CUVITRU®

Normal Immunoglobulin Infusion 20% (Human) for Subcutaneous Use

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about CUVITRU.

It does not contain all of the available information. All medicines have risks and benefits. Your doctor has weighed the risks of using your medicine against the benefit that it will have for you. It does not take the place of talking to your doctor or pharmacist.

If you have any concerns about having this medicine, ask your doctor or pharmacist.

Please read this leaflet carefully and keep it for future reference.

Please also note that this leaflet is subjected to change, therefore, ask your doctor whether this is the latest information regarding this medicine.

What CUVITRU is

Your medicine is CUVITRU, an immunoglobulin solution for subcutaneous infusion.

CUVITRU contains human immunoglobulins. 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 defences) and help your body to fight infections. If you do not have enough antibodies you may not be able to fight off infections.

What CUVITRU is used for

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.

CUVITRU has not been evaluated in patients aged < 2 years.

Ask your doctor if you have any questions about why it has been prescribed for you.

Before you use CUVITRU

About blood products

When medicines are made from human blood or plasma, processes are used to prevent infections 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.

When you must not use it

CUVITRU must not be used if you are allergic to immunoglobulins or are allergic to any ingredients in CUVITRU (see "Product Description").

Tell your doctor if you:

- if you have antibodies against immunoglobulin A (IgA) in your blood. This may occur if you have IgA deficiency.
- have allergies to any other medicines, or if you have ever had an allergic reaction to an injection.

Patients with pre-existing factors for thrombotic events or that increase risk of renal complications.

Please discuss the risks and benefits of this product with your doctor.

What should I tell my doctor before using CUVITRU

You should tell your doctor if you:

- have or have had any medical problems.
- take any medicines, including prescription and non-prescription medicines, such as over-the-counter medicines, supplements or herbal remedies including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.
- have had a vaccination recently
- are planning to become pregnant, pregnant or breastfeeding

If you have not told your doctor about any of the above, tell him/her before you start using CUVITRU.

How to use CUVITRU

Always use CUVITRU exactly as your doctor has told you. Check with your doctor if you are not sure.

Ensure you are adequately hydrated before administration of CUVITRU.

CUVITRU has to be infused under the skin.

Treatment with CUVITRU will be started by your doctor or nurse, but you may be allowed to use the medicine at home 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 doing the following procedures. Use germ-free methods during the making up procedure and during injection.

CUVITRU is for single use in one patient only.

Instructions for use

If you do not understand the instructions ask your doctor or health professional.

Always follow the specific instructions given by your healthcare provider. The steps listed below are general guidelines for using your medicine.

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

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 expiration date.
- Do not use if the protective cap is missing or broken.
- Look at the colour: 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

- Gather all supplies:

  Items 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, infusion log.

- Clean work area.
- Program the infusion pump according to prescribed infusion rates and manufacturer's instructions.
- Wash hands thoroughly and allow to dry.

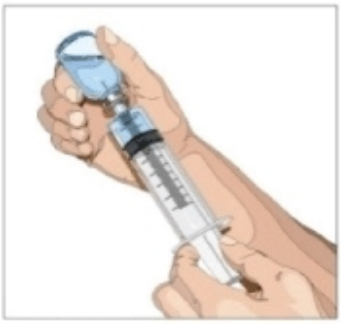
- Open supplies as shown by your healthcare professional.

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 IG vial.
- Turn the vial upside down and pull back on the plunger to pull the IG into the syringe(s).

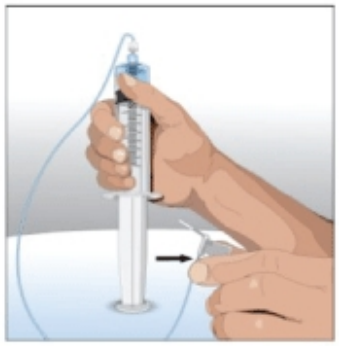


- Repeat these steps, if using multiple vials to achieve the desired dose.
- Start the infusion promptly after drawing CUVITRU into the syringe(s). It is suggested to complete the administration within 2 hours.

  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.

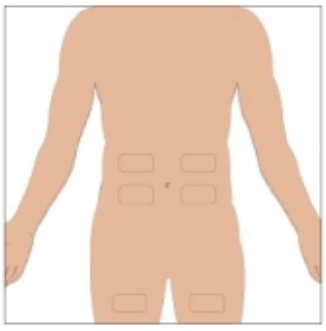
4. Prepare the infusion pump and tubing:

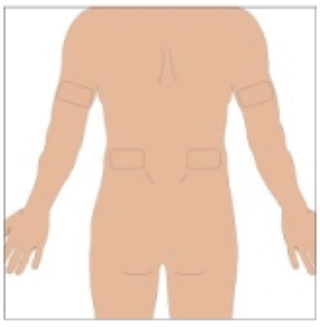
- Use manufacturer directions for filling the tubing and using the pump.
- Attach the syringe filled with CUVITRU to the needle set.
- Point the syringe tip up and gently push the plunger of the syringe to remove the air and fill the needle set up to the needle hub.



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.

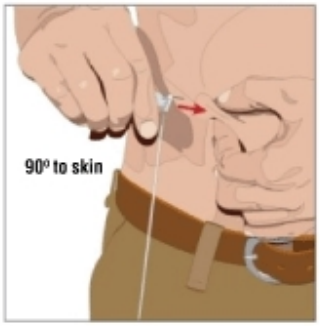




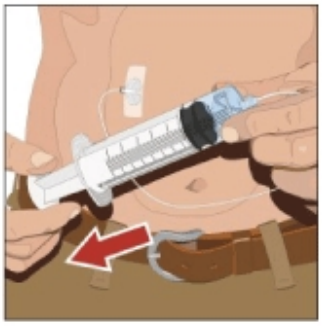
- Infuse CUVITRU from 1 to 4 infusion sites at the same time. Select sites at least 4 inches apart.
- Rotate sites between future infusions.
- Wipe the infusion site(s) with a sterile alcohol wipe beginning at the centre of each infusion site and moving outward in circular motion. Allow the infusion 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).

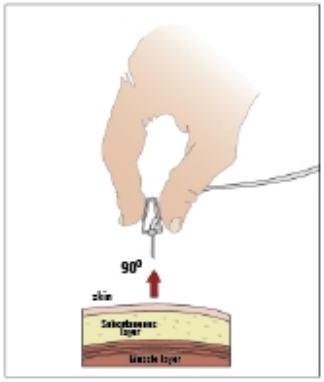


- If more than one site is used, repeat the steps.
- Check for proper needle placement by pulling back on the syringe plunger to check for blood return in the tubing of the needle set.



- 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:
- Follow the manufacturer’s instructions to turn pump on and start the infusion.
- 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.

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 take too much(overdose)

The effects of an overdose of CUVITRU are not known. Please tell your doctor if you accidently use more than instructed.

While you are using CUVITRU

Things you must do

- Stop the infusion immediately and contact your doctor, 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
- Always follow your doctor's instructions carefully
- Tell all the doctors, dentists and pharmacists who are treating you that you are using CUVITRU
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking CUVITRU
- If you become pregnant while you are using your medicine, tell your doctor.
- Talk to your healthcare provider before traveling. 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 must 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.

Side effects

Like all medicines, this medicine can have side effects, although not everybody gets them. Certain side effects, such as headache, chills, or body aches, may be reduced by slowing the infusion rate.

Do not be alarmed by the following lists of possible side

effects. You may not experience any of them. If you have any questions, ask your doctor.

Tell your doctor immediately or go to Accident and Emergency Department at your nearest hospital if you notice any of the following symptoms:

- reduced urination
- severe headache
- neck stiffness
- inability to stand bright light
- 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.

Tell your doctor if you notice any of the following and they worry you.

This list includes the more common side effects of CUVITRU. They are usually mild and often reduce over time.

- 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 or chills
- feeling faint, dizzy or light headed (fall in blood pressure)
- infusion site ulcer.

Other side effects not listed above may also occur in some patients.

Tell your doctor if you notice any other effects.

After using CUVITRU

CUVITRU contains no preservatives.

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

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

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

Storage

CUVITRU should be stored in the refrigerator at 2C to 8C.

Do not freeze.

Store in the original package in order to protect from light.

Keep out of the reach and sight of children.

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.

Product description

What CUVITRU looks like

CUVITRU is a clear and colourless to pale yellow or light brown solution.

CUVITRU is available in the following pack sizes:

8 g in 40 mL

4 g in 20 mL

1 g in 5 mL

2 g in 10 mL

Ingredients

Active ingredient: 20% plasma proteins of which at least 98% are immunoglobulins.

Inactive ingredients: Glycine and water for injection

Manufacturer/Distributor/Supplier

CUVITRU is distributed in Australia by:

Takeda Pharmaceuticals Australia Pty Ltd
Level 39
225 George Street,
Sydney NSW 2000
Australia
Phone: 1800 012 612

Australian Register Number: 282579

Not all pack sizes may be marketed.

This leaflet was prepared in February 2022.