubing/needle set

B

Begin

- Select and clean infusion site(s)
- Insert and secure needle set
- Start infusion tubing/needle set

C

Complete

- Remove needle(s)
- Record infusion



Please refer to the Detailed Instructions for Administration for Patients for full step-by-step instructions on how to administer CUVITRU.

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.

How can you make infusion time more comfortable?

Keeping disruptions to a minimum is very important during infusions. To establish infusion time as a routine and reduce potential stress, create an “infusion zone.” You can set up your child’s infusion zone however you wish, but here are some suggestions:



Consider using sensory distraction techniques, like a buzzing toy or a smooth rock that the child can paint and keep in the freezer. Your child can hold their sensory toy or cold rock for comfort and to feel involved in their treatment. You can even decorate your own “comfort item” with your child to remind them that you’re there for them during their infusions.



A toy, book, smartphone, or laptop game might help your child stay calm, still, and distracted from needles or pain. These simple, everyday objects can help keep your child’s mind occupied, and divert their attention from the infusion experience.



If you feel it’s appropriate, involve siblings in the process. They may feel like the child with PI is receiving all the attention, so getting them involved could help avoid hurt feelings.

What are some possible common side effects of CUVITRU?

After their CUVITRU infusion, your child may experience one or more possible side effects. These effects generally go away within a few hours and are less likely to occur after their first few infusions.

Local side effects can include: Mild or moderate pain, redness, and itching

Systemic side effects can include: Headache, fatigue, vomiting, nausea, and diarrhea



Contact your HCP if any of these side effects bother your child, or don’t go away.
















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

How can CUVITRU

fit into your child's life?

The length and frequency of infusions will depend on your child's prescribed dose, the way they respond to treatment, and their individual needs. Their doctor will work with you to customize their administration plan to best suit your family's lifestyle.

Below, you'll find a few examples of theoretical treatment plans—so you can have an idea of what can be achieved with CUVITRU.*

	George: 3 years, 31 lbs	 3 grams/ 15 mL <small>Dose</small>	 Once a week <small>Infusion frequency</small>	 30 mL/h/site in 1 site <small>Infusion rate</small>	 About 30 minutes <small>Infusion time</small>
<small>Theoretical patient with PI.</small>					
	Alexie: 10 years, 82 lbs	 8 grams/ 40 mL <small>Dose</small>	 Every 2 weeks <small>Infusion frequency</small>	 45 mL/h/site in 1 site <small>Infusion rate</small>	 Just under an hour <small>Infusion time</small>
<small>Theoretical patient with PI.</small>					
	Sam: 14 years, 106 lbs	 12 grams/ 60 mL <small>Dose</small>	 Every 2 weeks <small>Infusion frequency</small>	 60 mL/h/site in 2 sites <small>Infusion rate</small>	 About 30 minutes <small>Infusion time</small>
<small>Theoretical patient with PI.</small>					

*Results represent a theoretical patient experience. Individual results may vary.

IMPORTANT SAFETY INFORMATION (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
- Fatigue
- Vomiting
- Nausea
- Diarrhea

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.

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.

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

“ I'm on 3 dance teams and the treatment I was on before CUVITRU was every week, so it slowed me down. Now that I infuse with CUVITRU every other week, I feel like I have more time to dance. ”

– Hadlie Jo, actual 9-year-old with PI

Before CUVITRU, Hadlie Jo was on a weekly treatment that took her 2.5 hours to infuse. With CUVITRU, she infuses for less than an hour every other week—and that allows her the time to live a more active life.

Results represent one patient's experience. Individual results may vary.



Wherever you are on this journey,
you have resources and support.

HelloCUVITRU Free Trial Program*

HelloCUVITRU can help you and your child's doctor decide if CUVITRU is right for them. If your child is eligible, HelloCUVITRU covers the entire cost of the first 4 infusions of CUVITRU, along with ancillary supplies, pump, and administration.†

- The program is available to eligible patients with PI 2 years of age and older, regardless of insurance
- There is no obligation to continue use of CUVITRU after the trial has been completed
- For any future use of CUVITRU, you must obtain a new prescription for your child

*This free trial offer is solely intended to allow new patients with PI to try CUVITRU and to determine with their HCP whether CUVITRU is right for them. There is no obligation for the patient to continue use of CUVITRU after the free trial has been completed. HelloCUVITRU is not meant to induce or require future/continuing prescriptions of CUVITRU.

†Eligible patients must have an ICD-10 code verifying diagnosis of PI and be a new patient not currently using CUVITRU who has not previously enrolled in the HelloCUVITRU Program.



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.

- 📞 **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.

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 takedapatientssupport.com/cuvitru/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.



***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.

my Ig source

Learn more about PI and connect with someone who is living with PI or has a loved one with PI.

Go to MyIgSource.com or call **1-855-250-5111**.

Talk to your child's doctor to see
if CUVITRU is right for them.

You can learn more about CUVITRU and find resources about living with PI at [CUVITRU.com](https://www.cuvitru.com).

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