

cutaquig[®]

Human Normal Immunoglobulin (SCIg)
165 mg/mL solution for infusion

Your step-by-step infusion guide



octapharma

How to infuse cutaquig®

This step-by-step guide will help you to administer cutaquig® subcutaneously.

Cutaquig® contains immunoglobulin G (IgG), helping your immune system to fight off bacterial and viral infections.

Cutaquig® is a medicine for people who are born with a reduced ability or inability to produce antibodies (primary immunodeficiency), or who are suffering from an acquired deficiency of antibodies (secondary immunodeficiency) due to specific diseases and/or treatments and experiencing severe or recurrent infections.

Recommended dosage

Your individual dosage and infusion rate will be decided by your doctor, who will adapt the dose especially for you, taking into account your weight, any previous treatment you may have received and your response to treatment. Always follow your doctor's instructions.

If you are suffering from primary immunodeficiency, your doctor will determine whether you need a loading dose (for adults and children) of at least 0.2 to 0.5g/kg (1.2 to 3.0 mL/kg) of body weight divided over several days. Following this, you will receive cutaquig® on a regular basis from daily up to every other week. The cumulative dose per month will be about 0.4 to 0.8 g/kg (2.4 to 4.8 mL/kg) of body weight.

If you are suffering from secondary immunodeficiency, the cutaquig® cumulative monthly dose will be about 0.2 to 0.4g/kg (1.2 – 2.4 mL/kg) of body weight, administered at regular intervals from daily up to every other week.



You and your doctor will discuss the right cutaquig® dose for you. Your doctor may adjust your dose depending on your response to treatment. Do not change the dose or dosing interval without contacting your doctor

Recommended infusion volume

The amount infused per site varies but it is recommended to divide large infusion volumes (>30 mL) and infuse into several infusion sites. In infants and children infusion sites may be changed every 5 to 15 mL.

Recommended infusion rates

Initially: 15 mL/h/site if you are naïve on subcutaneous immunoglobulin (SCIg) therapy. In case you are already on SCIg therapy, and you are switching to cutaquig®, it is recommended to use previously used administration rates for the initial infusions.

For subsequent infusions, if well-tolerated: Gradual increase by approximately 10 mL/h/site every 2-4 weeks in adults (≥ 40 kg) and up to 10 mL/h/site every 4 weeks for pediatrics (< 40 kg).

If you tolerate the initial infusions at the full dose per site and maximum rate: An increase in the infusion rate of successive infusions may be considered until reaching a maximum flow rate of 67.5 mL/h/site for adults (≥ 40 kg) and 25 mL/h/site for pediatrics (< 40 kg).

Storage



Cutaquig® can be stored at normal room temperature (up to 25°C, so you don't need to store it in the refrigerator) for up to 9 months.

However, for long-term storage, cutaquig® should be stored in a refrigerator at 2°C – 8°C.

If you store cutaquig® in the fridge, it should be brought to room temperature before use.

After first opening, cutaquig® should be used immediately.

Keep cutaquig® vials in the outer carton to protect them from light.

Keep cutaquig® away from the reach and sight of children.



Do not freeze.

If you store cutaquig® at room temperature it should not be placed back into the refrigerator.

Cutaquig® should be thrown away if it is stored at room temperature for longer than 9 months, regardless of the expiry date.

Do not use after the expiry date.



The steps below give an overall summary.
See the following pages for more details.



Prepare for the infusion

1. Prepare the necessary number of cutaquig® vials
2. Get ready for the infusion
3. Check and open the vials
4. Prepare and fill the syringe
5. Prepare the infusion pump and tubing (optional)
6. Decide on the infusion site(s) and clean it
Insert the infusion needle(s) and secure in place
7. Check the needle insertion



Perform the infusion

8. Start the infusion



Finalise the infusion

9. Record the infusion
10. After the infusion is complete

Cutaquig® is for subcutaneous administration only. Do not inject into a blood vessel. Follow the administration guidance and use aseptic technique when administering cutaquig®



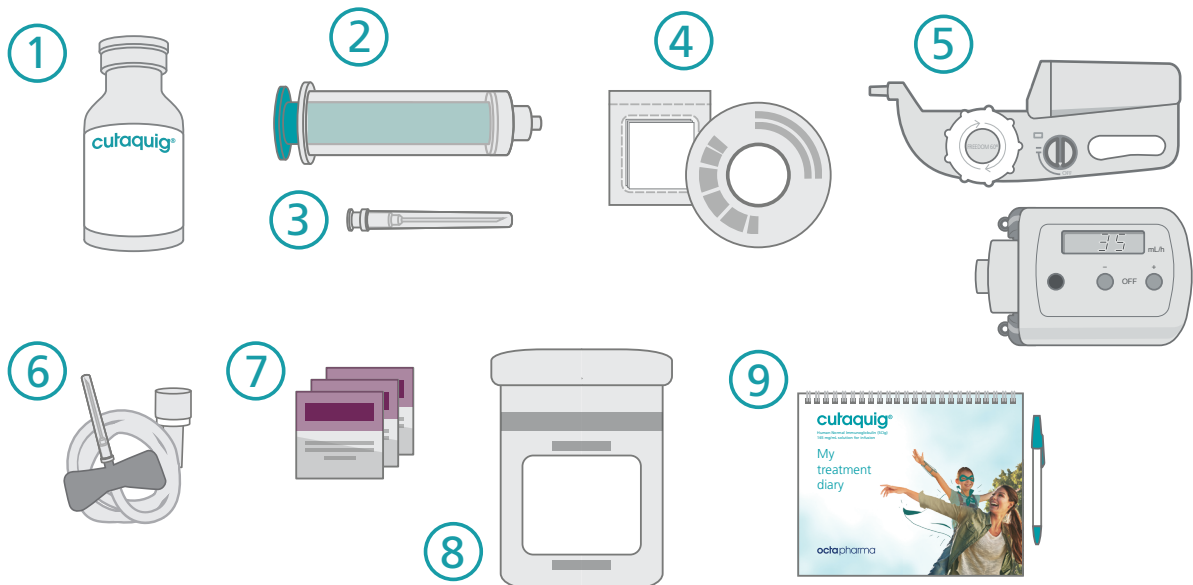
Prepare for the infusion

1. Prepare the necessary number of cutaquig® vials

- If stored in the fridge, take the cutaquig® vial(s) out at least 90 minutes before starting the infusion to allow the solution to reach room temperature. This is not necessary if your cutaquig® vials are stored at room temperature.
- Do not heat the vials or put them into the microwave.
- Do not shake the vials as this may cause foaming.

2. Get ready for the infusion

- Prepare a clean work area using antiseptic wipes or disinfecting solution. Gather your equipment:



1. Cutaquig® solution vial
2. Compatible syringe(s)*
3. Needle or spike (for drawing up product from the vial)
4. Sterile gauze or transparent dressing and tape
5. Infusion pump* (optional)
6. Infusion set*
7. Alcohol and alcohol wipes/antiseptic wipes
8. Sharps container
9. Treatment diary & pen

*Choice of equipment may vary

- Wash your hands thoroughly with soap and water, and let them dry. Use disinfectant gel as has been shown to you during training.



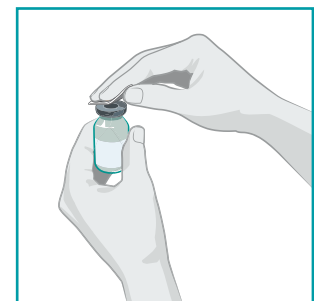
3. Check and open the vials

- The cutaquig® solution should be at room temperature.
- Check the labelled dose based on your prescription.
- Check the appearance of the solution (it should be clear and colourless to pale yellow or light brown).

WARNING: Do not use the vial:

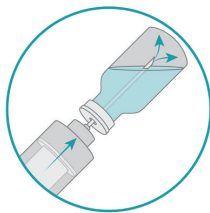
- If the solution is cloudy or contains particles
- If the protective cap has been tampered with or is missing
- If the vial is damaged
- After the expiry date
- If the batch number is missing
- If the vial is not labelled with the correct dose based on the prescribed amount

- Only open the vial directly before you use it.
- Remove the protective cap from the vial and disinfect the rubber stopper with an antiseptic wipe and let it dry.



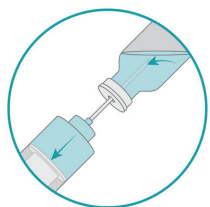
4. Prepare and fill the syringe

- Open the sterile syringe and needle or spike.
- Attach the needle or spike to the syringe.



If you are using a needle

- Draw back on the syringe plunger to fill the syringe with air. The volume of air should be roughly equal to the amount of cutaquig[®] solution needed.
- Insert the needle into the vial and turn the vial upside down. Make sure the tip of the needle is not in the solution to avoid foaming, and inject air into the vial. Move the tip of the needle into the solution.



If you are using a vented spike

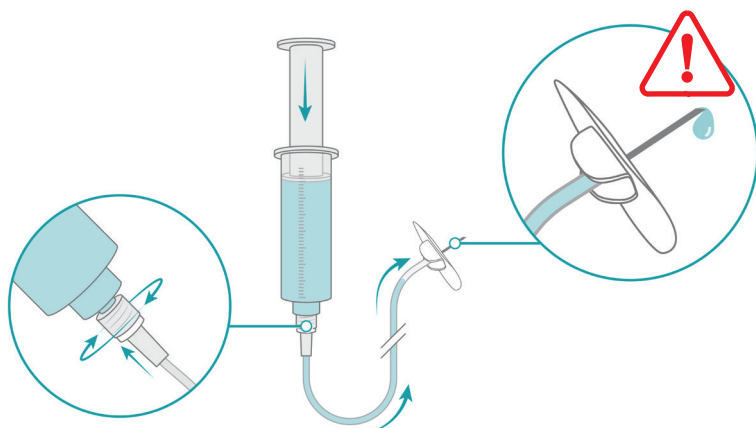
- Just insert the spike into the vial and turn the vial upside down.

While keeping the tip of the needle or spike in the solution, slowly draw the cutaquig[®] solution up into the syringe.

- Withdraw the needle or spike from the vial.
- If more than one vial is needed for your specific dose, repeat this procedure.
- Once the correct amount of cutaquig[®] has been drawn up, remove the needle or spike and dispose in the sharps bin.

5. Prepare the infusion pump and tubing (optional)

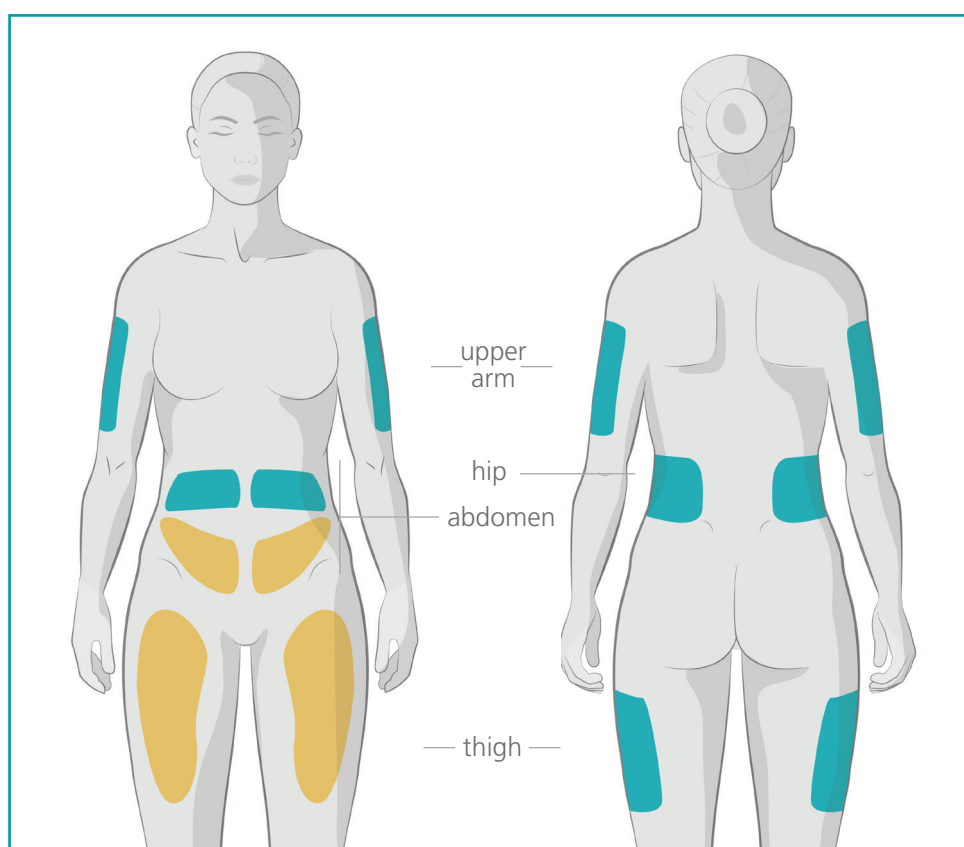
- If using an infusion pump (e.g. the FREEDOM60[®] or the CRONO S-PID pump), follow the manufacturer's instructions for preparing the infusion pump.
- Connect the filled syringe to the infusion tubing and prime the lines. To do this, gently push the syringe plunger to fill the tubing lines with cutaquig[®] and to remove all air.



WARNING: Do not allow the cutaquig[®] solution to drip out of the tip of the needle, as this can cause unnecessary infusion site reactions. The needle should be dry when inserting into the skin

6. Decide on the infusion site(s) and clean it

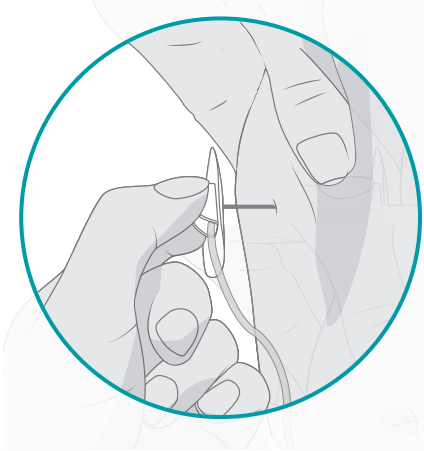
- Cutaquig® can be infused in the following areas: the abdomen, thighs, upper arms, and/or upper leg/hip areas (see illustration below).
- Avoid inserting the needle into scars, tattoos, stretch marks or injured/inflamed/red skin areas.
- Use different infusions sites than you used for the previous administration.
- If more than one infusion site is used at the same time, the infusion sites should be at least 5 cm apart.
- Clean your skin at the selected infusion site(s) with an antiseptic skin wipe and let the skin dry.



Yellow: Preferred infusion sites

Green: Alternative infusion sites

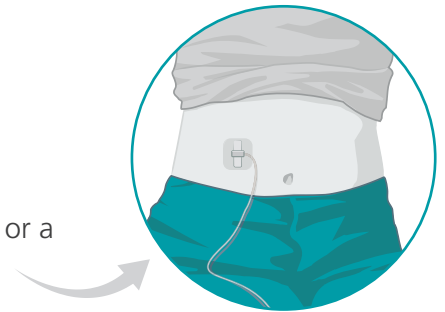
Insert the infusion needle(s) and secure in place



- Pinch the skin between your thumb and forefinger around the injection site.
- Carefully remove the needle cover and insert the infusion needle into the skin as was shown to you during your training. The angle of the needle insertion will depend on the infusion set used.
- Repeat these steps if more than one infusion site is being used.

7. Check the needle insertion

- The solution should not be infused into a blood vessel.
- There should not be any blood in the tubing near the needle.
- Secure the needle in place by applying sterile gauze and tape or a transparent dressing.



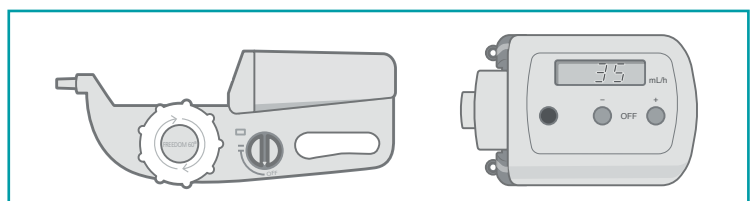
WARNING: Should blood flow back into the tubing, remove the needle and discard the infusion set into the sharps bin. Attach a new infusion set and select a different infusion site, repeating steps 5, 6 and 7



Perform the infusion

8. Start the infusion

- If using an infusion pump, refer to the manufacturer's instructions for full details on how to operate the pump. Two examples of a pump are shown below, but others may also be used.





Finalise the infusion

9. Record the infusion

- On each vial of cutaquig® you will find a peel-off label giving the batch number details.
- Stick this batch label in your treatment diary as a record of the infusion, alongside details of the cutaquig® dose, the date and time of infusion, infusion site location(s), any side effects, and any other comments in connection with this infusion.
- Take your treatment diary with you for your doctor visits and tell your doctor about any problem you have during your infusions.

10. After the infusion is complete

- Gently remove the tape and needle(s), and immediately place into the sharps bin.

It is not unusual for a small spot of blood to appear at the infusion site once the needle(s) is removed. If this happens, firmly press the infusion site with a piece of gauze until the bleeding has stopped

- Throw away all used disposable supplies as well as any unused product and the empty vial(s) as recommended by your healthcare professional. You should also follow any local requirements for disposing of the used supplies.
- Tidy up and securely store all the reusable equipment (e.g. pump) until the next infusion.

Please consult the Patient Information Leaflet for full product information relating to side effects, drug interactions and dosing information which have not been discussed in this document.

This document may not correspond to the guidelines in your country. Please refer to your local guidelines and the Patient Information Leaflet for further details of your cutaquig® treatment. For further information about your treatment or medical condition, please contact your healthcare professional.

Reference

Cutaquig® Package Leaflet: Information for the user. November 2023.



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