The ABCs to Infuse CUVITRU™
[Immune Globulin Subcutaneous (Human)] 20%

Your Step-by-Step Guide

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

Please see the Indication and Important Safety Information on page 19, and click here for FDA-approved patient labeling.
The ABCs to Infuse CUVITRU

Infusion Overview
This guide is designed to help you infuse CUVITRU [Immune Globulin Subcutaneous (Human)] 20%.

Do not use CUVITRU at home until you get instructions and training from your healthcare professional 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.

- CUVITRU is a subcutaneous, or subQ, immunoglobulin treatment for primary humoral immunodeficiency, or PI, in adults and children 2 years of age and older.
- CUVITRU contains immunoglobulin G, or IgG, antibodies, which help your body fight off infections from bacteria or viruses.
- It is suggested to complete the administration within 2 hours due to the potential formation of particles caused by siliconized syringes.

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What You’ll Need

Below are the supplies you’ll need to infuse CUVITRU.*
The supplies you receive from your pharmacy may look different.

CUVITRU [Immune Globulin Subcutaneous (Human)] 20% vial(s)

Alcohol swabs, antibacterial cleaner, soap, tape, and bandages†

Syringe(s)

Sterile tip cap(s) (as needed)

Vented spike(s)‡

Subcutaneous needle set with clear dressing

Infusion pump§

Sharps container

Infusion log

* Your supplies may also include rescue medications, such as antihistamines or epinephrine, if recommended by your healthcare professional.
† You may also need gloves, if recommended by your healthcare professional.
‡ A needle or needle-less transfer device may be used instead.
§ CUVITRU can be infused with a mechanical or an electromechanical pump.

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Assemble

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

- When bringing CUVITRU to room temperature, do not apply heat or place it in the microwave.
- Do not shake the vial(s).
- Do not use CUVITRU beyond the expiration date.
- Do not use CUVITRU if the solution is cloudy or has particles.
- Do not use CUVITRU if the protective cap is missing or broken.
- You should be ready to start the infusion promptly after drawing CUVITRU into the syringe. It is suggested to complete the infusion within 2 hours.

- Allow CUVITRU [Immune Globulin Subcutaneous (Human)] 20% to reach room temperature.*
- This may take up to 90 minutes.
- Take CUVITRU out of the box and check the vials for color—it should be clear and colorless to pale yellow or light brown.

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

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

- Open your supplies.
- Keep them in their packages and place them near your clean work area.

*To protect from light, store CUVITRU in its original box. Do not freeze CUVITRU. CUVITRU can be stored in a refrigerator (36° to 46°F [2° to 8°C]) for up to 36 months.

Taking CUVITRU out of the box may help warm it more efficiently. You can store CUVITRU at room temperature (up to 77°F [25°C]) for up to 12 months. Do not return CUVITRU to the refrigerator if you take it out to room temperature.

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Assemble

- Check vial(s)
- Gather supplies
- Prepare syringe(s)
- Set up pump and tubing/needle set
Remove the cap from the CUVITRU [Immune Globulin Subcutaneous (Human)] 20% 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.

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

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.
Cover the syringe with the sterile tip cap.

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.

TIP

Please see the Indication and Important Safety Information on page 19, and click here for FDA-approved patient labeling.
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Assemble

- Check vial(s)
- Gather supplies
- Prepare syringe(s)
- Set up pump and tubing/needle set
You're ready for step B!

A11
• Set up the pump using manufacturer directions.*
• Attach the syringe filled with CUVITRU [Immune Globulin Subcutaneous (Human)] 20% to the needle set.

*Depending on the type of pump used, pump tubing may be required.

A12
• 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.

A13
• Clamp the needle set tubing.
• Lay the syringe and needle set down on the clean work surface.

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Begin

• Select and clean infusion site(s)
• Insert and secure needle set
• Start infusion
Choose an infusion site or sites 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. For future infusions, rotate your sites.

If instructed to use 2, 3, or 4 sites at the same time, ensure they are at least 4 inches apart.

Wash your hands with soap. If instructed by your healthcare professional, put on gloves when your hands are dry. Wipe each infusion site with a sterile alcohol wipe and let it dry (at least 30 seconds).

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 the steps 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.

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Complete

- Remove needle(s)
- Record infusion
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 outlined in your infusion log.

Follow up with your healthcare professional as directed.

Congratulations!
Your infusion with CUVITRU is complete! If you have any questions about CUVITRU [Immune Globulin Subcutaneous (Human)] 20%, contact a Nurse Advocate at 1-855-250-5111 or visit www.cuvitru.com.

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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.1

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

- Remove the needle because it may be in your muscle.2
- Contact your healthcare professional if severe pain does not fade when you remove the needle or if it happens each time you infuse.
- Talk to your healthcare professional or specialty pharmacy about changing the length of your needle; it may be too long for you.3
- 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.2
- Place a clean, cold or warm compress (post-infusion), as directed by your healthcare professional on your irritated site.2,3
- Talk to your healthcare professional about a possible allergy to your tape or dressing or the possible use of a mild pain reliever, if recommended.2,3

Itching at or around the infusion site

- Place a clean, cold compress, as directed by your healthcare professional, on your itchy site.2
- Talk to your healthcare professional about the possible use of an over-the-counter antihistamine, if recommended.2
- 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 professional or emergency services; these could be signs of a serious allergic reaction.3

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.1 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.1 Ask your healthcare professional whether you should have rescue medications, such as antihistamines or epinephrine available.1

Tell your healthcare professional about any side effect that bothers you or that does not go away.

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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 the Indication and Important Safety Information on page 19, and click here for FDA-approved patient labeling.
**Indication and Important Safety Information**

**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.

**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

**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.

**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 100ºF. This could be sign of an infection.

**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.**

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.

The risk information provided here is not comprehensive. To learn more, talk about CUVITRU with your healthcare provider or pharmacist. Please click here for FDA-approved patient labeling.

**References:**
1. CUVITRU [prescribing information]. Westlake Village, CA: Baxalta US Inc.
3. Murphy E, Burton J, Riley P. Nursing approaches to a novel subcutaneous therapy: a look at 4 patients during transition from IVIg to SCIg. *Infusion.* 2007;13(4)(suppl):1-8.