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Pharmaceutical
Services by Novolog

Product	HyQvia	Size	297 x 210 mm
Product spec	Step by step		(W) x (H)
	English	Font (type & min. size / language)	Helvetica (TT) 8 p (eng)
	HyQvia 24p new copy. indd		
Tech ref		Color	 CMYK
Type	Brochure		
Date	29/08/2023		
Artwork operator	Nurit Assayag		
Job no.	23000794		

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Reference

HyQvia Patient Leaflet, approved by the Ministry of Health, June 2020

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HyQvia is a registered trademark of Baxalta, which is currently a part of Takeda and remains the registration holder.

The information is correct as of December 2022.



For patient leaflet



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HyQvia
Human Normal Immunoglobulin (10%)
Recombinant Human Hyaluronidase

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Human Normal Immunoglobulin (10%)
Recombinant Human Hyaluronidase

'Step-by-Step' – A user manual for HyQvia infusion using a peristaltic infusion pump

Additional information following training by healthcare professionals

HyQvia is prescribed as replacement therapy to patients (including children and adolescents aged 0-18 years and adult patients) with:

- Primary immunodeficiency syndromes with impaired antibody production.
- Deficiency of antibody production (hypogammaglobulinaemia) and recurrent bacterial infections in patients with chronic lymphocytic leukaemia (CLL), in whom prophylactic antibiotics have failed or are contraindicated.
- Deficiency of antibody production (hypogammaglobulinaemia) and recurrent bacterial infections in multiple myeloma (MM) patients.
- Deficiency of antibody production (hypogammaglobulinaemia) in patients pre- and post-allogeneic hematopoietic stem cell transplantation (HSCT).

For further questions, contact your doctor or pharmacist



Introduction

General overview on the infusion

Coping with primary immunodeficiency involves numerous challenges. Treatment administration should not be one of them. This Step-by-Step guide is designed to help you learn how to use **HyQvia** with a peristaltic infusion pump. Get familiar with the 5 steps which will help you achieve a convenient, effective and safe infusion experience.

If you have any questions or concerns regarding the mode of administration or treatment with **HyQvia**, contact your healthcare professionals.

Perform HyQvia infusion only after training by your healthcare professionals and after reading the information provided in the patient leaflet.



The 5 steps of HyQvia infusion

1. Preliminary preparations

- Check the vials
- Prepare the necessary supplies
- Wash your hands

2. HY preparation

- Draw HY into syringe(s)
- Connect the needle set
- Fill the needle set

3. IG preparation

- Draw IG into the pump tubing

4. HyQvia infusion

- Insert the needle and secure it in place
- Infuse HY manually (first infusion)
- Infuse IG using the pump (second infusion)

5. Completion

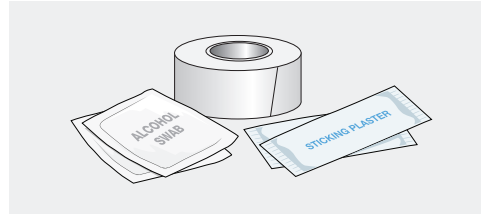
- Remove the needle
- Record the infusion details

Necessary supplies

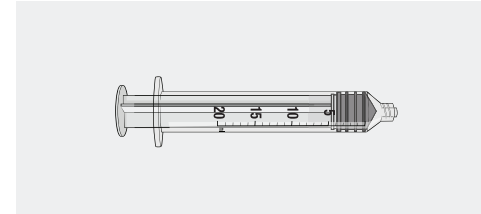
Below are the supplies required for **HyQvia** infusion. Your supplies may look slightly different.



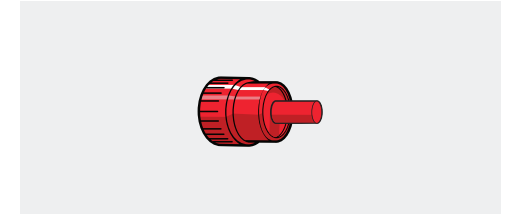
HyQvia vials (IG + HY)



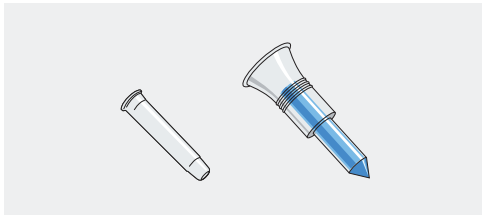
Alcohol swabs, clean and sterile adhesive bandage*



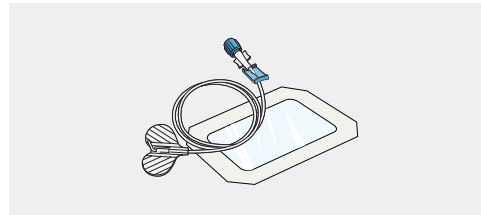
20 ml syringe(s)



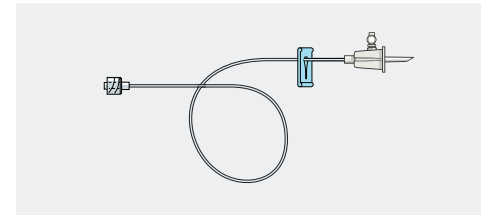
Optional: Sterile tip caps (one per syringe)



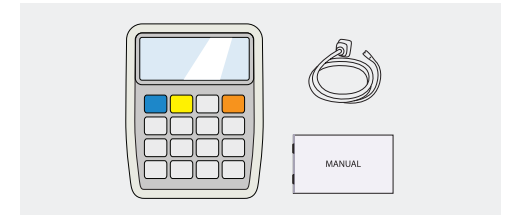
Non-vented transfer device or needle (one per HY vial)



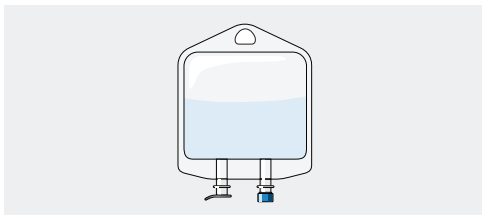
Subcutaneous needle set with a sterile dressing (one per infusion site)



Vented pump tubing



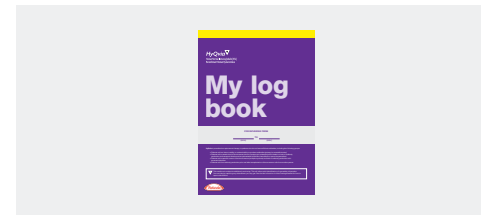
Peristaltic infusion pump, power supply and manual



Optional: Saline infusion bag (if required by the healthcare professionals)



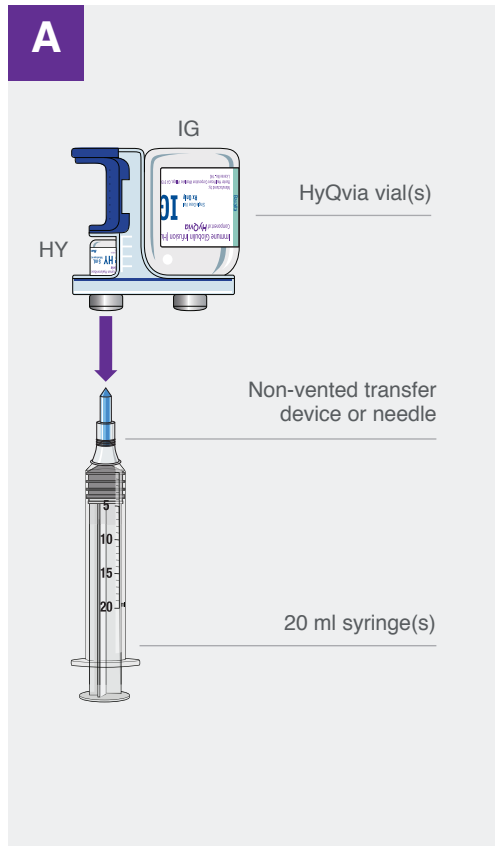
Sharps container



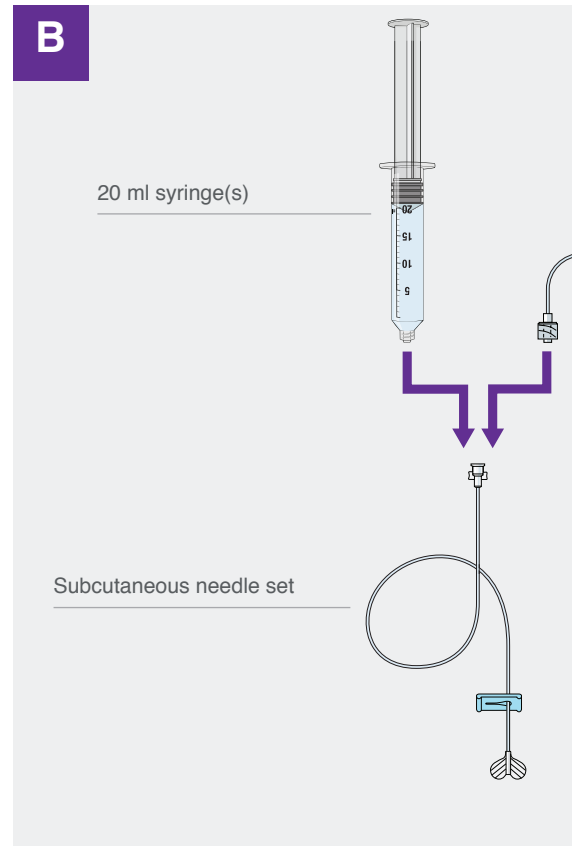
Log book

*Wear gloves if instructed to do so by the healthcare professionals.

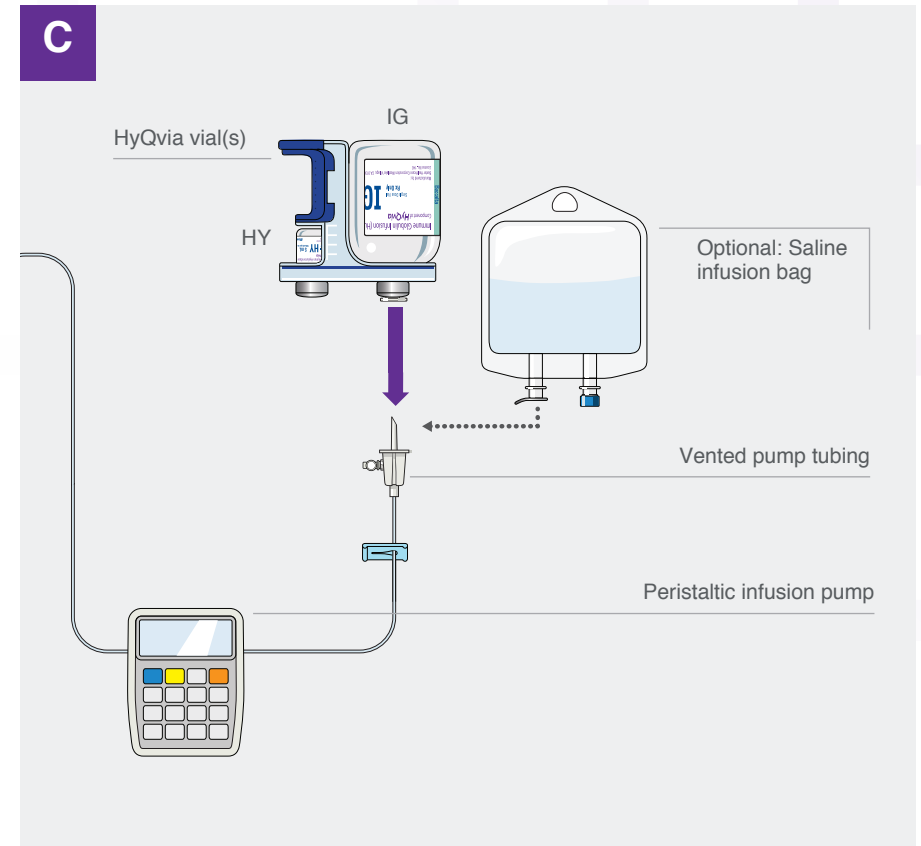
Assembling the components



Transfer HY to the syringe(s).



Perform HY infusion manually (first infusion)



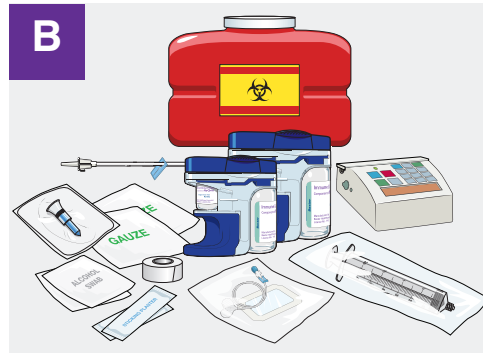
Perform IG infusion with the peristaltic pump (second infusion)

Step 1

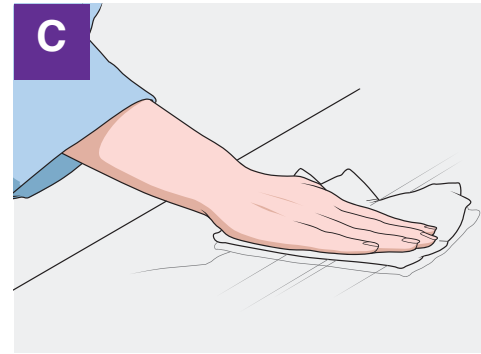
Preliminary preparations



Take **HyQvia** out of the box and inspect it. Check the colour and expiry date. Ensure that the liquid is not cloudy and does not contain any particles. Allow **HyQvia** to reach room temperature (this can take up to 60 minutes). Do not use heating devices, including microwave oven. Do not shake **HyQvia**.



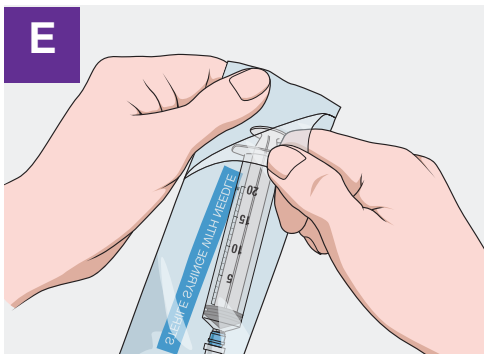
Prepare the necessary supplies.



Clean the work area.



Wash your hands thoroughly.



Open the supplies as instructed by the healthcare professionals.

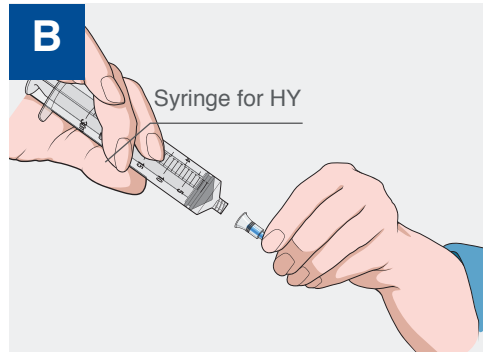
A large, stylized number '2' is positioned on the left side of the slide. It is composed of two shades of blue: a darker blue for the main outline and a lighter blue for the inner shape. The '2' is partially cut off by the left edge of the frame.

Step 2

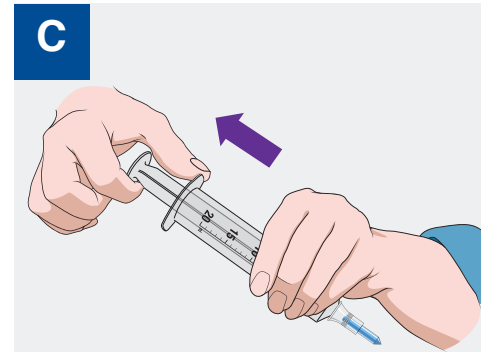
HY preparation



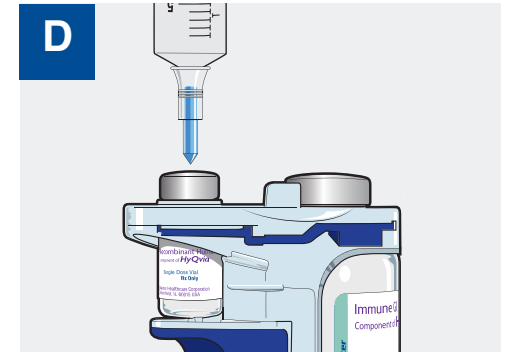
Remove the blue cap. Clean the rubber stopper exposed under the cap by wiping it with the alcohol swab. Let it dry for 30 seconds.



Remove the sterile 20 ml syringe from its package. Attach the non-vented transfer device or needle to the syringe.



Pull the plunger backwards to fill the syringe with air (amount equal to the entire amount of HY).



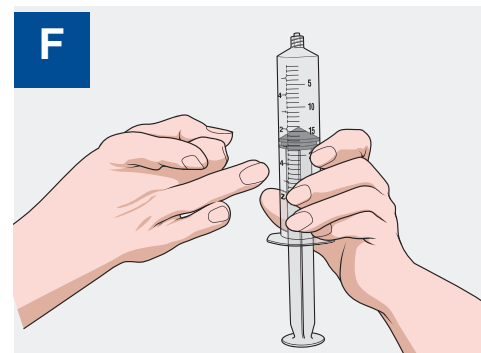
Insert the non-vented transfer device or needle into the center of the HY vial stopper. **Push the air into the vial.**



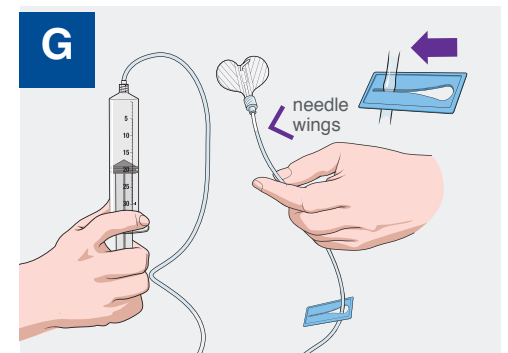
Turn the vial upside down. Pull the plunger backwards to draw the entire HY content into the syringe.

Advice

Cover each syringe with a sterile tip cap when using several syringes.



After transferring the full dose into the syringe, hold the syringe pointing upwards and tap it gently to remove any air bubbles. Then slowly push the plunger until the substance reaches the top of the syringe.



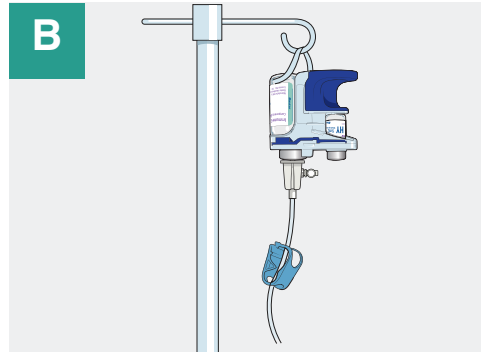
Attach the subcutaneous needle set to the HY syringe. Slowly push the plunger to fill the needle set tubing up to the needle wings.
* If more than one HY vial is required for your dose, use a new set and repeat steps C-E.

Step 3

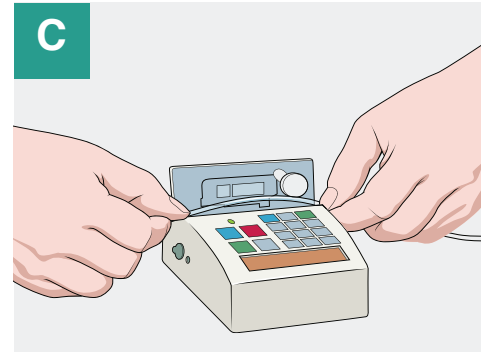
IG preparation



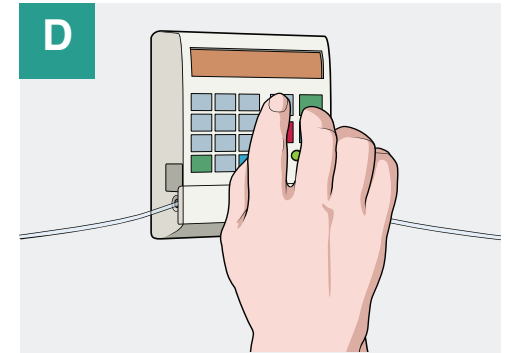
Remove the blue cap. Clean the rubber stopper exposed under the cap by wiping it with the alcohol swab. Let it dry for 30 seconds.



Insert the spike of the vented pump tubing straight down into the IG vial stopper. Turn the vial upside down and hang it on a pole or a hanging hook.



Let the substance fill the tube to the end of tube, as instructed by the healthcare professionals.

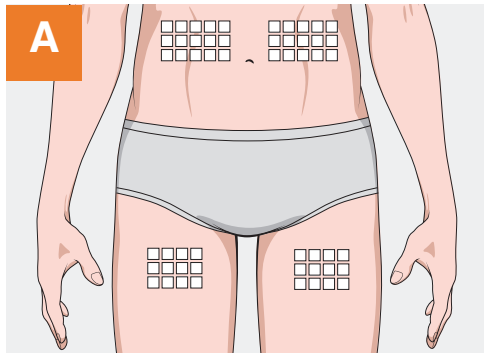


According to the manufacturer's instructions, set the pump to the recommended infusion flow rate. Turn the pump off.

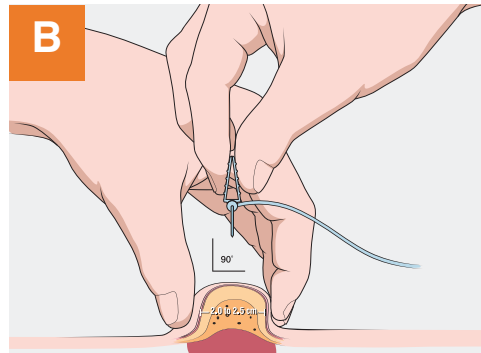
Step 4

HyQvia infusion

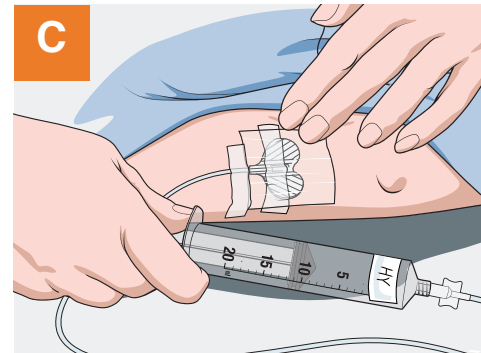
Remember: HY before IG



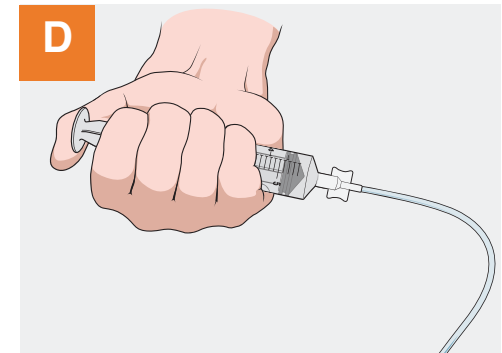
Choose an infusion site (or several sites) in the middle to upper abdomen or thigh. Avoid bony areas, visible blood vessels, scars and any areas of inflammation or infection. Rotate infusion sites by choosing opposite sides of the body for the next infusion. If instructed by the healthcare professionals, clean the infusion site(s) with an alcohol swab. Allow the site to dry for at least 30 seconds. Select sites on the opposite sides of the body if instructed to infuse in two sites for doses exceeding 600 ml.



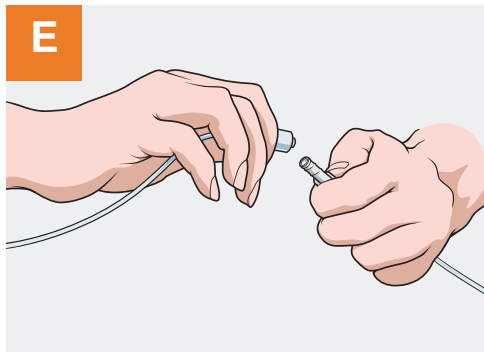
Remove the subcutaneous needle cover. Pinch a skin fold of at least 2 to 2.5 cm. Insert the needle with a rapid motion straight into the skin at a 90-degree angle. Open the needle set wings and secure the needle in place with a sterile dressing.



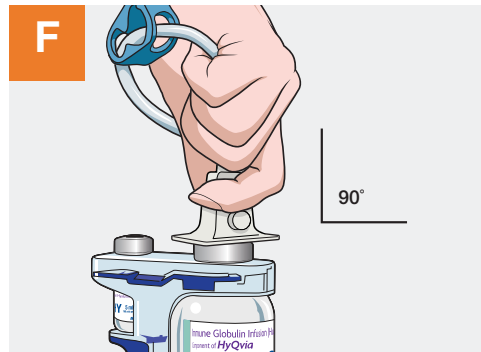
If you are using more than one infusion site, repeat steps A to C. Ensure appropriate needle position before starting the infusion, as instructed by the healthcare professionals.



Slowly push the plunger of the recombinant HY- containing syringe at an initial rate of 1 to 2 ml per minute and increase the rate as tolerated. If you are using more than one infusion site, divide the HY equally between the sites.



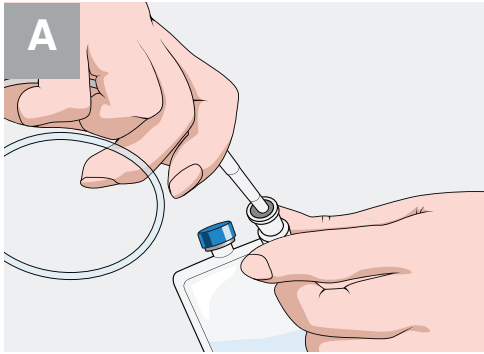
After infusing the entire HY content, remove the syringe and attach the same subcutaneous needle set to the vented pump tubing. Do not remove the needle from the infusion site(s).



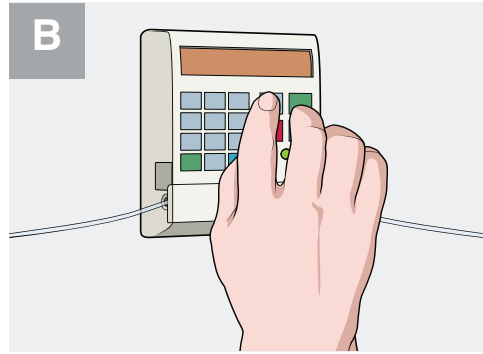
When the vial is empty, stop the pump and reset it if required. Insert the vented pump tubing spike into the disinfected IG vial. Then restart the pump. Repeat the process for each of the remaining IG vials.

Step 5 Completion

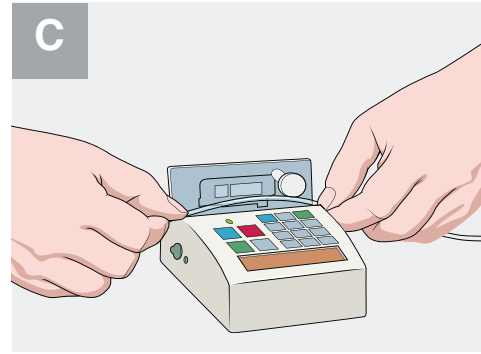




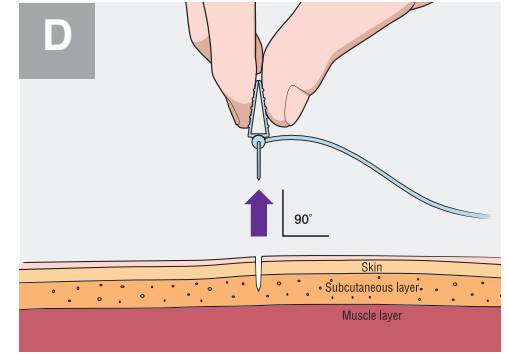
After emptying the last IG vial, remove it and attach a saline infusion bag to the vented pump tubing, if instructed to do so by the healthcare professionals.



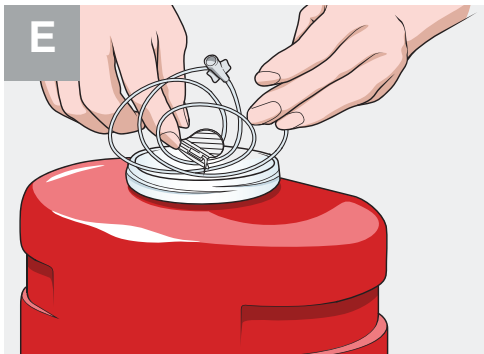
Restart the pump – at the same rate, to flush the IG up to the needle wings.



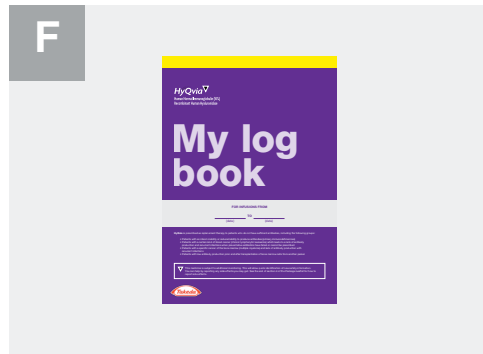
Turn the pump off and close the clamp on the vented pump tubing. Remove the tubing from the pump.



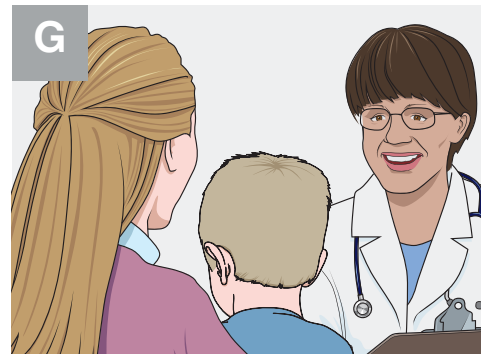
Remove the subcutaneous needle set by loosening the sterile dressing at all its edges. Pull the needle wings straight up and out. Gently place a clean sterile dressing over the infusion site.



Dispose of the needle set in the sharps container, and dispose of the residual medicine remaining in the vial and disposable supplies as recommended by the healthcare professional.



Record the infusion details in your log book.



Continue follow up with the healthcare professional as instructed.

After HyQvia infusion

After HyQvia infusion, there may be swelling at the infusion site. The swelling should only last several days.

Before, during and after HyQvia treatment

An example of a patient who received HyQvia. Your body may respond to HyQvia infusion in the same manner or in a different manner.



Before **HyQvia** infusion



Immediately after **HyQvia** infusion



24 hours following infusion

HyQvia infusion administered: 235 ml (the infusion volume was in accordance with the healthcare professionals' instructions based on the specific clinical condition of this patient; it may be different for you).

Management of the possible side effects of HyQvia treatment

Local side effects

These side effects usually resolve within several days. Contact your doctor to find out the best way to treat any local side effect of increasing severity or lasting more than several days.

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

- Remove the needle – it may have penetrated into your muscle.
- If the pain is severe and does not subside upon needle removal, or if the pain appears during each infusion, contact your doctor.
- Talk to your doctor or appropriate pharmacy about changing your needle length; it may be too long for you. The subcutaneous tissue thickness of each person may vary in accordance with age, sex, body mass index and infusion site.
- Record in your log book that this infusion site may not be suitable for you.

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

- Talk to your doctor, he/she may slow or stop the infusion.
- Place a clean, warm or cold cloth on the irritated area according to your doctor's instructions for short time periods (no more than 10 minutes).
- Talk to your doctor about a possible allergic reaction to your adhesive tape or dressing, or about possible use of a mild analgesic.

Swelling at or around the infusion site

Following HyQvia infusion, temporary swelling may occur due to the volume of fluids infused.

- Place a clean warm cloth on the swollen area for short time periods (no more than 5 to 10 minutes).
- Your doctor may advise you to ambulate or gently massage the swollen area.

Itching or rash at or around the infusion site

- Slow or stop the infusion.
- Place a clean cold cloth on the itchy area for short time periods (no more than 10 minutes).
- While using the subcutaneous needle, avoid staining the needle with HyQvia drops.
- Talk to your doctor about possible use of an antihistamine, if recommended.
- If you experience uncontrollable skin rash/irritation, **immediately stop the infusion and contact your doctor or emergency services;** these signs may indicate a severe allergic reaction.

General (systemic) side effects

General side effects appear over the entire body and not in a certain part. The most common side effects are:

Headache

- Talk to your doctor about using a non-prescription analgesic.
- If the headache persists or worsens, contact your doctor.

Fatigue

- Rest after the infusion.
- Go to sleep early on the infusion day.

Fever

- Talk to your doctor about using a non-prescription antipyretic.
- If the fever persists or worsens, contact your doctor.

Additional uncommon side effects are mentioned in the HyQvia leaflet, including severe, but rare allergic reactions.

In addition, you may experience side effects not listed in the HyQvia leaflet.

Talk to your doctor if you experience any side effects, especially those which are not listed in the patient leaflet, which are severe or lasting more than 2 days.

Please note: The above advices are not intended to replace your doctor's guidelines/instructions.

You can also report side effects directly to the following email: AE.ISR@takeda.com.

Reporting side effects may help provide additional information about the safety of this medicine.

You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il), which directs to an online form for reporting side effects, or you can also use this link: <https://sideeffects.health.gov.il>

For reporting quality complaints: QA-IL@takeda.com

Information resources for the patient and caregiver

Communities and support organizations assisting with the issue of primary immunodeficiency (PID)

Joining community groups and patient organizations is another way of taking control of your primary immunodeficiency (PID). These organizations may be helpful for you.

International Patient Organization for Primary Immunodeficiencies (IPOPI)

<http://www.ipopi.org>

Jeffrey Modell Foundation

<http://info4pi.org>

European Society for Immunodeficiencies (ESID)

<http://esid.org>

Bubble Care Association – Israeli association for immunodeficiency patients

<https://www.bubblecare.org.il>

