

Reconnect with volunteer days.

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

This is your Step-by-Step Guide for infusing.

To help with the infusion process, we've created TRU4—four sections to help you learn how to self-infuse. This guide is intended for use only as a supplement to in-person training from your healthcare professional. Do not infuse CUVITRU until you have been trained, have read the Information for Patients, and are comfortable that you can perform the steps on your own.

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 scroll for additional Important Safety Information, click for <u>Information For Patients</u>, and discuss with your HCP.



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Learn to infuse with four sections.

These instructions are designed to help you learn how to self-infuse CUVITRU.

As you complete each infusion, be sure to jot down any questions or concerns in your Wellness Journal that you want to discuss.

Do not use CUVITRU at home until you get instructions and training from your doctor and you're comfortable that you can perform all of the steps on your own. At home, you should have another responsible person present to help treat side effects or get help if you have a serious adverse reaction.

Detailed instructions for self-infusing CUVITRU can be found in your Information For Patients.

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.

Please scroll for additional Important Safety Information, click for <u>Information For Patients</u>, including Warning about Blood Clots, and discuss with your HCP.



2 This guide is intended for use only as a supplement to in-person training from your healthcare professional.

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Four sections to infuse CUVITRU.

Our goal is to make sure that you feel confident in your ability to complete your infusions in the comfort of your own home.

tru 1 Get organized

tru2 Prep and draw CUVITRU

tru 3 Start infusion

tru2, Remove needle(s) and wrap up

IMPORTANT SAFETY INFORMATION (continued)

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 scroll for additional Important Safety Information, click for <u>Information For Patients</u>, including Warning about Blood Clots, and discuss with your HCP.

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IMPORTANT SAFETY INFORMATION

What you'll need



From your CUVITRU vials to the Wellness Journal where you can track your treatment-these are your supplies.

It may seem a bit overwhelming at first, but this guide will walk you through the supplies you'll be using and the infusion process. Something to know—**the supplies that you receive from your pharmacy may look different, and that's OK.** They may include rescue medications, such as antihistamines or epinephrine, if recommended by your doctor. Supplies may vary based on what brands the specialty pharmacy has in stock.



CUVITRU vial(s) The number of vials you will have will depend on your prescribed dose.



Sterile tip cap(s) (as needed)



Mechanical or electromechanical infusion pump



Alcohol swabs, antibacterial cleaner, soap, tape, and bandages. Gloves can be used if recommended by your doctor



Vented spike(s), or a needle or needleless transfer device



Sharps container



Syringe(s)



Subcutaneous needle set with a clear dressing



Wellness Journal





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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 scroll for additional Important Safety Information, click for <u>Information For Patients</u>, including Warning about Blood Clots, and discuss with your HCP.







Gather supplies



- Gather your infusion supplies.
- Follow manufacturer guidelines to set up your pump.

tru 1 Get organized

tru¹ Get organized (continued)



Check vials



*CUVITRU can be stored in the refrigerator (36°F-46°F [2°C-8°C]) for up to 36 months, or at room temperature (77°F [25°C]) for up to 24 months. Do not freeze CUVITRU. To protect from light, store CUVITRU in its original box.

- Take CUVITRU out of the box and allow the vial(s) to reach room temperature. This may take up to 90 minutes. Do not apply heat or place in the microwave.
- Do not return CUVITRU to the refrigerator if you take it out to room temperature.*
- Do not shake the vial(s).
- Do not use CUVITRU beyond the expiration date.
- Do not use CUVITRU if the protective cap is missing or broken.
- Check the vials for color-CUVITRU should be clear and colorless to pale yellow. Do not use CUVITRU if the solution is cloudy or has particles.

tru 1 Get organized

tru 1 Get organized (continued)



Clean your work area



- Clean your work area with an antibacterial cleaner.
- If you have an infusion mat, lay it out and clean as directed by your healthcare provider.



- Wash your hands with soap.
- If instructed by your healthcare provider, put gloves on when your hands are dry.



- Open your supplies, as shown by your healthcare provider.
- Keep them in their packages and place them near your clean work area.

tru 1 Get organized

tru2 Prep and draw CUVITRU

Well done! You're ready for TRU2.



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

Please scroll for additional Important Safety Information, click for <u>Information For Patients</u>, including Warning about Blood Clots, and discuss with your HCP.



IMPORTANT SAFETY INFORMATION





Prepare syringe(s)



- Remove the cap from the CUVITRU vial(s).
- Without shaking the vial(s), wipe the stopper with a sterile alcohol swab and let it dry.





Draw CUVITRU



- Attach a sterile syringe to a vented spike.
- Remove the cap from the spike and discard it in the trash.



• Insert the vented spike straight down into the center of the vial stopper.



- Turn the vial upside down and pull back on the plunger to withdraw CUVITRU into the syringe.
- When the syringe is full or you have reached your dose, turn the vial rightside up and remove the syringe from the spike.
- Leave the spike in the vial.

tru 1 Get organized

tru 2 draw CUVITRU

IF USING A STERILE NEEDLE

- 1. Attach a sterile syringe to the sterile needle.
- 2. Pull back the plunger of the syringe to fill with air that equals the amount of the solution you will be taking from the vial.
- 3. Insert the needle into the center of the vial stopper and inject the air in.
- 4. Turn the vial upside down and pull back on the plunger to withdraw the desired volume.
- 5. Remove the syringe from the needle, leaving the needle in the vial.





Draw CUVITRU (continued)



- Hold the syringe with the tip up, and tap the syringe to remove air bubbles.
- Slowly push the plunger until the fluid is at the tip of the barrel. (Repeat if your infusion requires more than one syringe.)
- Cover the syringe with the sterile tip cap.

If using multiple vials, repeat steps for each vial.

Start the infusion promptly after drawing CUVITRU into the syringe(s). It is suggested to complete the administration within 2 hours.





Set up pump tubing and needle set



- Set up the pump using manufacturer directions.
- Attach the syringe filled with CUVITRU to the needle set.
- Depending on the type of pump used, pump tubing may be required.



- Point the syringe tip up and gently push the plunger of the syringe to remove the air and fill the needle set up to the needle hub.
- Avoid coating the needle with CUVITRU.



- Clamp the needle set tubing.
- Lay the syringe and needle set down on the clean work surface.
- Attach needle to set.
- Fill needle set.



Cuvitru [Immune Globulin Subcutaneous (Human)] 20%



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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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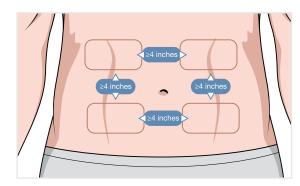


tru 3 Start infusion

Cuvitru [Immune Globulin Subcutaneous (Human)] 20%

Select and clean infusion site(s)

- Wash your hands with soap.
- If instructed by your doctor, put gloves on when your hands are dry.
- Choose an infusion site or sites, based on the direction from your doctor, in the upper arms, abdomen, thighs, or lower back.
- Avoid bony areas, visible blood vessels, scars, and any areas of inflammation (irritation) or infection.



- If instructed to use 2, 3, or 4 sites at the same time, ensure they are at least 4 inches apart.
- For future infusions, rotate your sites.



• Wipe each infusion site with a sterile alcohol wipe (beginning at the center of the site and moving outward in a circular motion) and let it dry (at least 30 seconds).





Insert and secure subcutaneous needle set



- Remove the subcutaneous needle cover.
- Firmly grasp and pinch at least 1 inch of skin.
- Insert the needle with a rapid motion straight into your skin at a 90-degree angle.
- Secure the needle in place with sterile tape.
- If using more than 1 infusion site, clean the next site. Then insert and secure each additional needle as needed for the total dose.



• Secure the needle set by applying a sterile clear dressing over the site.





Infuse



- Following pump manufacturer's instructions, start your prescribed infusion. Be sure to check your infusion site(s) from time to time during your infusion.
- When the syringe is empty, remove it from the pump and detach it from the needle set. If multiple syringes are needed to complete the dose, remove the syringe from the pump tubing/needle set and replace with the next syringe.

Well done! You're ready for TRU4.



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IMPORTANT SAFETY INFORMATION

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Remove needle(s) and dispose of needle set



- When the infusion is complete, loosen the edges of the sterile dressing and pull the needle wings straight up and out.
- Place a bandage over the infusion site(s).
- Dispose of the needle set in your sharps container.
- Check with your specialty pharmacy to learn how to dispose of your sharps container, vials, and other supplies.





Record infusion details



- Record the infusion details as instructed by your doctor and as outlined in your Wellness Journal.
- Follow up with your doctor as directed or if you have any questions or concerns.

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Congratulations – you did it!

Your infusion is complete! Take a deep breath, let it out, and get back to enjoying the moments that matter most to you.

Don't forget, you've got resources available to you. If you have any questions about CUVITRU, write them down in your Wellness Journal and talk to your doctor, visit <u>CUVITRU.com</u>, or reach out to a Nurse Advocate at 1-855-250-5111.

It's normal to experience some infusion site reactions after your infusion. Talk to your healthcare professional about any side effects that bother you or that don't go away.

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.

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IMPORTANT SAFETY INFORMATION (continued)

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.
- 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.
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Mild or moderate pain
Redness
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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 <u>Information For Patients</u> and discuss with your HCP.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit <u>www.fda.gov/medwatch</u>, or call 1-800-FDA-1088.



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