

It all starts here.

This is your overview guide.

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 <u>Information For Patients</u>, and discuss with your HCP.



Resources are available. Scan to read about a program that offers co-pay assistance if you're eligible, helpful guides, and so much more.

We know the little things in life are really the big things.

For patients with primary immunodeficiency (PI), CUVITRU is likely the result of a history of doctor appointments, tests, questions, conversations, and absorbing info. But think of this as a big next step, one that leads to the possibility of taking in more moments with weekly or every-other-week infusions.

Whether you're switching from another immunoglobulin subcutaneous (subQ) or intravenous (IV) treatment, this brochure can help you understand the flexible infusion options available to you.

You've worked hard to get here. We're here to support you.

Sincerely, All of us behind CUVITRU



Let's do this.

The contents of everything here (including this brochure) are designed to make sure you know what to expect and when-and that you have all the information needed to start CUVITRU.

Identifying y Your pump + About infusi Side effects c Resources for

IMPORTANT SAFETY INFORMATION (continued) Who should not use CUVITRU?

Do not use CUVITRU if you:

What should I avoid while taking CUVITRU?

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

Here's what you'll find on the following pages:

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• Have had a severe allergic reaction to immune globulin or other blood products.

• Have a condition called selective (or severe) immunoglobulin A (IgA) deficiency.

• 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.





Get familiar with your supplies.

First things first: "What is all this?!"

Everything you'll need to infuse CUVITRU, or help your child or a loved one infuse, is listed on the following page.

Before you infuse!

You'll get appropriate training before you infuse CUVITRU for the first time.

What's a specialty pharmacy? (We're glad you asked.)

Specialty pharmacies provide specific medication for certain chronic illnesses, like PI. Different than a regular pharmacy, specialty pharmacy professionals are specifically focused on—and trained for—filling prescriptions and providing the supplies necessary to help patients with these conditions.

What you'll need to infuse CUVITRU



Takeda does not prefer, recommend, or attest to using any specific infusion pump or other ancillary device. The graphic is an example of what you can expect. Talk to your doctor or specialty pharmacist to ensure you're receiving the supplies necessary to achieve your intended infusion rate.

Worth noting about your supplies:

What you get may not look exactly like what is pictured here, and that's OK. Some things may look different from time to time, depending on what brands/supplies the pharmacy has in stock.

When infusing, please remember to refer to the Information For Patients.

Just-in-case extras:

You may receive supplies like an antihistamine or epinephrine. Ask your doctor what's right for you.

Transfer device

to transfer CUVITRU into syringe(s).

A vented spike used

Subcutaneous needle set

A needle delivers CUVITRU into your body. Your needle size (gauge) can vary depending on your dose and personal preference.

Alcohol swabs

These are included so you can clean the tops of the vial caps and vour infusion site.

Infusion log

To write down the details of each infusion, like dose and number of sites.

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

- serious allergic reaction.
- of the lining around your brain.

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



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

• Bad headache with nausea, vomiting, stiff neck, fever, and sensitivity to light. These could be signs of irritation and swelling

• 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.



Here's a closer look at the syringe driver pump.

To use this pump, you insert the syringe filled with CUVITRU and then it slowly, steadily pushes your prescribed dose out of the syringe, through the tubing, to you.



edle gauge: helps achieve the desired infusion rate of CUVITRU* *To achieve the maximum infusion rate of 60 mL/hour/site with CUVITRU, you'll need a 24-gauge needle.

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:

- 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.

Training is essential.

This is so important-please don't infuse until you've trained with a nurse. This is what they do. They know the process and are crucial to safely and successfully self-infusing.

The infusion process is broken up into four sections to help you to remember.



- Gather supplies
- Check vials
- Clean work area
- Lay out infusion mat
- to set up pump
- or nurse
- Open supplies

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

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

Think of tru_{-} to remember.

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

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
• Fatique
• Diarrhea
• Vomiting



There's also a video.

Sometimes it's helpful to see a demonstration. Scan the QR code to watch a video about infusion



Want to know what infusing is like?

Here's a little about a typical experience. Your results may be different because they vary from person to person, but this gives you an idea. And, give yourself some grace. It'll take a few times to get a handle on the infusion process.



- You'll pick an infusion site (or sites) based on direction from your doctor. With CUVITRU, you can infuse in the upper arms, abdomen, thighs, or lower back
- Setup only takes a few minutes, depending on how many infusion sites you have
- Grab whatever you'll want close by, like a drink, a book, a blanket, cell phone, etc

DURING the infusion

- Mild or moderate pain, redness, and itching (local side effects) may be experienced at the infusion site
- Contact your doctor if a local reaction increases in severity or persists for more than a few days
- Try to relax, and check on your infusion site from time to time to make sure everything looks OK

AFTER the infusion

- Record your infusion details and any other notes you want to make in your Wellness Journal
- The most common side effects that may occur (systemic side effects) are headache, nausea, fatique, diarrhea, and vomiting





IMPORTANT SAFETY INFORMATION (continued) Who should not use CUVITRU?

Do not use CUVITRU if you:

What should I avoid while taking CUVITRU?

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

IMPORTANT SAFETY INFORMATION

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

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

Infusion time is still your time.

Nervous, hopeful, anxious, excited...these are just a few emotions you might feel when starting a new treatment. It's normal to feel all of them (and then some). But once you get the hang of infusing, you'll get comfortable with using this time to do more of what you want. To help the time pass, here are some ways others like to spend their infusion time:

- Movie night or binge a series you've been wanting to see
- Reading-grab a book from your nightstand you've been meaning to start
- Call someone and catch up
- Tune in to a new podcast
- Craft-people have done everything from cross-stitch to scrapbooking
- If you want to get caught up on some light work, like reading emails or meal planning for next week, go for it

Make room for relaxation.

It's helped others to set up a dedicated space for infusing. Usually it's a comfy, calm, and serene spot with a lounge-style chair, soft lighting to chill, and a few favorite things, like books, crossword puzzles, crafts, etc.

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





CUVITRU helps to prevent infections, but what about side effects?

What you should know.

Infusion site reactions generally go away within a few hours and are less likely after the first few infusions. They can include mild or moderate pain, redness, and itching.

The most common side effects that may occur are headache, nausea, fatigue, diarrhea, or vomiting.





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

- Dark colored urine, swelling, fatigue, or difficulty breathing

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

How you feel is important.

If you and/or your loved one have questions about potential side effects with CUVITRU-either before or after infusing-always ask your doctor.

Want more info on potential side effects?

Scan the QR code to get the numbers and facts.

CUVITRU was studied in 77 people with primary immunodeficiency (PI) ≥2 years of age, with the main goal of measuring how many acute serious bacterial infections (ASBIs) were experienced over the course of 1 year. ASBIs are short-term but serious infections that require immediate medical care. For an immunoglobulin (Ig) treatment to be effective, the rate of ASBIs must be <1 per year. On average, people taking CUVITRU experienced 0.012 per year, which is significantly less.

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What is CUVITRU?

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Who should not use CUVITRU?

Do not use CUVITRU if you:

What should I avoid while taking CUVITRU?

- (HCP) that you take CUVITRU.

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

HCP or call emergency services:

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.

- Blood clots in the heart, brain, lungs, or elsewhere in the body
- Severe headache, drowsiness, fever, painful eye movements,

• Dark colored urine, swelling, fatigue, or difficulty breathing

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

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• 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.

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

- 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 sign of an infection.

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.

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 out-of-pocket expenses, up to the program maximum.

Patient **Program may cover**

Not enrolled or need assistance?

You can join Takeda Patient Support in a few simple steps. Visit TakedaPatientSupport.com/CUVITRU or scan this QR code.

Monday through Friday, 8 AM to 8 PM ET.

my g 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 an advocate? Call 1-855-250-5111 to talk or visit MylgSource.com to learn more.



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



of your out-of-pocket costs

Our support specialists are never more than a tap or a call away. Reach us at 1-866-861-1750,



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 guestions about your treatment. Our nurses cannot provide medical advice.

C 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.

MPORTANT 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.



What reconnections are you excited for?

Visit <u>CUVITRU.com</u> or have a conversation with your doctor to learn more about CUVITRU.

Our emails are packed full of good stuff too.

Share your email address with us, and we'll share helpful, insightful content with you.



Scan to sign up now.

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