The ABCs to Infuse CUVITRU®
Your Step-by-Step Guide

CUVITRU [Immune Globulin Subcutaneous (Human)] 20% Solution is for people 2 years of age and older living with primary immunodeficiency (PI)\(^1\)

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

**Important Safety Information**

**What is the most important information that I should 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, and click for Information for Patients and discuss with your healthcare provider.*
Do not use CUVITRU at home until you get instructions and training from your healthcare provider and you’re comfortable that you can perform all 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.

If you have any questions about your CUVITRU infusion, contact a Nurse Advocate at 1-855-250-5111.

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

What is CUVITRU?
• CUVITRU is a ready-to-use, liquid medicine that contains immunoglobulin G (IgG) antibodies, which protect the body against infection.
• CUVITRU is indicated for the treatment of primary humoral immunodeficiency (PI) in adult and pediatric patients two years of age and older.
• CUVITRU is made from human plasma that is donated by healthy people. CUVITRU contains antibodies collected from these healthy people that replace the missing antibodies in PI patients.
• CUVITRU is given under the skin (subcutaneously).
• Most of the time infusions under the skin are given at home by self infusion or by caregivers. Only use CUVITRU by yourself after you have been instructed by your healthcare provider.

Please scroll for additional Important Safety Information, and click for Information for Patients, including Warning about Blood Clots, and discuss with your healthcare provider.
What You’ll Need

Below are the supplies you’ll need to infuse CUVITRU [Immune Globulin Subcutaneous (Human)] 20% Solution. The supplies you receive from your pharmacy may look different, and they may also include rescue medications, such as antihistamines or epinephrine, if recommended by your healthcare provider.

- CUVITRU vial(s)
- Alcohol swabs, antibacterial cleaner, soap, tape, and bandages. Gloves may be used if recommended by your healthcare provider.
- Sterile tip cap(s) (as needed)
- Vented spike(s), or a needle or needle-less transfer device
- Subcutaneous needle set with clear dressing
- Mechanical or electromechanical infusion pump
- Syringe(s)
- Sharps container
- Infusion log
Important Safety Information (continued)

Who should not use CUVITRU?
Do not use CUVITRU if you:
• Are allergic to immune globulin or other blood products.
• Have selective (or severe) immunoglobulin A (IgA) deficiency with antibodies to IgA.

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The ABCs to Infuse CUVITRU

Assemble
• Check vial(s)
• Gather supplies
• Prepare syringe(s)
• Set up pump and tubing/needle set
• Take CUVirTU 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 CUVirTU to the refrigerator if you take it out to room temperature.*
• Do not shake the vial(s).
• Do not use CUVirTU beyond the expiration date.
• Do not use CUVirTU if the protective cap is missing or broken.
• Check the vials for color—it should be clear and colorless to pale yellow. Do not use CUVirTU if the solution is cloudy or has particles.

• Gather your infusion supplies (refer to page 3).
• Follow manufacturer guidelines to set up your pump.

• 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.

*CUVirTU 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 12 months. Do not freeze CUVirTU. To protect from light, store CUVirTU in its original box.
Important Safety Information (continued)
CUVITRU can cause serious side effects. Call your healthcare professional or go to the emergency department right away if you get:

• 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 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.
• 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 a sign of an infection.

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• Remove the cap from the CUVITRU [Immune Globulin Subcutaneous (Human)] 20% Solution vial(s).
• Without shaking the vial(s), wipe the stopper with a sterile alcohol wipe and let it dry.
• You should be ready to start the infusion promptly after drawing CUVITRU into the syringe.
• It is suggested to complete the administration within 2 hours.

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.

TIP
If the full dose requires multiple vials, repeat steps A6-A10 to draw CUVITRU from each additional vial until the prescribed dose is reached. If your dose requires more than one syringe, do not fill the next syringe until you have completed infusing the previous one. It is suggested to complete the administration within 2 hours.
The ABCs to Infuse CUVITRU

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Important Safety Information (continued)

What are the possible or reasonably likely side effects of CUVITRU?
The following one or more possible side effects may occur at the site of infusion: mild or moderate pain, redness, and itching. These generally go away within a few hours, and are less likely after the first few infusions.
The most common side effects that may occur are: headache, nausea, fatigue, diarrhea, and vomiting.

These are not all the possible side effects. Talk to your healthcare professional about any side effects that bother you or that don’t go away.

Please scroll for additional Important Safety Information, and click for Information for Patients, including Warning about Blood Clots, and discuss with your healthcare provider.
• Set up the pump using manufacturer directions.
• Attach the syringe filled with CUVITRU [Immune Globulin Subcutaneous (Human)] 20% Solution 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.

You’re ready for stage B!
Important Safety Information
What is the most important information that I should know about CUVITRU?
CUVITRU can cause the following serious reactions:
• Severe allergic reactions causing difficulty in breathing or skin rash
• 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

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The ABCs to Infuse CUVITRU

Begin
• Select and clean infusion site(s)
• Insert and secure needle set
• Start infusion
• Choose an infusion site or sites, based on the direction from your healthcare provider, in the back of 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.

• 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.

• Check needle placement by opening the clamp on the needle set and gently pulling back on the syringe plunger.
• Make sure there is no blood in the tubing.
• Secure the needle set by applying a sterile clear dressing over the site.
• If you see blood in the tubing, remove and discard the needle, and repeat steps A11-B5 with a new subcutaneous needle and infusion site.

• 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.
The ABCs to Infuse CUVITRU

Complete

• Remove needle(s)
• Record infusion

Important Safety Information (continued)
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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 the infusion details as instructed by your healthcare provider and as outlined in your infusion log.

Follow up with your healthcare provider as directed.

Congratulations!

Your infusion with CUVITRU [Immune Globulin Subcutaneous (Human)] 20% Solution is complete! If you have any questions about CUVITRU, contact a Nurse Advocate at 1-855-250-5111, or your healthcare provider, or visit www.cuvitru.com.
What to Do If You Experience a Local Reaction

A reaction may occur at the site of infusion, such as mild or moderate pain, redness, or itching. These reactions generally go away within a few hours and are less likely after the first few infusions.

Contact your healthcare professional if a local site reaction increases in severity or persists for more than a few days.

Discomfort or pain at the infusion site when inserting the subcutaneous needle

- Remove the needle because it may be in your muscle.
- Contact your healthcare provider if severe pain does not fade when you remove the needle or if it happens each time you infuse.
- Talk to your healthcare provider or specialty pharmacy about changing the length of your needle; it may be too long for you.
- Note in your infusion log that this site may not work for you.

Discomfort, pain, or redness at the infusion site during or after your infusion

- Slow or stop the infusion.
- Place a clean, cold or warm compress (post-infusion), as directed by your healthcare provider on your irritated site.
- Talk to your healthcare provider about a possible allergy to your tape or dressing or the possible use of a mild pain reliever, if recommended.

Itching at or around the infusion site

- Place a clean, cold compress, as directed by your healthcare provider, on your itchy site. Do not apply directly to skin.
- Talk to your healthcare provider about the possible use of an over-the-counter antihistamine, if recommended.
- If you experience hives, swelling in the mouth or throat, itching, trouble breathing, wheezing, fainting or dizziness, stop your infusion immediately and contact your healthcare provider or emergency services; these could be signs of a serious allergic reaction.

What to Do If You Experience a General (Systemic) Reaction

In addition to local reactions, the most common side effects of CUVITRU are headache, nausea, fatigue, diarrhea, and vomiting.

If any of the following problems occur after starting treatment with CUVITRU, stop the infusion immediately and contact your healthcare provider or call emergency services. These could be signs of a serious problem.

- Bad headache with nausea, vomiting, stiff neck, fever, and sensitivity to light. These could be signs of irritation 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 problem or a 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 a sign of an infection.

Whenever giving yourself treatments at home, you should have another responsible person present to help treat side effects or get help if a serious adverse reaction occurs. Ask your healthcare provider whether you should have rescue medications, such as antihistamines or epinephrine available.

Tell your healthcare provider about any side effect that bothers you or that does not go away.
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You are encouraged to report suspected side effects by contacting FDA at 1-800-FDA-1088 or www.fda.gov/medwatch or Shire at 1-800-999-1785.

**Please click for Information for Patients, and discuss with your healthcare provider.**

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**References:**

Cuvitru

[Immune Globulin Subcutaneous (Human)] 20%