CUVITRU®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using CUVITRU?

CUVITRU contains the active ingredient human immunoglobulins. CUVITRU is used in patients who do not have enough antibodies in their blood.
For more information, see Section 1. Why am I using CUVITRU? in the full CMI.

2. What should I know before I use CUVITRU?

Do not use CUVITRU if you have severe immunoglobulin A (IgA) deficiency and history of hypersensitivity to human immunoglobulin treatment. Do not use if you have ever had an allergic reaction to CUVITRU or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**
For more information, see Section 2. What should I know before I use CUVITRU? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CUVITRU and affect how it works.
A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use CUVITRU?

- The recommended dose and schedule will be established by your doctor. Your doctor may adjust the dose based on your response to the treatment.

CUVITRU must be infused under the skin by either using an infusion pump or manual administration using a syringe. Your doctor will determine the appropriate infusion technique and the infusion rate for you taking into account your individual dose, dosing frequency and product tolerability. More instructions can be found in Section 4. How do I use CUVITRU? in the full CMI. If your doctor considers that you should receive CUVITRU at home, they will ensure you receive detailed instructions and training on how to use it.

5. What should I know while using CUVITRU?

Things you should do	• Remind any doctor, dentist, or pharmacist you visit that you are using CUVITRU • Call your doctor straight away, if you experience any allergic symptoms (skin rash, itching, chest tightness, wheezing, dizziness, hives, faintness, chills, flushing, rapid heartbeat, shortness of breath and/or a swollen face).
Things you should not do	• Do not stop using your medicine or alter the dosage, without checking with your doctor, unless you have an allergic reaction
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how CUVITRU affects you.
Looking after your medicine	• Keep CUVITRU in the fridge where the temperature is between 2°C - 8°C. Do not freeze. • If needed, you can keep CUVITRU at room temperature below 25°C for up to 3 months. Once CUVITRU has been kept at room temperature, do not put it back in the refrigerator. Dispose CUVITRU after 3 months if stored at room temperature.

For more information, see Section 5. What should I know while using CUVITRU? in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.
If you experience sudden signs of allergy such as swelling of the lips, tongue, or eyes, loss of consciousness, hives, difficulty in breathing, call your doctor straight away, or go straight to the Emergency Department at your nearest hospital. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

CUVITRU®

Active ingredient(s): *Normal Immunoglobulin infusion 20% (Human)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using CUVITRU. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using CUVITRU.**

Where to find information in this leaflet:

1. Why am I using CUVITRU?
2. What should I know before I use CUVITRU?
3. What if I am taking other medicines?
4. How do I use CUVITRU?
5. What should I know while using CUVITRU?
6. Are there any side effects?
7. Product details
8. How to use CUVITRU - Instructions for use

1. Why am I using CUVITRU?

CUVITRU is an immunoglobulin solution for subcutaneous infusion.

CUVITRU contains the active ingredient human immunoglobulin.

Immunoglobulins are also known as antibodies and are found in healthy people's blood. Antibodies are part of the immune system (the body's natural defenses) and help your body to fight infections. If you do not have enough antibodies, you may not be able to fight off infections.

CUVITRU is used in patients who do not have enough antibodies in their blood. CUVITRU can be used as antibody replacement therapy to raise antibody levels in your blood to normal levels.

Your doctor may have prescribed CUVITRU for another reason.

2. What should I know before I use CUVITRU?

About blood products

When medicines are made from human blood or plasma, processes are used to prevent infections from being passed from the blood/plasma donor to the person receiving the medicine.

These processes include careful selection of the people who donate blood and plasma to make sure that those who might be carrying infections are excluded. In addition, each donation and pools of donations are tested for indicators of virus or virus infection(s).

Manufacturers of these medicines also include steps in the processing of blood or plasma that inactivate or remove viruses. A three-step viral inactivation/reduction has been applied during the manufacturing of the normal immunoglobulin infusion.

Despite the stringent measures which have been put in place during the manufacturing processes, the risk of contamination by viral and other unknown agents cannot be totally excluded.

The measures taken during manufacturing are considered effective for enveloped viruses such as human immunodeficiency virus (HIV), hepatitis B virus and hepatitis C virus, and for the non-enveloped viruses hepatitis A (HAV) and B19 virus (B19V).

Immunoglobulins have not been associated with hepatitis A or parvovirus B19 infections possibly because the antibodies against these infections, which are contained in the product, are protective.

Warnings

Do not use CUVITRU if:

- you have known history of allergic or severe hypersensitivity reactions to the subcutaneous administration to immunoglobulins, or any of the ingredients listed at the end of this leaflet (see Product details)
- you have severe immunoglobulin A (IgA) deficiency and history of hypersensitivity to human immunoglobulin treatment.

Check with your doctor if you:

- have antibodies against immunoglobulin A in your blood. This may occur if you have IgA deficiency
- have allergies to any other medicines, or if you ever had an allergic reaction to an injection
- take any medicines for any other condition
- have pre-existing factors for thrombotic events or that increase the risk of renal complications
- have or have had any medical problems

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor if you

- have had a vaccination recently
- if you are taking any other medicines, including any medicines, vitamins, or supplements that you buy without a prescription from your pharmacy, supermarket, or health food shop.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect CUVITRU.

4. How do I use CUVITRU?

How much to use

- Always use CUVITRU exactly as your doctor has told you. Check with your doctor if you are not sure
- Follow the instructions provided and use CUVITRU until your doctor tells you to stop.

When to take CUVITRU

Ensure you are adequately hydrated before the administration of CUVITRU.

How to use CUVITRU

- CUVITRU must be infused under the skin
- Your doctor or healthcare professional will first infuse CUVITRU slowly and monitor you throughout the first infusions so that any allergic reaction can be detected and treated immediately.
- Treatment with CUVITRU will be started by your doctor or healthcare professional, but you may be allowed to use the medicine at home (e.g., by using an infusion pump or manual administration using a syringe) once you have received the first few infusions under medical supervision and you (and/or your guardian) have been adequately trained
- You and your doctor will decide if you can use CUVITRU at home
- Do not begin treatment with CUVITRU at home until you have received complete instructions
- **Always wash your hands before using** CUVITRU**. Use germ-free methods during the making up procedure and during injection**
- CUVITRU is for single use in one patient only.
- When using manual administration:
    - CUVITRU may be administered using a syringe at a single infusion site. If administration at additional sites is required, a new sterile injection needle should be used
    - The amount of product infused into a single site varies and doses over 30 mL may be divided according to your preference
    - Consult with your doctor. Start with an infusion speed that does not cause discomfort. At no time should the infusion be painful. The recommended infusion rate is approximately 1-2 mL per minute. You may find that some injection sites will tolerate larger volumes of infusion than others.

Instructions for use

Refer to 8. How to use CUVITRU - Instructions for use

If you miss/forget your injection

Do not infuse a double dose of CUVITRU to make up for a missed dose. If you think that you have missed a dose, speak to your doctor as soon as possible.

If you use too much CUVITRU (overdose)

The effects of an overdose of CUVITRU are not known.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using CUVITRU?

Things you should do

Call your doctor straight away if you:

- experience allergic reactions such as skin rash, itching, chest tightness, wheezing, dizziness, hives, faintness, chills, flushing, rapid heartbeat, shortness of breath and/or a swollen face.

Remind any doctor, dentist, or pharmacist who are treating you, that you are using CUVITRU.

If you are about to start on any new medicine, tell your doctor or pharmacist that you are taking CUVITRU.

Talk to your healthcare provider before travelling. Plan to bring enough medicine for your treatment during this time. It is important to obtain a written statement from your physician, explaining the reasons why you need to have this medicine and injecting devices with you, otherwise you may not be allowed to bring it into the country of travelling.

Things you should not do

- Do not give your medicine to anyone else, even if they have the same condition as you
- Do not use your medicine to treat any other complaints unless your doctor tells you to
- Do not stop using your medicine or lower the dosage, without checking with your doctor, unless you have an allergic reaction.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how CUVITRU affects you.

Looking after your medicine

- CUVITRU should be stored in the refrigerator at 2°C to 8°C.
- Do not freeze
- If needed, you can keep CUVITRU at room temperature below 25°C for up to 3 months.

- Once CUVITRU has been kept at room temperature, do not put it back in the refrigerator.
- Dispose CUVITRU after 3 months if stored at room temperature.
- Store in the original package to protect from light
- Keep it where young children cannot reach it.

When to discard your medicine

CUVITRU **contains no preservatives.**

Discard any medicine left in the vials at the end of your infusion.

Dispose off all materials, including any leftover reconstituted medicine, in an appropriate container.

Getting rid of any unwanted medicine

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of the medicines no longer required.

Do not use CUVITRU after the expiry date which is printed on the label after the word 'EXP'. The expiry date refers to the last day of that month.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• Swelling, pain, redness or itching where the injection was given • Headache/migraine • Nausea or vomiting • Pain (including pain in the chest, back, joints, arms, legs) • Muscle pain • Fatigue • Diarrhoea • Stomach ache or bloating • Cough • Fever of chills • Feeling faint, dizzy, or lightheaded (fall in blood pressure) • Infusion site ulcer.	**Speak to your doctor if you have any of these less serious side effects and they worry you.** Certain side effects, such as headache, chills, or body aches, may be reduced by slowing the infusion rate.

Serious side effects

Serious side effects	What to do
• Reduced urination • Severe headache • Neck stiffness • Inability to stand bright light	**Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**
• Painful eye movements • Pain/tenderness, swelling/discolouration of an arm or leg • Tingling, numbness, or weakness on one side of the body • Shortness of breath • Chest pain • Fever • Allergic or anaphylactic reaction; symptoms of which may include - swelling of the lips, tongue, or eyes, loss of consciousness, hives, difficulty in breathing. • Non-bacterial (viral) infection of the tissues covering brain and spinal cord (aseptic meningitis)	

Tell your doctor or healthcare professional if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What CUVITRU contains

Active ingredient	20% plasma proteins of which at least 98% are immunoglobulins.
Other ingredients	Glycine and water for injections
Potential allergens	Trace amounts of IgA (≤ 280 mcg/mL)

Do not take this medicine if you are allergic to any of these ingredients.

What CUVITRU looks like

CUVITRU (ARTG 282579) is a clear and colourless to pale yellow or light brown solution in a glass vial.

CUVITRU is available in the following pack sizes:

1 g in 5 mL

2 g in 10 mL

4 g in 20 mL

8 g in 40 mL

10g in 50 mL.

Not all pack sizes may be marketed.

Who distributes CUVITRU

CUVITRU is distributed in Australia by:

Takeda Pharmaceuticals Australia Pty Ltd

Level 39; 225 George Street

Sydney NSW 2000

Australia

Phone: 1800 012 612

This leaflet was prepared in August 2026.

8. How to use CUVITRU - Instructions for use

- If you do not understand the instructions, ask your doctor or healthcare professional.
- Always follow the specific instructions given by your healthcare provider. The steps listed below are general guidelines for using your medicine.

Prepare CUVITRU vial(s)

- Remove CUVITRU from the box. Allow vials to reach room temperature. This may take up to 90 minutes
- Do not apply heat or place in microwave
- Do not shake the vial(s).

1. **Check the vial(s)**

- Do not use beyond the expiration date
- Do not use, if the protective cap is missing or broken
- Look at the colour of the solution in the vial. It should be clear and colourless to pale yellow or light brown
- Do not use if the solution is cloudy or has particles.

2. **Gather all supplies**

- The supplies include vial(s) of CUVITRU, infusion supplies, subcutaneous needle set, transfer device(s), syringe(s), sterile tip caps, sterile clear bandage, tape, gauze, sharps container, infusion pump (if using), tubing, infusion log.



- Clean work area
- When using an infusion pump:
  Program the infusion pump according to prescribed infusion rates and manufacturer's instructions
- Wash hands thoroughly and allowed to dry.



- Open supplies as shown by your healthcare professional.

3. **Prepare the syringe(s)**

- Remove the cap from the vial.



- Wipe each stopper with a sterile alcohol wipe and allow to dry.



- Attach a sterile syringe to a vented spike
- Insert the vented spike into the centre of the CUVITRU vial.
- Turn the vial upside down and pull back on the plunger to pull back on the plunger to pull the solution into the syringe(s).



- Repeat the steps, if using multiple vials to achieve the desired dose.
- Start the infusion promptly after drawing CUVITRU into the syringe(s). It is suggested to complete the administration within 2 hours.

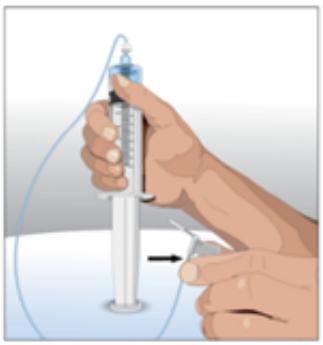
If using a sterile needle:

- Attach a sterile syringe to the sterile needle and pull back the plunger of syringe to fill with air which should equal the amount of the solution you will be taking from the vial.
- Insert the needle into the centre of the stopper, and inject air in. Pull back on the plunger to withdraw the desired volume.

4. **Prepare for the infusion**

a. When using an infusion pump:

- Use manufacturer directions for filling the tubing and using the pump.
- Attach the syringe filled with CUVITRU to the needle set.
- 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.



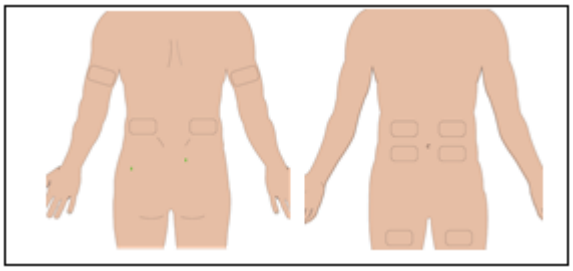
b. When using manual administration:

Follow the instructions by your nurse or healthcare professional.

- Attach the syringe filled with solution to the needle set
- 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.

5. **Prepare the infusion site(s):**

- Select the number of infusion sites based on the volume of the total dose.
- Choose infusion site(s): upper arms, abdomen, thighs, or lower back.
- Avoid bony areas, visible blood vessels, scars, and any areas of inflammation (irritation) or infection.



- Infuse CUVITRU from 1 to 4 infusion sites at the same time. Select sites at least 4 inches apart.
- Rotate sites between future infusions

Wipe the infusion site(s) with a sterile alcohol wipe beginning at the centre of each infusion site and moving outward in circular motion. Allow the infusion site(s) to dry (at least 30 seconds).

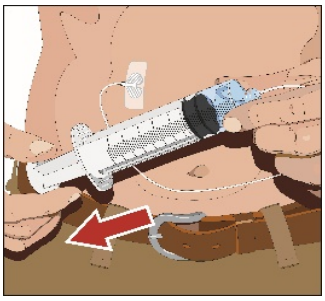


6. **Insert and secure the subcutaneous needle set:**

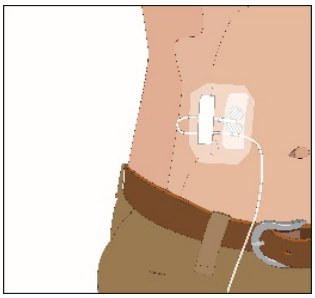
- Remove the needle cover. Firmly grasp and pinch at least 1 inch of skin between two fingers.
- Insert needle with a rapid motion straight into the skin at a 90-degree angle. Tape needle in place with sterile tape (included on transparent dressing).



- If more than one site is used, repeat the steps
- Check for proper needle placement by pulling back on the syringe plunger to check for blood return in the tubing of the needle set.



- If blood is seen in the tubing, remove and discard the subcutaneous needle and repeat steps 4, 5 and 6 with a new subcutaneous needle and infusion site.
- Secure the needle set in place by applying a sterile protective dressing over the site(s).

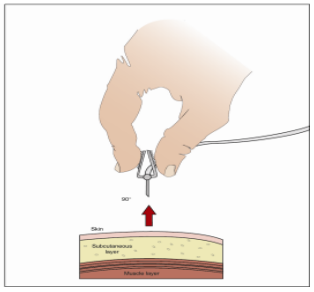


7. **Start the infusion:**

- <u>When infusing by pump</u>:
  Follow the manufacturer's instructions to turn pump on and start the infusion
- <u>When infusing manually</u>:
  Gradually press on the plunger of the syringe as shown by your doctor or nurse, until all fluid in the syringe has been injected, or as explained by your doctor or nurse.
- Check infusion site(s) occasionally throughout the infusion.

8. **Remove subcutaneous needle(s) from the infusion site(s):**

- Remove the needle set by loosening the tape on all edges.
- Pull the needle wings straight up and out
- Gently press a small piece of gauze over the needle site and cover with a dressing.
- Throw away the needle(s) into the sharps container.



9. **Record the infusion**

- Remove the peel-off label from the vial(s), which has the product lot number and expiration date, and place the label in your treatment record/infusion log.
- Write down the date, time, dose, site(s) of infusion (to assist in rotating sites) and any reactions after each infusion.
- Throw away the disposable supplies, vials, and unused product as recommended by your healthcare professional.

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