Step by Step

Instructions for Using HyQvia with a Peristaltic Infusion Pump Supplementary information to be used after receiving training from the medical staff.

HyQvia is prescribed as:
<u>Replacement therapy in adults, children and adolescents (0–18 years) in:</u>

- **Primary immunodeficiency syndromes with impaired antibody production.**
- **Secondary immunodeficiencies (SID) in patients who suffer from severe or recurrent infections, ineffective antimicrobial treatment and either proven specific antibody failure (PSAF)* or serum IgG level of < 4 g/L.**

***PSAF, Failure to achieve at least a twofold increase in the IgG antibody titre in response to pneumococcal polysaccharide and polypeptide antigen vaccines.**

<u>Immunomodulation in adults, children, and adolescents (0 to 18 years) in:</u>

- **Chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) as maintenance therapy after stabilization with IVIg.**

***This guide is intended for use after the patient has been prescribed HyQvia.**
***Although this guide is written in the masculine form, it is intended for all genders**

HyQvia
Normal Immunoglobulin (Human) 10%
Recombinant Human Hyaluronidase

Introduction

Infusion overview

You have received this “Step by Step” guide because a healthcare professional has prescribed HyQvia for you or for someone in your care.This guide is intended to help you administer HyQvia using a peristaltic infusion pump.

Use this guide to administer the infusion directly from the vial. If you have any questions or concerns regarding the administration method or treatment with HyQvia, contact your treating physician.

Administer the infusion in accordance with your treating physician’s instructions, after receiving training from a nurse and reading the information provided in the patient information leaflet.

To help you learn how to administer HyQvia independently, Takeda Israel Ltd. operates/provides a support programme for HyQvia patients, which is intended, among other things, to teach patients the skills required to self-administer their infusions independently at home. **To contact a company representative, call: *5015**

Name and telephone number of the healthcare professional:



HY = Recombinant human hyaluronidase
IG = Human immunoglobulin (10% IG concentration)

Reference Source

HyQvia Patient Information Leaflet, approved by the Ministry of Health, January 2026
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HyQvia is a registered trademark of Baxalta, which is now part of Takeda and remains the registered owner.
This booklet and its contents were approved by the Ministry of Health in May 2026.
For the Patient Information Leaflet:

Reference:
1. HyQvia Israel Summary of Product Characteristics, January 2026.
2. CarepathRx. PATIENT EDUCATION HyQvia Continuous Subcutaneous Infusion Via CADD Solis Pump.
Available at: carepathrxllc.com/wp-content/uploads/2021/06/30.-HYQVIA-Continuous-Subcutaneous-Infusion-via-CADD-Solis.pdf Accessed November 2021
3. National Prescribing Service Limited MEDICINEWISE. Consumer medicine information. Available at: https://www.nps.org.au/medicine-finder/hyqvia-solution-for-infusion Accessed November 2021

C-NPRMCDA/IL/HYQ/0001 APR 2026

5 Steps for Administering HyQvia by Subcutaneous Infusion

1.

Preliminary preparations

- Check the vials (expiry/colour).
- Prepare the required equipment (see list below).
- Wash your hands.

2.

Preparing the HY

- Draw the HY into the syringe(s).
- Attach the tubing of the subcutaneous needle to the syringe.(See diagram below)
- Prime the subcutaneous needle tubing with HY to remove any air.

3.

Preparing the IG

- Connect the infusion set to the IG vial
- Connect the infusion tubing to the pump.
- Using the pump, prime the infusion tubing with IG to remove any air.

4.

HyQvia Infusion

- Insert and secure needle.
- Infuse HY manually (first).
- Infuse IG with pump (second).

5.

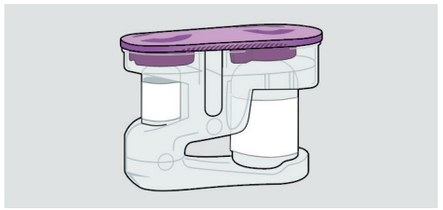
Finish

- Remove the needle.
- Record the infusion details.

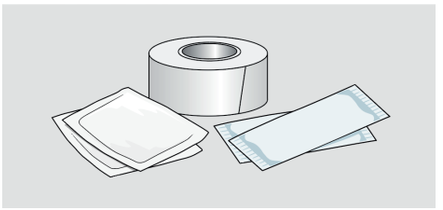
Infuse HyQvia only after receiving training from the medical staff and reading the information in the patient information leaflet.

Required equipment

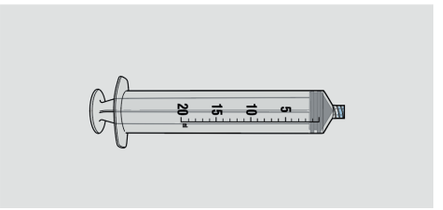
The equipment required to administer a HyQvia infusion is listed below. Your equipment may differ slightly.
****Please note that the equipment used for your HyQvia infusion is intended for single use only. Do not reuse it.**



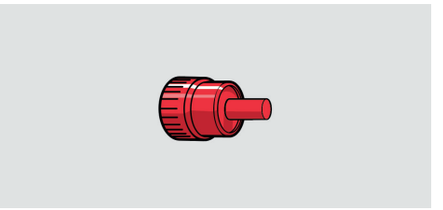
The HyQvia kit contains 2 vials:
1. HY
2. Immunoglobulins (IG)



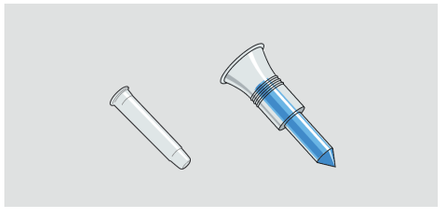
Alcohol swabs, adhesive tape and a clean, sterile dressing*



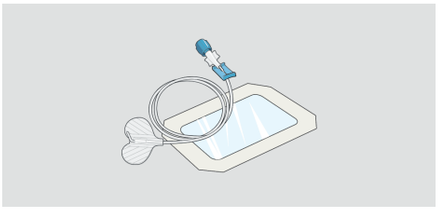
20 mL and 10 mL syringe(s)



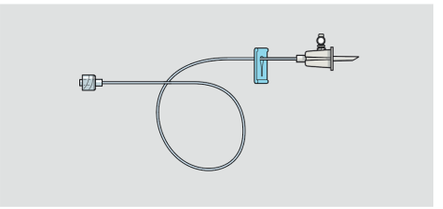
Optional:
Sterile tip caps (one per syringe)



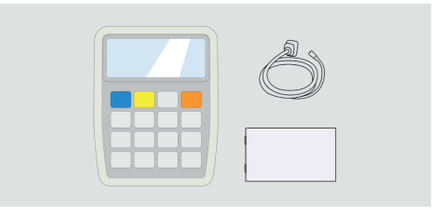
Drawing-up needle



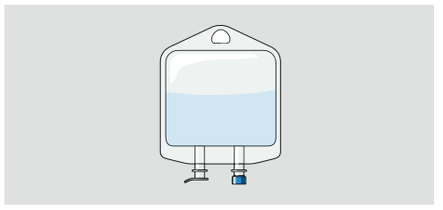
Subcutaneous needle set with a sterile dressing



Dedicated pump infusion tubing



Peristaltic infusion pump, power cord, pump holder and instruction guide.
The guide can be downloaded at:
eitanmedical.com/quick-guide-training



Bag of saline solution
for flushing the infusion tubing at the end of treatment



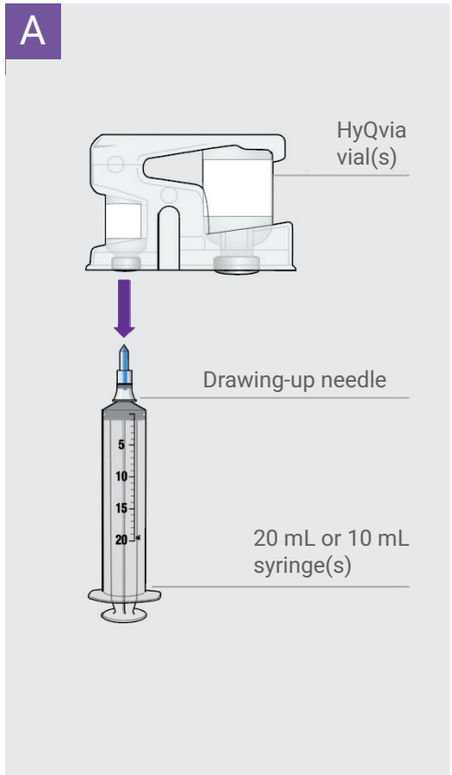
Sharps container



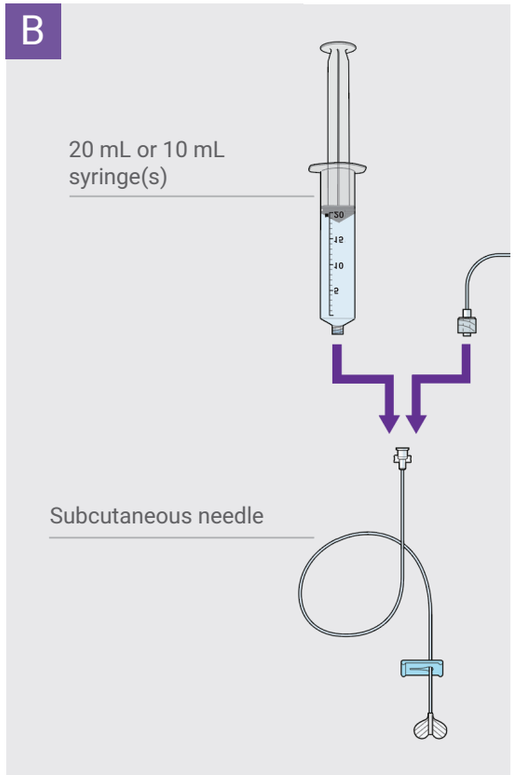
Treatment record log

Wear gloves if instructed to do so by the medical staff.

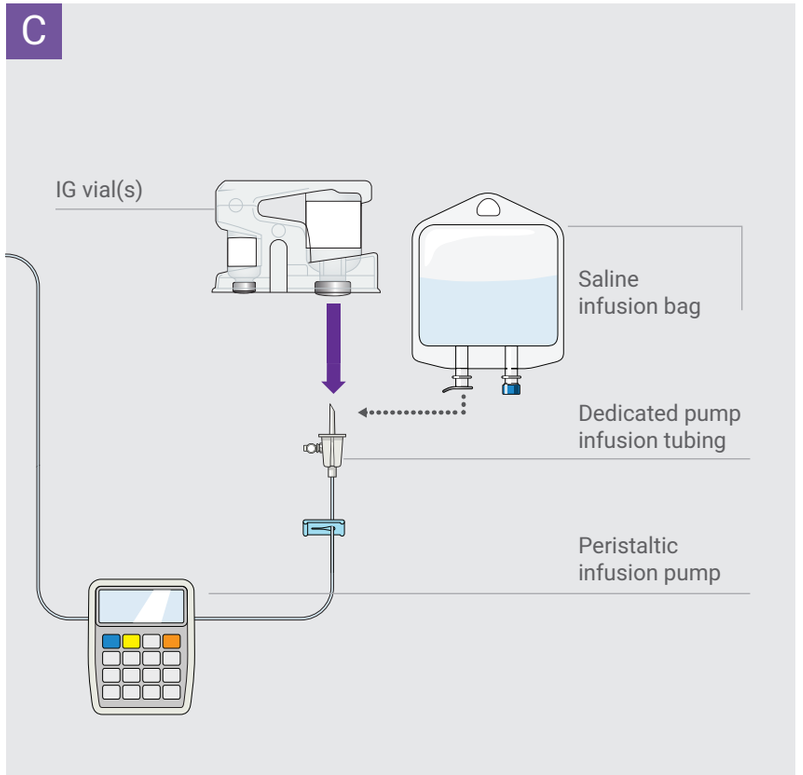
Required equipment



- Attach the syringe to the drawing-up needle.
- Insert the needle attached to the syringe into the HY vial.
- Disconnect the drawing-up needle from the 20 mL syringe.
- Connect the syringe containing the HY to the subcutaneous needle.



- Insert the subcutaneous needle into the designated infusion site on the body.
- Manually infuse the HY (Step 1)



- Connect the infusion tubing to the IG vial.
- Connect the tubing to the pump
- Infuse the IG using the peristaltic pump (Step 2)
- Disconnect infusion line from IG vial and connect tubing to a saline infusion bag

Step 1

Preliminary preparations

A



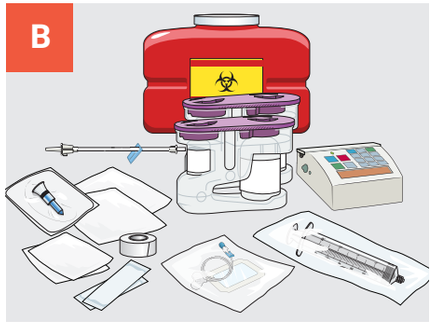
Remove **HyQvia** from the box.
Check each vial before use:

- Expiry date
- Colour: Make sure that the solution is colourless to pale yellow, is not cloudy and does not contain particles.
- Integrity of the purple protective cap.

Allow **HyQvia** to reach room temperature (this may take up to 60 minutes).
Do not use any heating devices, including a microwave.

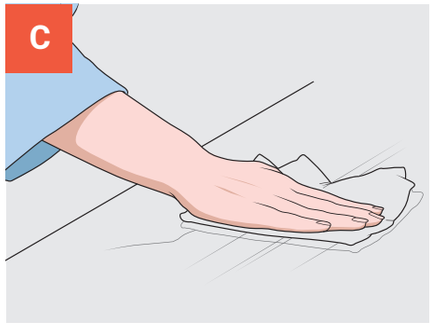
- **Do not heat or shake HyQvia.**

B



Gather the required equipment.

C



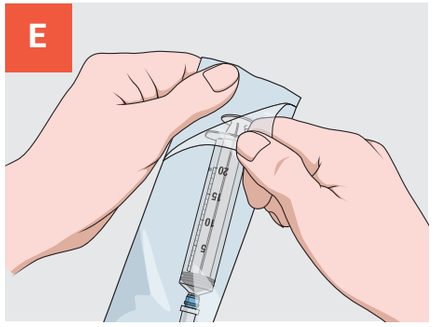
Prepare a clean work surface.

D



Wash your hands thoroughly.

E

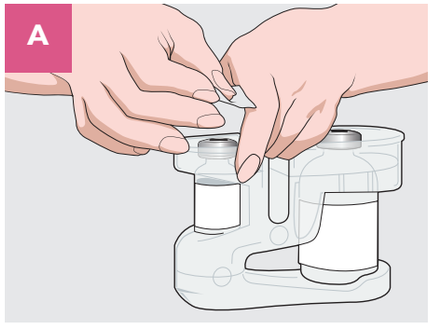


Open the equipment as instructed by your treating physician.

Step 2

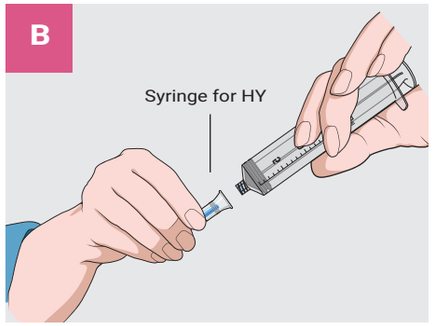
Preparing the HY

A



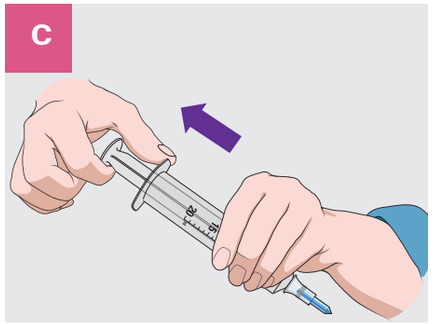
Remove the cap. Wipe the rubber stopper of each HY vial with an alcohol swab and allow it to air-dry for at least 30 seconds.

B



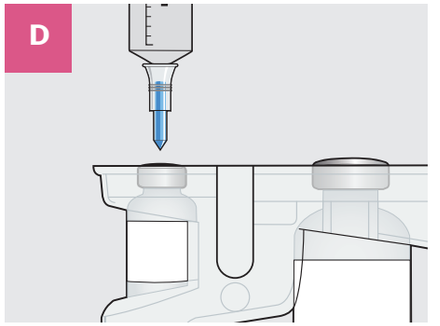
* Remove the sterile 20 mL or 10 mL syringe from its packaging and attach it to the drawing-up needle.

C



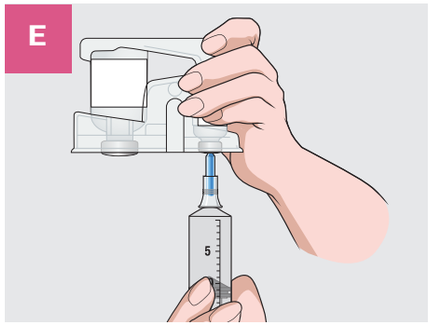
Pull back the plunger to fill the syringe with a volume of air equal to the volume of HY.

D



Insert the tip of the needle into the centre of the HY vial stopper.
Push the air into the vial.

E

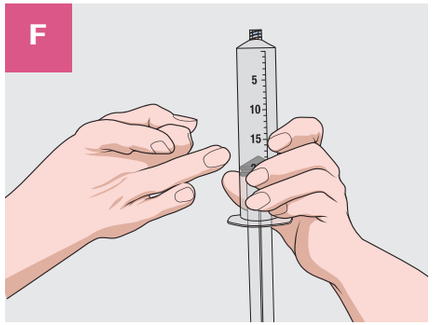


Turn the vial upside down so that the tip of the syringe is pointing upwards.
Draw all the HY into the syringe.
Repeat Steps C through E if you require more than one vial of HY for your dose.
Use additional syringes if necessary.

Tip

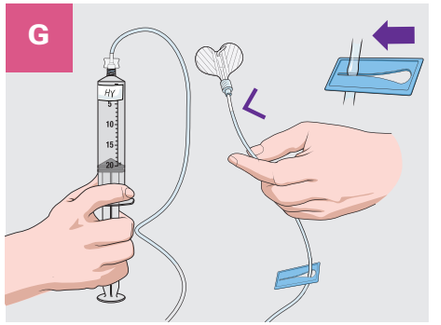
Fit each syringe with a sterile tip cap when using multiple syringes.

F



Once the full dose has been transferred into the syringe, hold the syringe with its tip pointing upwards and remove all air bubbles by gently tapping the syringe with your finger. Then slowly push the plunger to expel any remaining air.

G



Remove the drawing-up needle from the syringe and attach the subcutaneous needle to the HY syringe in its place.
Slowly push the plunger to prime the subcutaneous needle tubing up to the needle wings.

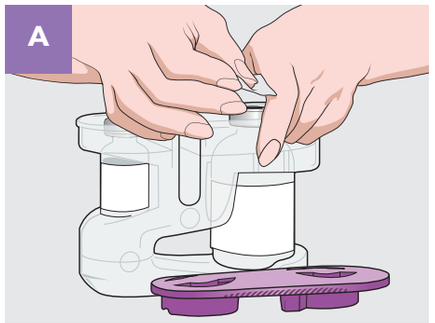
*These are the recommended syringe volumes.

Step 3

Preparing the IG

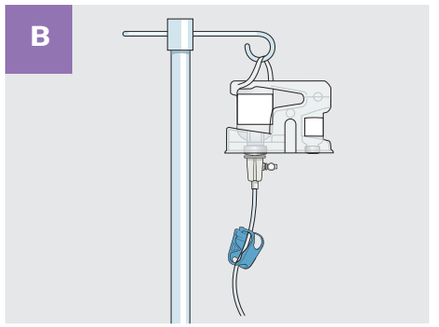
3

A



Wipe the rubber stopper of each IG vial with an alcohol swab and allow it to air-dry for at least 30 seconds.

B



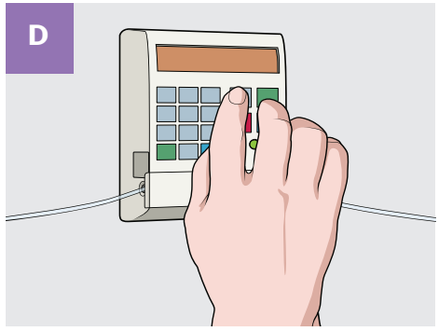
* Insert the spike of the pump tubing into the stopper of the IG vial(s). Turn the vial(s) upside down, with the stopper facing downwards. Hang the vial(s) from an IV pole or hook. Connect the infusion tubing to the pump.

C



Prime the pump tubing with IG as instructed by the medical staff.

D



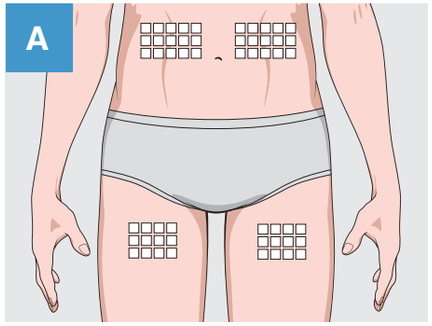
Select the infusion programme in accordance with the pump manufacturer's instructions and the infusion rate prescribed for you.

*If more than one vial is required for a full dose, do not pierce the additional vials until the contents of the first vial have been completely infused.

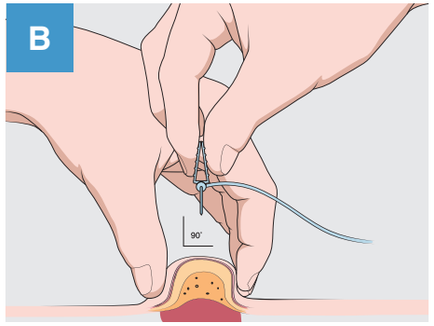
Step 4

HyQvia Infusion

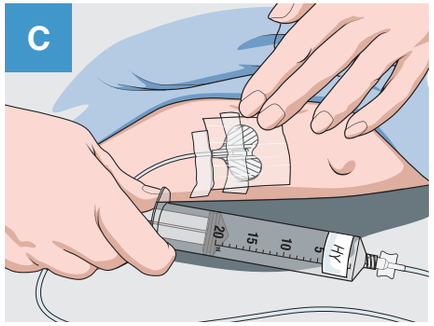
***Remember: HY before IG**



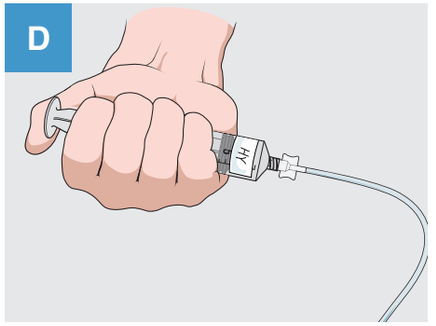
Select an infusion site on either side of the abdomen (at least 4–5 cm away from the navel) or on the thigh.
Avoid areas close to a bone where the bone can be easily felt, as well as areas with visible blood vessels, moles, scars, inflammation or infection. Alternate infusion sites with each infusion to allow the site used for the previous infusion to heal.
*Clean the infusion site(s) with an alcohol swab. Allow the site(s) to air-dry for at least 30 seconds.



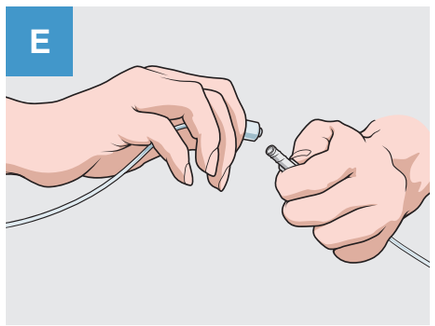
Remove the cap from the subcutaneous needle. Pinch a fold of skin measuring at least 2.0–2.5 cm. Using a quick, straight motion, insert the entire needle into the skin at a 90-degree angle, up to the needle wings. The needle wings should lie flat against the skin. Secure the needle in place with a sterile adhesive dressing.



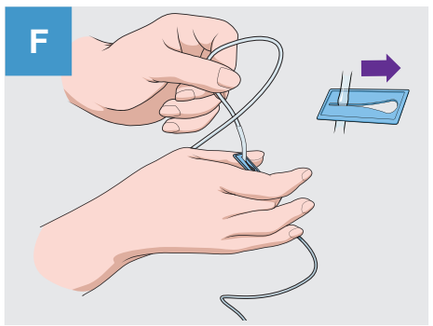
Repeat Steps A through C if you have a second or third infusion site.
Check that the needle is positioned correctly before beginning the infusion, as instructed by the medical staff.



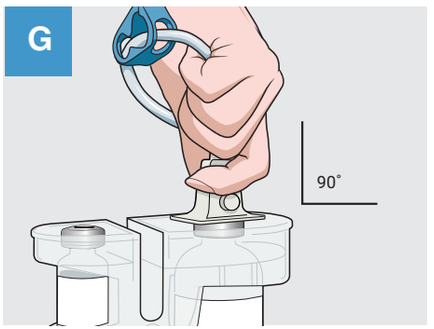
Slowly push the plunger of the syringe containing HY at an initial infusion rate of approximately 1–2 mL per minute, increasing the rate according to tolerability.
If more than one infusion site is used, consult a nurse or another member of your medical staff regarding how to administer the infusion.



Once all the HY has been infused, disconnect the syringe from the subcutaneous needle tubing and connect the end of the subcutaneous needle tubing to the pump tubing.
Do not remove the subcutaneous needle. Wait 10 minutes before starting the IG infusion.



After waiting, start the pump to infuse the IG at the rate or according to the programme prescribed by your treating physician.



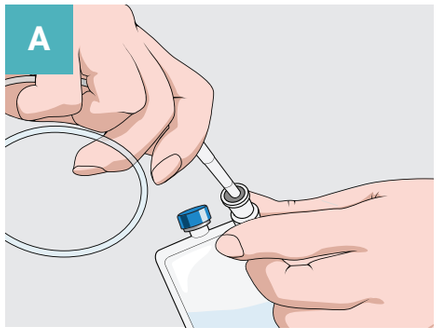
When a vial is empty, it must be replaced with the next vial. To do so: Pause the pump. Remove the pump-tubing spike from the empty vial and insert it into the next disinfected IG vial (as you did with the first vial). Then restart the pump. Repeat the process for each of the remaining IG vials.

For patients weighing less than 40 kg, select sites on opposite sides of the body if you have been instructed to infuse at two sites when the dose exceeds 300 mL.
For patients weighing more than 40 kg, select sites on opposite sides of the body if you have been instructed to infuse at two sites when the dose exceeds 600 mL.

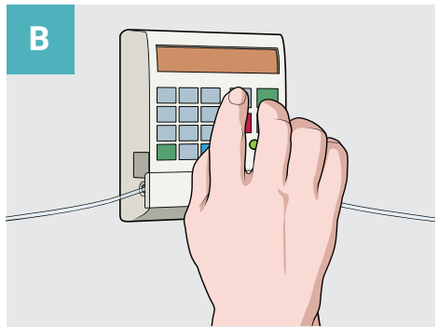
Step 5

Finish

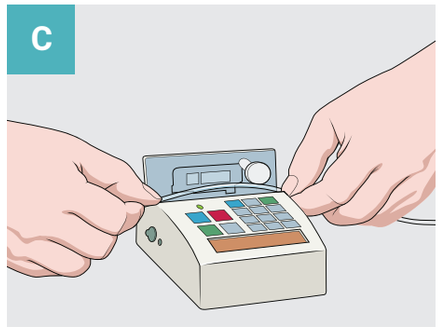
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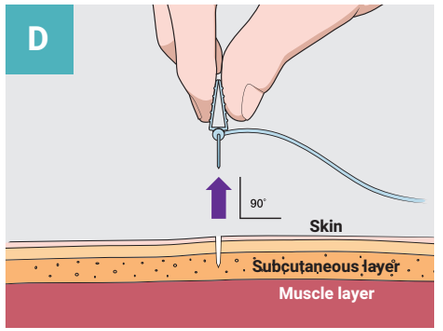
Once the last IG vial is empty, pause the pump, remove the IG vial and connect a saline infusion bag to the pump tubing to infuse the IG remaining in the infusion tubing.



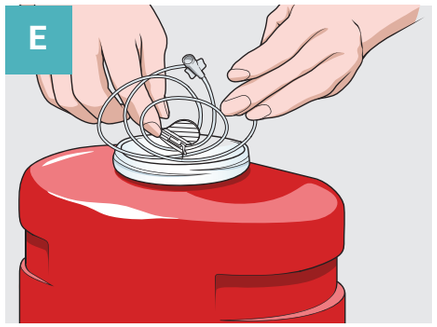
Restart the pump to flush the IG through to the needle wings. (The pump will stop automatically once the pump tubing and subcutaneous needle tubing have been flushed).



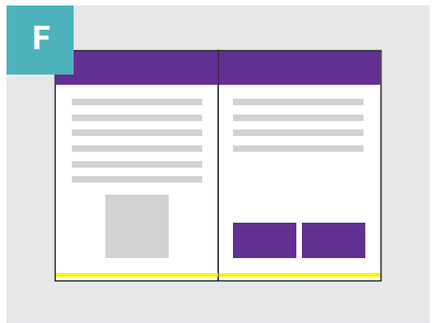
Turn off the pump and disconnect the tubing from the pump.



Remove the needle set by loosening the dressing around all its edges.
Pull the needle straight upwards and out by its wings. Apply gentle pressure to the needle insertion site with a small piece of gauze and cover it with a protective dressing.



Dispose of any medicinal product remaining in the vial and all single-use items in a sharps container, as recommended by your healthcare professional.



Record the infusion details in your treatment record log.



Continue your follow-up with your treating physician as instructed.

What Might Your Body Look Like After a HyQvia Infusion?

After the **HyQvia** infusion, you may experience swelling at the infusion site. The swelling may last for several days.

Before, During and After Treatment with HyQvia

Example of a patient who received **HyQvia**. Your body may respond to the **HyQvia** infusion in the same way or differently.



Before the HyQvia infusion



Immediately after the HyQvia infusion.
In the example shown, the patient received 235 mL of HyQvia.



24 hours after infusion

What Are the Possible Adverse Reactions* of HyQvia Treatment?

Local reactions occur at the infusion site. These reactions usually resolve within a few days.

No long-term (chronic) skin changes were observed in clinical studies. Tell your treating physician about any persistent inflammation, swelling or lumps, or inflammation at the infusion site that lasts for more than a few days.

General adverse reactions are not limited to the infusion site and may occur throughout the body.
Allergic reactions

Allergic reactions

Infusions of medicines such as HyQvia may, in rare cases, cause serious allergic reactions.
You may experience a sudden drop in blood pressure and, in isolated cases, anaphylactic shock.
Healthcare professionals are aware of these possible adverse reactions and will monitor you during and after your initial infusions.

Typical signs or symptoms of an allergic reaction include:
Light-headedness, dizziness, fainting, skin rash, tingling, swelling of the mouth or throat,
difficulty breathing, wheezing, abnormal heart rate, chest pain, blue discolouration of the lips or fingertips or toes, and blurred vision.

Tell your doctor or nurse right away if you notice any of these signs during the infusion.

***For a complete list of adverse reactions, please refer to the patient information leaflet.**

Managing the Possible Adverse Reactions of HyQvia Treatment

Local Adverse Reactions

The following local reactions may occur at the infusion site and usually resolve within a few days. Contact your treating physician to determine the best way to manage any local reaction that worsens or persists for more than a few days.

Discomfort, pain or redness at the infusion site when the subcutaneous needle is inserted

- Remove the needle – it may have entered the muscle.
- If the pain is severe and does not subside after the needle is removed, or if pain occurs with every infusion, contact your treating physician.
- Speak with your treating physician or pharmacist about changing the needle length, as the needle may be too long for you.
- The thickness of subcutaneous tissue varies from person to person depending on age, sex, body mass index and the infusion site.
- Record in your log that this infusion site may not be suitable for you.

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

- Speak with your treating physician, who may advise slowing or stopping the infusion.
- Apply a clean, warm or cold cloth, as instructed by your physician, to the irritated area for short periods (no more than 10 minutes).
- Speak with your treating physician about a possible allergy to the adhesive tape or dressing, or about using a mild pain reliever.

Swelling at or around the infusion site

- Temporary swelling may occur after a HyQvia infusion because of the volume of fluid infused.
- Apply a clean, warm cloth to the swollen area for short periods of time (no more than 5–10 minutes).
- Your treating physician may advise you to walk around or gently massage the swollen area.

Itching or a rash at or around the infusion site

- Slow down or stop the infusion.
- Apply a clean, cold cloth to the itchy area for short periods of time (no more than 10 minutes).
- When using the subcutaneous needle, avoid coating the needle with drops of HyQvia.
- Speak with your treating physician about using an antihistamine, if recommended.

**If you experience uncontrollable itching or a rash or skin irritation, stop the infusion immediately and contact your treating physician or the emergency services.
These signs may indicate a severe allergic reaction.**

General (Systemic) Adverse Reactions

General adverse reactions affect the entire body rather than a specific part of the body. The most common adverse reactions include:

Headache
- Speak with your treating physician about using an over-the-counter pain reliever.
- If the headache persists or worsens, contact your treating physician.

Fatigue
- Rest after the infusion.
- Go to bed early on the day of the infusion.

Fever
- Speak with your treating physician about using an over-the-counter medicine to reduce the fever.
- If the fever persists or worsens, contact your treating physician.

Additional adverse reactions of lower or unknown frequency, as well as further information, are provided in the HyQvia patient information leaflet, including information about rare but serious allergic reactions.
You may also experience adverse reactions that are not listed in the HyQvia patient information leaflet.
Speak with your treating physician if you experience any adverse reactions, particularly reactions that are not listed in the patient information leaflet, that are severe or persist for more than a few days.

Please note: The suggestions above are not intended to replace the instructions provided by your treating physician.
You may report adverse reactions directly by email to: AE.ISR@Takeda.com,
Quality complaints may be reported by email to: QA-IL@Takeda.com.
Reporting adverse reactions may help provide additional information about the safety of this medicine.

Adverse reactions may also be reported to the Ministry of Health by clicking the “Reporting Adverse Reactions Following Drug Treatment” link on the Ministry of Health website (www.health.gov.il), which directs you to the online adverse-reaction reporting form, or by visiting: https://sideeffects.health.gov.il

Information Resources for Patients and Caregivers

Communities and Support Organisations Providing Assistance with Primary Immunodeficiency (PID)

Joining community groups and patient organisations is another way to take control of your primary immunodeficiency (PID).
You may find these organisations helpful.

Bubble Care Association | Primary Immunodeficiency | Israel /https://www.bubblecare.org.il