Cuvitru
[Immune Globulin Subcutaneous (Human)] 20%

Listen, PI.

I'll tell you who's

in charge.

How can CUVITRU help tailor your treatment experience to fit your lifestyle?

Learn more about how real people who all wanted different things from their PI treatment found what they needed with CUVITRU® [Immune Globulin Subcutaneous (Human)] 20% Solution—a subQ with customizable administration.

PI=primary immunodeficiency; subQ=subcutaneous immune globulin.

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
- 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 here for Information for Patients, and discuss with your HCP.

Cuvitru
[Immune Globulin Subcutaneous (Human)] 20%

CUVITRU can help you take control of your PI.

Fastest subQ infusion rates

In the North American clinical study, the average duration of once-weekly infusions was <1 hour.*

Flexible frequency

As a 20% subQ with the fastest infusion rates (60 mL/hour/site, as tolerated) and highest infusion volume (60 mL/site, as tolerated), a dosing schedule of daily to every 2 weeks is possible.†

Fewest needlesticks

In the North American study, most infusions (84.9%) used 1 to 2 infusion sites, but you can use up to 4 simultaneously.

CUVITRU was studied in 77 people with PI ≥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–which are short-term but serious infections caused by bacteria that require immediate medical attention–were evaluated in 74 people taking CUVITRU for an average of 380.5 days (range, 30-629 days). The FDA states that for an immunoglobulin treatment to work, less than 1 ASBI can be experienced per year. In the study, people taking CUVITRU experienced 0.012 ASBIs per year, which is significantly less.

*Average: 0.95 hours (range, 0.2-6.4 hours).
†Recommended to infuse 10 to 20 mL/hour/site for the first 2 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.

Please see additional safety information throughout, click here for Information for Patients, including Warning about Blood Clots, and discuss with your HCP.

Walter's CUVITRU Treatment Plan

12 grams	Once a week	1	F1200 or Infuset™ 930	1 hour
Dose	Frequency	Sites	Flow rate tubing*	Time

*Takeda does not prefer, recommend, or attest to using any specific infusion flow rate tubing or other ancillary device.

Walter wanted reliable protection and fewer needlesticks

Before my PI was diagnosed, I experienced a dramatic decline in my health. With recurrent pneumonia and recurrent sinusitis, I sometimes felt like infections were in control of my life.

Getting diagnosed was a huge relief, but my previous subQ treatment required 4 needlesticks, which felt like a burden. When I brought up my concerns to my doctor, she told me about CUVITRU.

My results with CUVITRU are just what I wanted. My infections have been kept under control, my infusions require just 1 needlestick, and I've even been able to reduce my infusion time, which is a huge plus.

"Now I'm back to living my life. My CUVITRU administration schedule helped give me that freedom."

– Walter, actual patient with PI

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

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.

Please see additional safety information throughout, click here for Information for Patients, including Warning about Blood Clots, and discuss with your HCP.

Hadlie Jo's CUVITRU Treatment Plan

12 grams	Every 2 weeks	2	F1200 or Infuset™ 930	<1 hour
Dose	Frequency	Sites	Flow rate tubing*	Time

*Takeda does not prefer, recommend, or attest to using any specific infusion flow rate tubing or other ancillary device.

Hadlie Jo wanted more time between treatments and protection from infections

Before CUVITRU, I was on a weekly treatment that took me 2.5 hours to infuse.

Because I'm on 3 dance teams and really active, I felt like the treatments were really slowing me down.

After my mom talked to my doctor, I was switched to CUVITRU. Now that I'm infusing every 2 weeks, I don't feel sick as much as I did before I was diagnosed, and I have more time for dance practice!

"I like that it's every other week instead of every week, so I can play or dance or whatever I want to do."

– Hadlie Jo, actual patient with PI

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

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:

- 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.

Please see additional safety information throughout, click here for Information for Patients, including Warning about Blood Clots, and discuss with your HCP.

Julie's CUVITRU Treatment Plan

14 grams	Every 2 weeks	2	F2400 or Infuset™ 1850 Flow rate tubing*	~35 min
Dose	Frequency	Sites		Time

*Takeda does not prefer, recommend, or attest to using any specific infusion flow rate tubing or other ancillary device.

Julie wanted shorter treatments and fewer side effects

After I was first diagnosed with PI, I began an IVIg treatment. While the treatments seemed to keep my infections under control, I'd experience 1 week of debilitating fatigue and malaise following each infusion.

Then, it started to become difficult to access my veins. This, coupled with the side effects that kept affecting me, got me to talk with my doctor about other options.

Now that I'm on CUVITRU, I don't experience the type of side effects I did with my IV infusions. Plus, the fact that my CUVITRU infusions only take about 35 minutes makes me optimistic for the future.

"CUVITRU has been very life-friendly, including the set-up and frequency. After my infusion, I don't have to think about it again for 2 more weeks."

– Julie, actual patient with PI

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

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 100ºF. This could be sign of an infection.

Please see additional safety information throughout, click here for Information for Patients, including Warning about Blood Clots, and discuss with your HCP.

Cuvitru
[Immune Globulin Subcutaneous (Human)] 20%

Customize without compromise.

Reliable infection protection and consistent Ig levels

CUVITRU delivers reliable protection against infection and provides consistent Ig levels, regardless of how frequently you dose—which means daily to biweekly (every 2 weeks) dosing is a reality for you.

Well tolerated, even at higher volumes and rates

98.2% (4247/4327) of CUVITRU infusions were completed with no local side effects such as pain, redness, and itching, even at higher infusion rates and increased volume per site, in the North American study. The most common side effects overall were local side effects and systemic side effects, including headache, nausea, fatigue, diarrhea, and vomiting.*

Fastest subQ infusion rates and fewest needlesticks

Whether you prefer infusions that take less than an hour or fewer needlesticks, CUVITRU is the subQ of choice that can be customized to meet your individual needs.

*Local side effects occur at the infusion site. Systemic side effects affect the entire body and can occur within 72 hours, excluding infections.

IMPORTANT SAFETY INFORMATION

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

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.

Please see additional safety information throughout, click here for Information for Patients, including Warning about Blood Clots, and discuss with your HCP.

S52795 01/20

Takeda