

Infusing HyQvia® treatment with a syringe driver pump

A step-by-step guide for healthcare professionals to use in educating patients and caregivers

Additional information following training from your healthcare team

Indications

HyQvia, a replacement therapy in adults, children and adolescents (0-18 years) in:

- 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 mount at least a 2-fold rise in IgG antibody titre to pneumococcal polysaccharide and polypeptide antigen vaccines

HyQvia is indicated for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) as maintenance therapy (after stabilisation with IVIg).

Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 of the Summary of Product Characteristics for how to report adverse reactions.

This guide is intended for use after a patient has been prescribed **HyQvia**

This guide is intended to be used by healthcare professionals in educating patients and caregivers. It should not be provided directly to patients. A separate Patient Guide is available.



Copyright 2021 @ Takeda Pharmaceutical Company Limited.
All rights reserved. All trademarks are the property of their respective owners.

Visit <https://axian.link/hyq-hcp-irl>
to access a digital guide.



How to use this guide

This guide has been developed to help you train patients and caregivers to self-administer HyQvia treatment. Before using this guide, consider the following:

- Begin by familiarising yourself with the content and functionality of this guide and the patient leaflet before you instruct patients
- Think of this guide as an aid to dialogue, not a script. Use the guide to facilitate your instruction
- Don't skip sections or steps. Use the additional points provided ('Points to emphasise') as suggestions to supplement your instruction

By making this guide an integral part of training, you can help provide a positive **HyQvia** infusion experience for your patients.

Patient considerations

Assessing your patients' knowledge of **HyQvia** treatment and their comfort level with the infusion process is an important part of training. Most of the patients you train will come from one of the categories below.

If you're training this kind of patient...	...keep these points in mind.
Switching from intravenous IG treatment	<ul style="list-style-type: none">• May be unfamiliar with subcutaneous administration• May have anxiety about self-infusion (for example, preparation of product and needle insertion)• May not be used to aseptic technique• May be unfamiliar with operating a pump
Switching from subcutaneous IG treatment	<ul style="list-style-type: none">• May be used to smaller volumes infused per site• May be unfamiliar with the faster infusion rates of HyQvia• May be unfamiliar with pumps that meet the criteria for use with HyQvia (including syringe driver pumps)



Once you've become familiar with the overview of this guide and how it functions, you're ready to use the remaining pages to train your patients and their caregivers

The 5 steps to infusing HyQvia treatment

Infusion overview

You have received this step-by-step guide because your healthcare professional has prescribed **HyQvia** treatment for you or the person you are caring for. This guide is designed to help you infuse **HyQvia** using a syringe driver pump. Use this guide for the direct-from-vial method. If you have any questions or concerns about how to infuse **HyQvia**, please discuss them with your healthcare professional.

Infuse HyQvia only after you or your caregiver have been trained by your healthcare professional and have read the information in the package leaflet.



HY = recombinant human hyaluronidase

IG = human normal immunoglobulin (IG 10%)

1. Get ready

- Inspect vials
- Gather supplies
- Wash hands

2. Prepare the HY

- Draw **HY** into syringe(s)
- Attach to needle set
- Fill needle set

3. Prepare the IG

- Draw **IG** into syringe(s)

4. Infuse HyQvia

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

5. Finish up

- Remove needle
- Log infusion

Infuse **HyQvia** only after you have been trained by your healthcare professional and have read the information in the **HyQvia** package leaflet.

The 5 steps to infusing HyQvia treatment

Train your patients and their caregivers on the steps below. Also cover the ‘Points to emphasise.’

The 5 steps to infusing HyQvia treatment

Infusion overview

You have received this step-by-step guide because your healthcare professional has prescribed **HyQvia** treatment for you or the person you are caring for. This guide is designed to help you infuse **HyQvia** using a syringe driver pump. Use this guide for the direct-from-vial method. If you have any questions or concerns about how to infuse **HyQvia**, please discuss them with your healthcare professional.

Infuse **HyQvia** only after you or your caregiver have been trained by your healthcare professional and have read the information in the package leaflet.



Presentation may vary from market to market

HY = recombinant human hyaluronidase
IG = human normal immunoglobulin (IG 10%)

1.

Get ready

- Inspect vials
- Gather supplies
- Wash hands

2.

Prepare the HY

- Draw **HY** into syringe(s)
- Attach to needle set
- Fill needle set

3.

Prepare the IG

- Draw **IG** into syringe(s)

4.

Infuse HyQvia

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

5.

Finish up

- Remove needle
- Log infusion

Infuse **HyQvia** only after you have been trained by your healthcare professional and have read the information in the **HyQvia** package leaflet.

Points to emphasise

➤ **Ensure patients have removed HyQvia treatment from the refrigerator.**
HyQvia should be at room temperature prior to infusing (this may take up to 60 minutes). Do not use heating devices, including microwaves.

➤ **Determine patients' knowledge about HyQvia and their comfort level with the infusion process.**

➤ **Reinforce that there are 5 steps to the process.**
Provide encouragement for patients to learn the infusion process through training provided.

➤ **Reinforce that HY is infused before IG.**
Explain that **HyQvia** is a dual-vial unit of **HY** and **IG**. **The IG infusion should be started right after the HY infusion is complete (within 10 minutes).** **HY** helps more **IG** get absorbed by the body. **IG** helps the body fight off infections.

The 5 steps to infusing HyQvia treatment

Infusion overview

You have received this step-by-step guide because your healthcare professional has prescribed **HyQvia** treatment for you or the person you are caring for. This guide is designed to help you infuse **HyQvia** using a syringe driver pump. Use this guide for the direct-from-vial method. If you have any questions or concerns about how to infuse **HyQvia**, please discuss them with your healthcare professional.

Infuse **HyQvia** only after you or your caregiver have been trained by your healthcare professional and have read the information in the package leaflet.



HY = recombinant human hyaluronidase
IG = human normal immunoglobulin (IG 10%)

1.

Get ready

- Inspect vials
- Gather supplies
- Wash hands

2.

Prepare the HY

- Draw **HY** into syringe(s)
- Attach to needle set
- Fill needle set

3.

Prepare the IG

- Draw **IG** into syringe(s)

4.

Infuse HyQvia

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

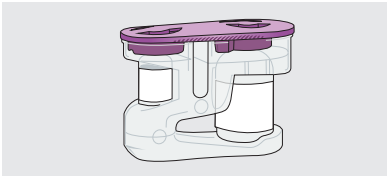
5.

Finish up

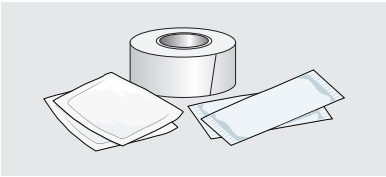
- Remove needle
- Log infusion

What you'll need

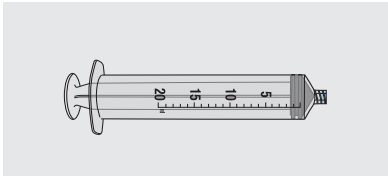
Below are the supplies you'll need to infuse your **HyQvia** treatment. Your supplies may look slightly different.



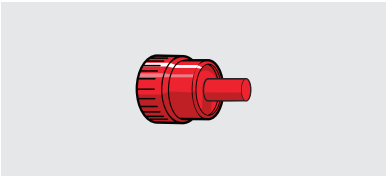
- **HyQvia** vial(s)



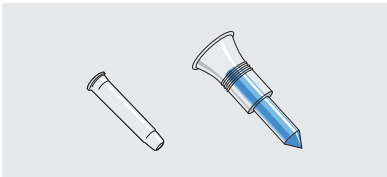
- Alcohol swabs, tape and clean, sterile bandage*



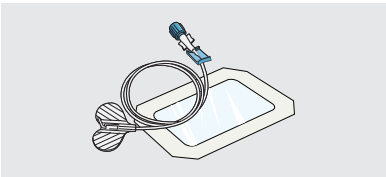
- 20 mL syringe(s)[†]



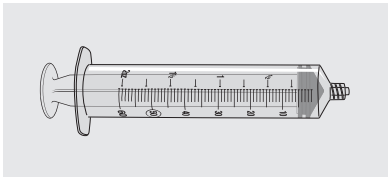
- Optional: Sterile tip caps (one per syringe)



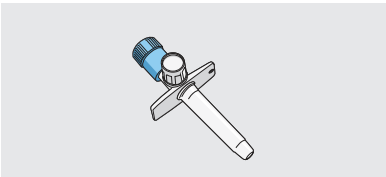
- Non-vented device or needle (one per **HY** vial)



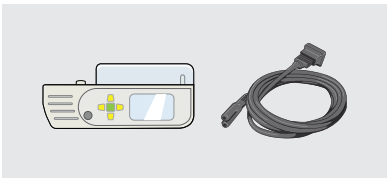
- Subcutaneous needle set with a sterile dressing (one per infusion site)



- 50 or 60 mL syringe(s)[†]



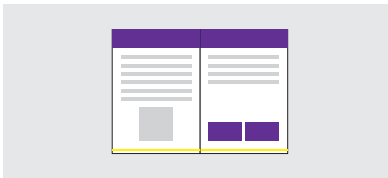
- Vented spike(s)



- Syringe driver pump, power supply and manual



- Sharps container



- Logbook


*Wear gloves if instructed by your healthcare professional.
†These are the recommended syringe volumes.

What you'll need


Train your patients and their caregivers on the steps below. Also cover the ‘Points to emphasise.’

What you'll need

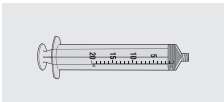
Below are the supplies you'll need to infuse your **HyQvia** treatment. Your supplies may look slightly different.



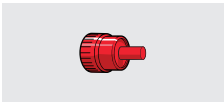
- HyQvia vial(s)



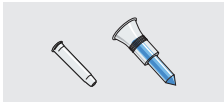
- Alcohol swabs, tape and clean, sterile bandage*




- 20 mL syringe(s)†



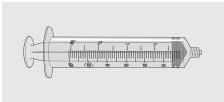
- Optional: Sterile tip caps (one per syringe)




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




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




- 50 or 60 mL syringe(s)†




- Vented spike(s)



- Syringe driver pump, power supply and manual



- Sharps container



- Logbook

*Wear gloves if instructed by your healthcare professional.
†These are the recommended syringe volumes.

Points to emphasise

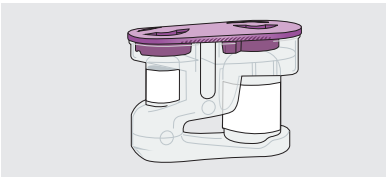
- Explain that the supplies patients receive may look different to these images.
- Ensure that patients know the number of vials they should receive based on their prescription.
- Explain that patients should have one vented spike per IG vial.
- Follow manufacturer’s guidelines when using supplies.

✓ **Assess patient knowledge**

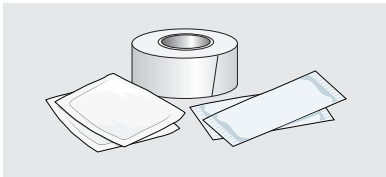
Ensure patients are familiar and comfortable with the supplies

What you'll need

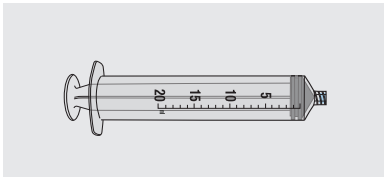
Below are the supplies you'll need to infuse your **HyQvia** treatment. Your supplies may look slightly different.



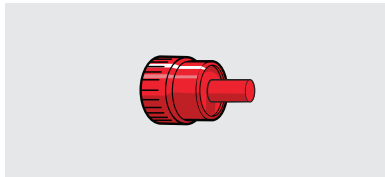
- HyQvia vial(s)



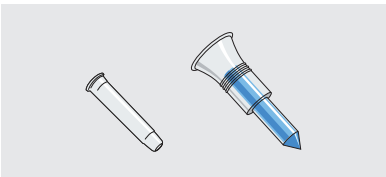
- Alcohol swabs, tape and clean, sterile bandage*



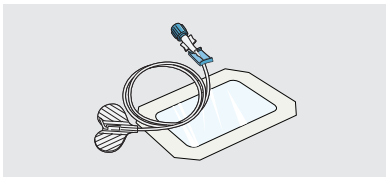
- 20 mL syringe(s)†



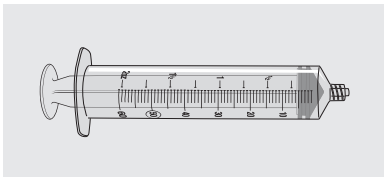
- Optional: Sterile tip caps (one per syringe)



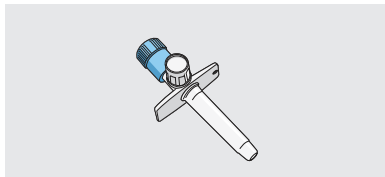
- Non-vented device or needle (one per HY vial)



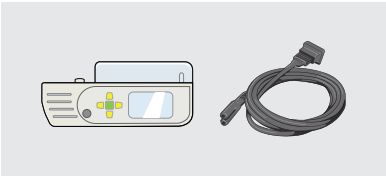
- Subcutaneous needle set with a sterile dressing (one per infusion site)




- 50 or 60 mL syringe(s)†




- Vented spike(s)



- Syringe driver pump, power supply and manual



- Sharps container



- Logbook

How they fit together

A Transfer the **HY** into the syringe(s)

1. HyQvia vial(s)

2. Non-vented device or needle

3. 20 mL syringe(s)

B Transfer the **IG** into the syringe(s)

4. HyQvia vial(s)

5. Vented spike(s)

6. 50 or 60 mL syringe(s)

C **First:** infuse **HY** manually
Second: infuse **IG** using syringe driver pump

7. Subcutaneous needle set

8. Syringe driver pump

9. 20 mL syringe(s)

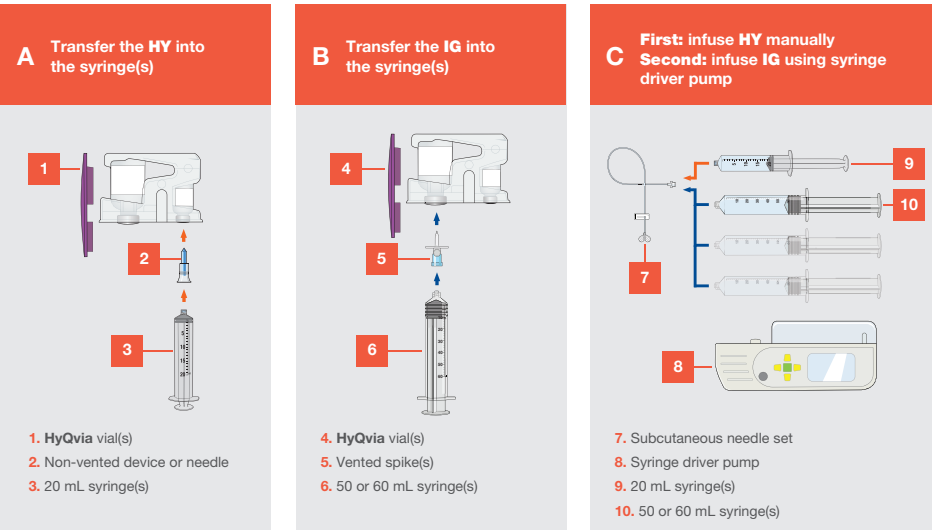
10. 50 or 60 mL syringe(s)

**This diagram is an example. The number of syringes required is dependent on your prescribed dose.*

How they fit together

Train your patients and their caregivers on the steps below. Also cover the ‘Points to emphasise.’

How they fit together



**This diagram is an example. The number of syringes required is dependent on your prescribed dose.*

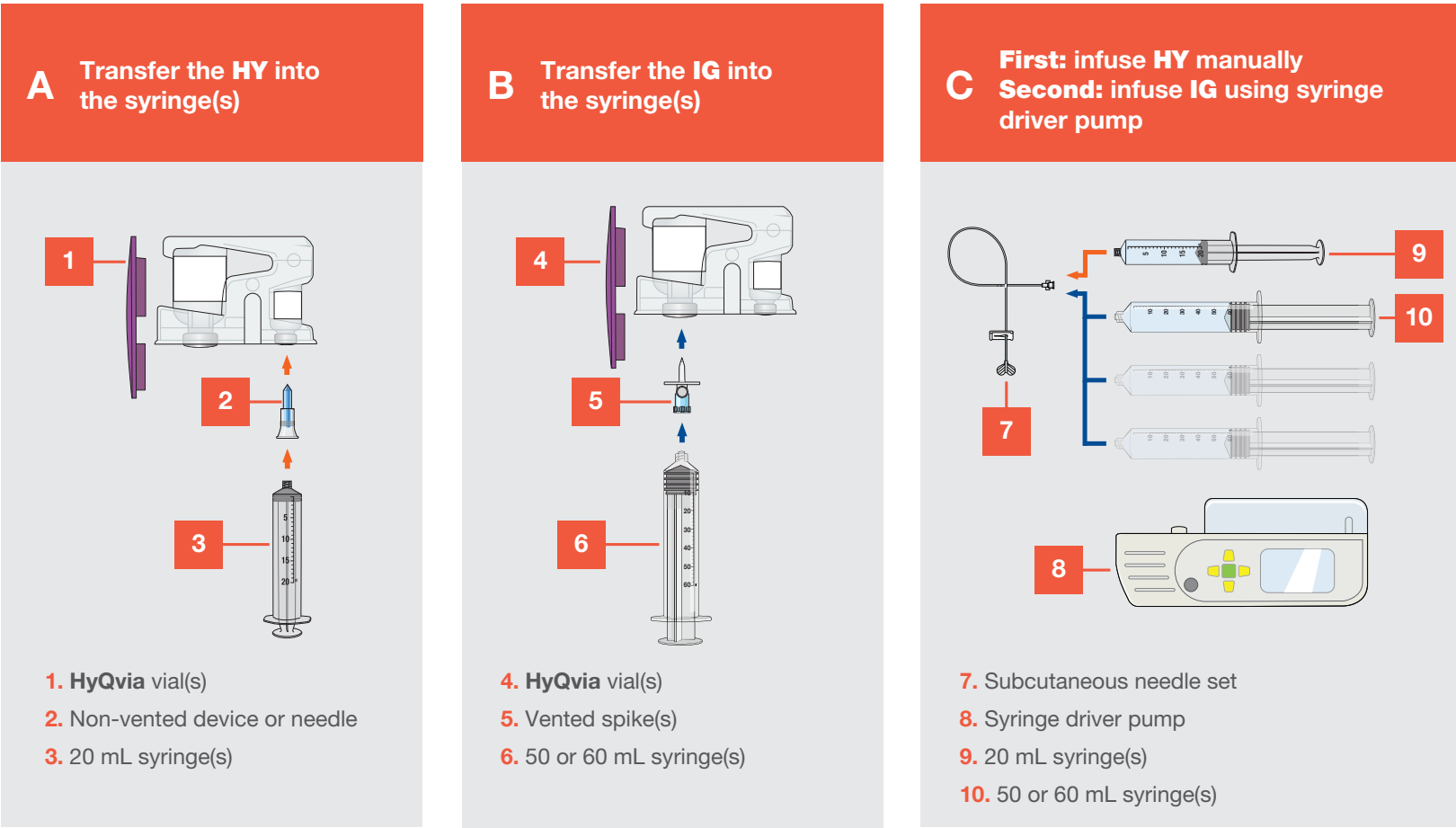
Points to emphasise

- Explain that these diagrams show how the **supplies fit together** as a preview to the next 5 steps. The number of syringes required depends on the prescribed dose. The diagram on the right side of the page is an example.
- Use these diagrams to reinforce the **order of the process**: transferring first, then infusing.
- Reinforce **HY before IG**. The **IG** infusion should be started right after the **HY** infusion is complete (within 10 minutes).
- Point out the option of using the syringe driver pump to infuse the **HY**.

- ✓ **Assess patient knowledge**

Evaluate the patient’s comfort level with how the supplies fit together

How they fit together

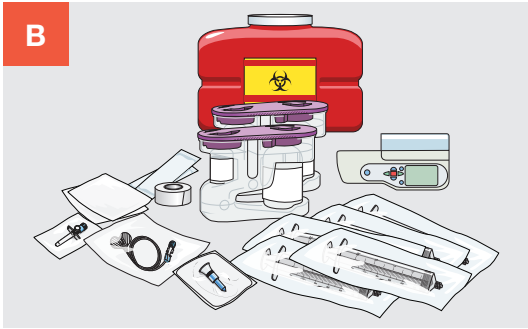


**This diagram is an example. The number of syringes required is dependent on your prescribed dose.*

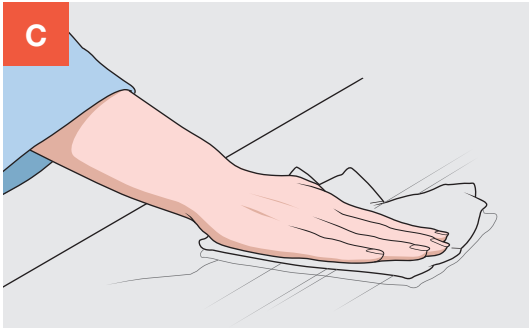
STEP 1 Get ready



Remove **HyQvia** from the box and inspect it. A purple protective cap is on the dual vial unit. Do not use the product if it does not have the cap. Allow **HyQvia** to reach room temperature (this may take up to 60 minutes). Check the colour and expiry date. Make sure the liquid isn't cloudy and doesn't have particles in it. Do not use heating devices, including microwaves. Do not shake **HyQvia**.



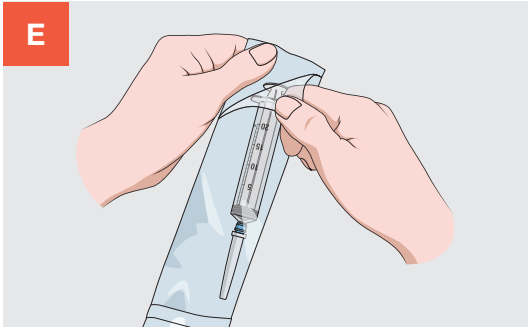
Gather your supplies.



Clean your work area.



Wash your hands thoroughly.



Open supplies as instructed by your healthcare professional.

STEP 1 Get ready

Train your patients and their caregivers on the steps below.
Also cover the ‘Points to emphasise’ in the grey boxes.

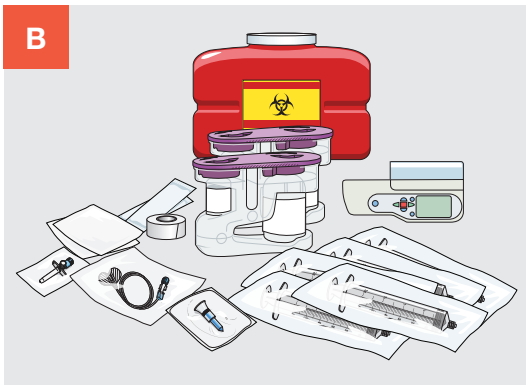


- Remove **HyQvia** from the box and inspect it
- A purple protective cap is on the dual vial unit. Do not use the product if it does not have the cap
- Allow **HyQvia** to reach room temperature. (This may take up to 60 minutes). Do not use heating devices, including microwaves
- Check the colour and expiry date. Make sure the liquid isn't cloudy and doesn't have particles in it
- Do not shake **HyQvia**

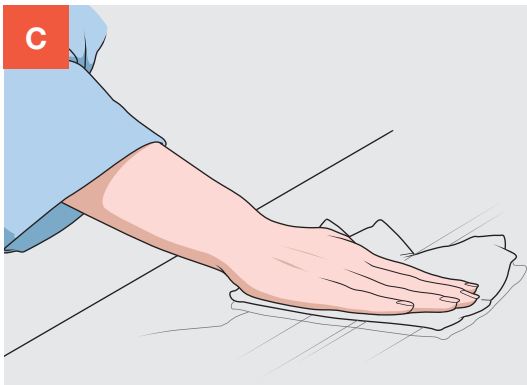
Points to emphasise

Ensure HyQvia is at room temperature – do not use heating devices to achieve this.

Check the vials for clarity and colour. The **HY** should be clear and colourless. The **IG** should be clear and colourless or pale yellow. Point out the removable label with the expiry date, lot number, and date of manufacture for use in the logbook.



- Gather your supplies



- Clean your work area

Points to emphasise

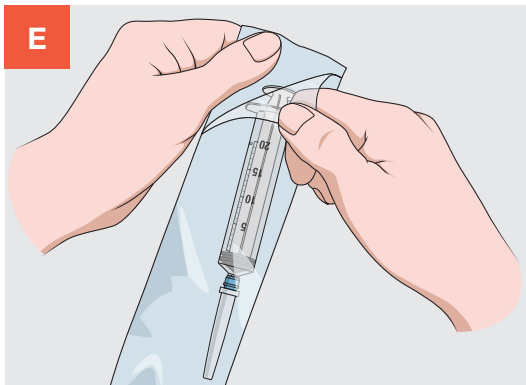
Prepare work area. Instruct patients to find a quiet work area with enough space.



- Wash your hands thoroughly

Points to emphasise

Consider use of gloves. Follow your institution's guidelines about the use of gloves.



- Open supplies as instructed by your healthcare professional

Points to emphasise

Explain aseptic techniques.

Keep sterile supplies in open packages near the work area.

Untangle the needle set before using the syringes.



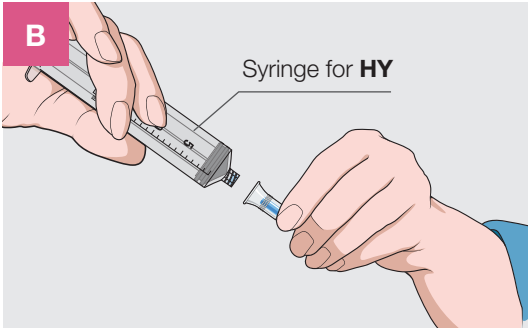
Assess patient knowledge

Ask patients to explain ‘**Step 1: Get Ready**’ in their own words. Provide encouragement, and correct any misunderstandings before moving to the next step.

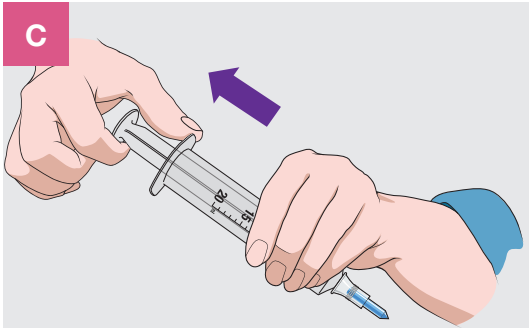
STEP 2 Prepare the HY



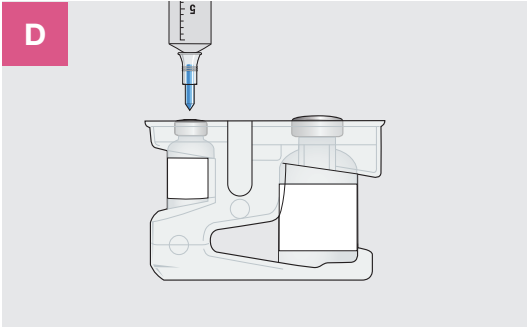
Remove the cap. Clean each vial of **HY** by wiping the stopper with an alcohol swab and allow to dry for at least 30 seconds.



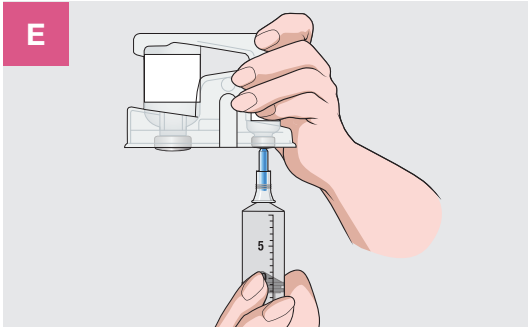
Remove the 20 mL sterile syringe from its package.* Attach a non-vented device or needle to the syringe.



Pull back on the plunger to fill the syringe with air (an amount equal to the full amount of **HY**).



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



Turn the vial upside down. Pull back on the plunger to withdraw all of the **HY** into the syringe. Repeat steps C to E if more than one vial of **HY** is needed for your dose. **Use the same syringe, if possible.**

TIP

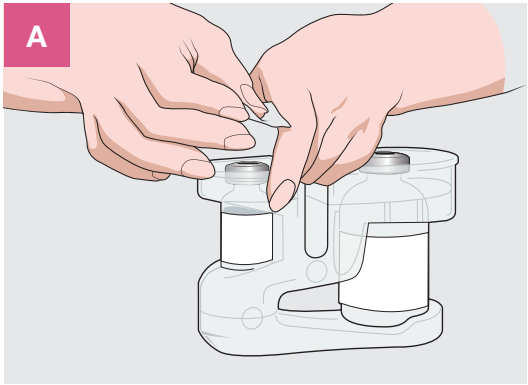
Cover each syringe with a sterile tip cap when drawing up multiple syringes.

*This is the recommended syringe volume.

STEP 2 continued

STEP 2 Prepare the HY

Train your patients and their caregivers on the steps below. Also cover the ‘Points to emphasise’ in the grey boxes.

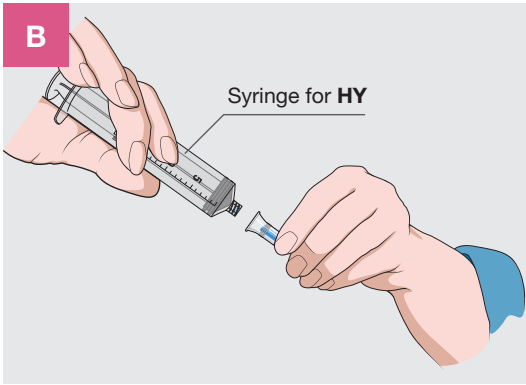


- Remove the cap
- Clean each vial of **HY** by wiping the stopper with an alcohol swab and allow to dry for at least 30 seconds

Points to emphasise

Help identify vials. In addition to vial size differences, point out that the **HY vial is silver** at the top and the **IG vial is crimped**.

Reinforce that it could take 30 seconds for the alcohol to dry.

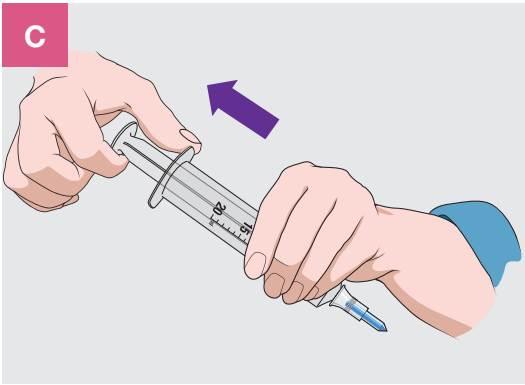


- Remove the 20 mL sterile syringe from its package*
- Attach a non-vented device or needle to the syringe

Points to emphasise

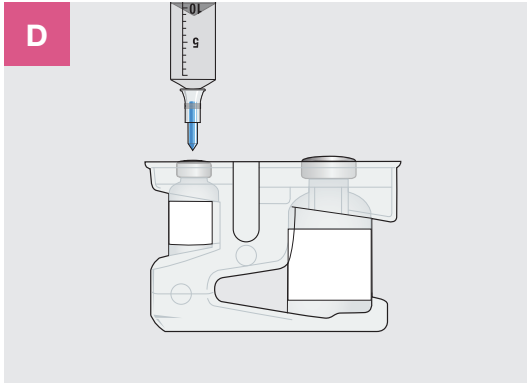
Reinforce aseptic techniques, especially when patients naive to subcutaneous infusion draw up medications.

Use only a non-vented device or needle. A vented spike could cause stopper push through.



- Pull back on the plunger to fill the syringe with air (an amount equal to the full amount of **HY**)

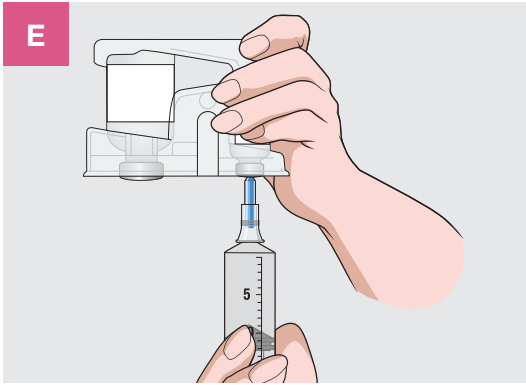
*This is the recommended syringe volume.



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

Points to emphasise

Insert the non-vented device or needle in the centre of the vial to prevent stopper coring or stopper push through.



- Turn the vial upside down
- Pull back on the plunger to withdraw all of the **HY** into the syringe
- Repeat steps C to E if more than one vial of **HY** is needed for your dose. Use the same syringe, if possible

Points to emphasise

Draw the full vial of HY into the syringe.

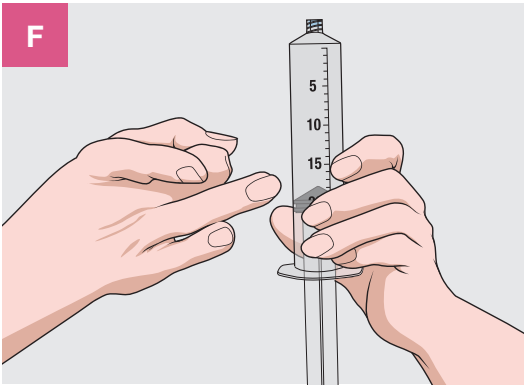
TIP

Cover each syringe with a sterile tip cap when drawing up multiple syringes.

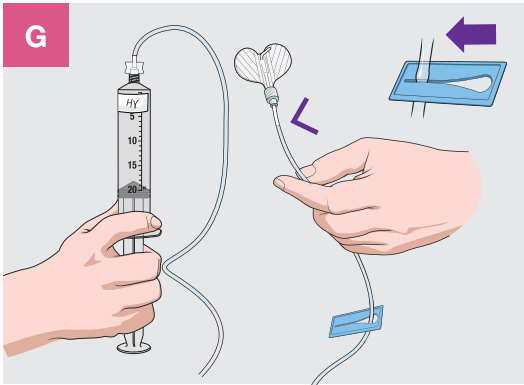
✓ Assess patient knowledge

Ask patients to explain ‘**Step 2: Prepare the HY**’ in their own words. Provide encouragement, and correct any misunderstandings before moving to the next step.

STEP 2 Prepare the HY



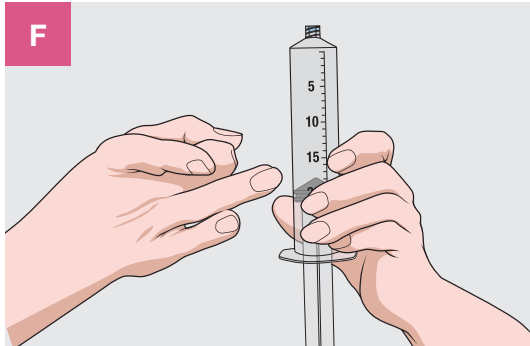
Gently tap it to remove air bubbles. Then slowly push the plunger until the **HY** reaches the tip of the barrel.



Attach the subcutaneous needle set to the **HY** syringe. Slowly push the plunger to fill the needle set tubing to the needle wings. Close the clamp on the needle set tubing. Label the syringe **HY**.

STEP 2 Prepare the HY

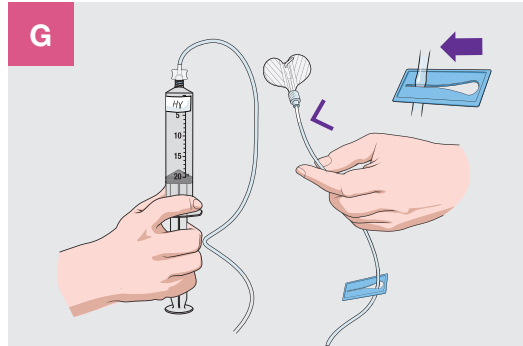
Train your patients and their caregivers on the steps below.
Also cover the 'Points to emphasise' in the grey boxes.



- **Gently tap it to remove air bubbles**
- Then slowly push the plunger until the **HY** reaches the tip of the barrel

Points to emphasise

Remove air bubbles. Reinforce the importance of tapping the syringe to remove air bubbles.



- Attach the subcutaneous needle set to the **HY** syringe
- Slowly push the plunger to fill the needle set tubing to the needle wings
- Close the clamp on the needle set tubing
- **Label the syringe HY**

Points to emphasise

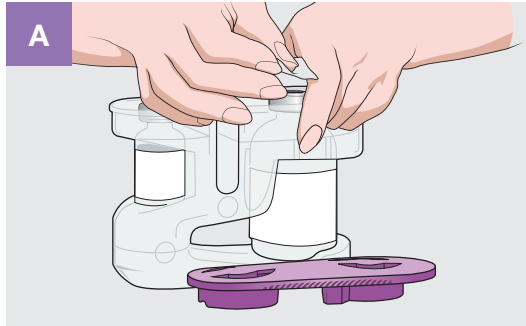
Discuss viscosity. Remind patients experienced with subcutaneous infusion that they may not be used to the low viscosity of the **HY**. Pushing the plunger too hard can shoot the **HY** out of the needle.

Stop at needle hub. Remind patients to fill the needle set tubing with **HY** only to the needle hub.

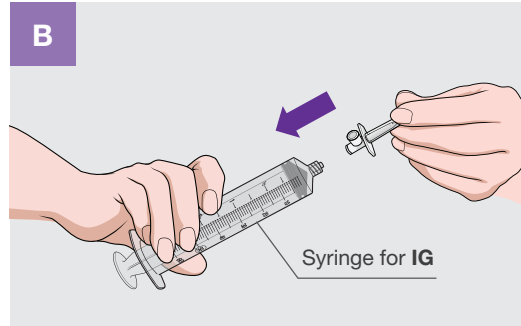
Close the clamp as shown when transfer of the **HY** is completed.

Label the syringe. Reinforce that patients should attach the **HY** label to the syringe after clamping the needle set tubing. Labels can be found in the logbook.

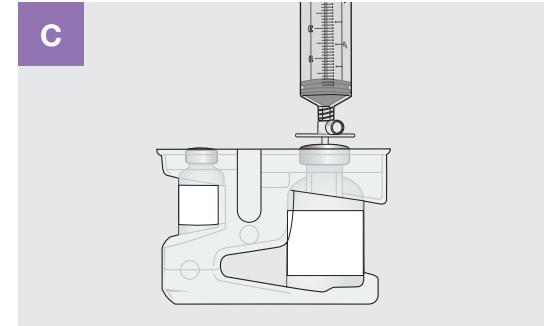
STEP 3 Prepare the IG



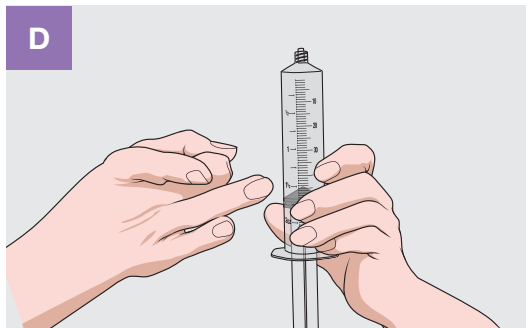
Clean each vial of **IG** by wiping the stopper with an alcohol swab and allow to dry for at least 30 seconds.



Open the larger 50 or 60 mL sterile syringe from its package.* Attach the syringe to a vented spike.



Insert the vented spike straight down into the **IG** vial stopper. Then turn the vial upside down and pull on the plunger to withdraw the desired dose of **IG**. Repeat steps A to C if using multiple vials to achieve the desired dose.



Gently tap the syringe to remove bubbles. Slowly push the plunger until the **IG** reaches the tip of the barrel.

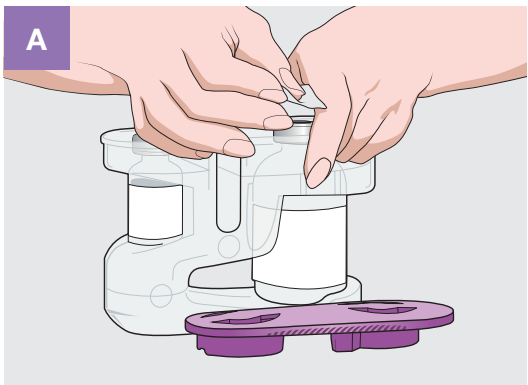
*These are the recommended syringe volumes.

TIP

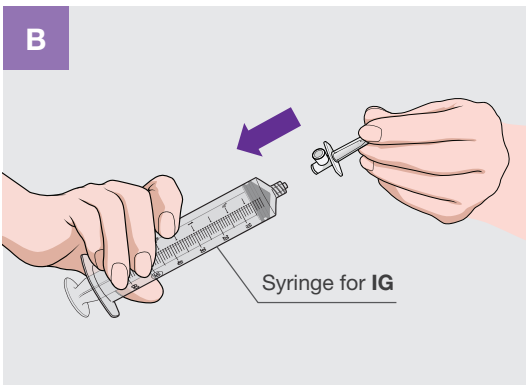
- Cover each syringe with a sterile tip cap when drawing up multiple syringes
- If using a non-vented device or needle to withdraw the **IG**, attach a larger 50 or 60 mL syringe to the non-vented device or needle. Pull back on the plunger to fill the syringe with air equal to the amount of **IG** you will be taking from the vial. Insert the non-vented device or needle into the centre of the **IG** vial stopper. Push the air into the vial. Then turn the vial upside down and pull on the plunger to withdraw the desired amount of **IG** into the syringe

STEP 3 Prepare the IG

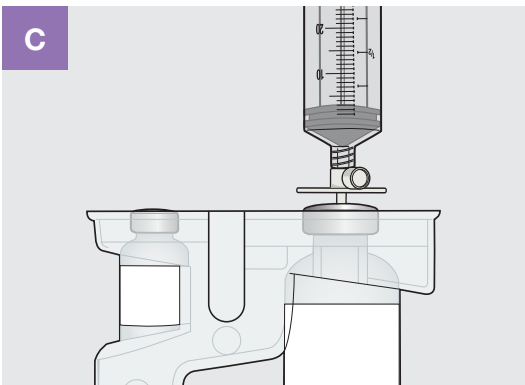
Train your patients and their caregivers on the steps below. Also cover the 'Points to emphasise' in the grey boxes.



- Clean each vial of IG by wiping the stopper with an alcohol swab and allow to dry for at least 30 seconds



- Open the larger 50 or 60 mL sterile syringe from its package.* Attach the syringe to a vented spike



- Insert the vented spike straight down into the IG vial stopper
- Then turn the vial upside down and pull on the plunger to withdraw the desired dose of IG
- Repeat steps A to C if using multiple vials to achieve the desired dose

Points to emphasise

Reinforce that it could take 30 seconds for the alcohol to dry.

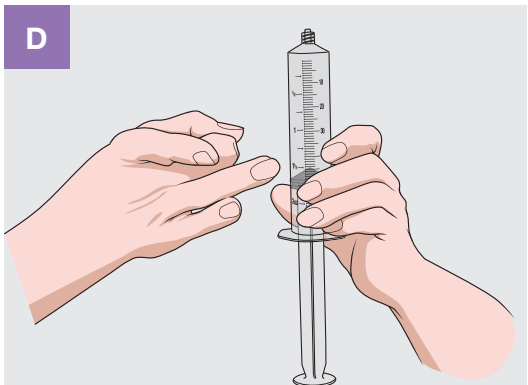
Points to emphasise

Reinforce that patients should use the larger syringe for this step.

Points to emphasise

Properly insert the vented spike. Explain that the vented spike should be inserted straight down into the centre of the IG vial stopper.

*These are the recommended syringe volumes.



- Gently tap the syringe to remove bubbles. Slowly push the plunger until the IG reaches the tip of the barrel

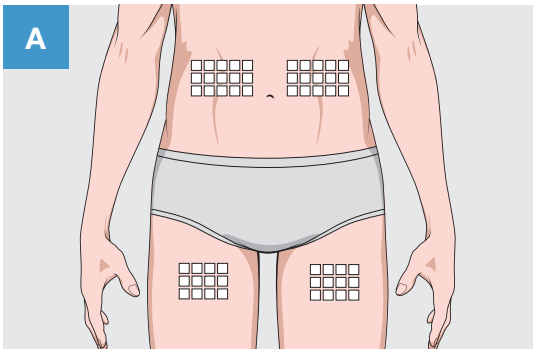
TIP

- Cover each syringe with a sterile tip cap when drawing up multiple syringes
- If using a non-vented device or needle to withdraw the IG, attach a larger 50 or 60 mL syringe to the non-vented device or needle
- Pull back on the plunger to fill the syringe with air equal to the amount of IG you will be taking from the vial
- Insert the non-vented device or needle into the centre of the IG vial stopper
- Push the air into the vial. Then turn the vial upside down and pull on the plunger to withdraw the desired amount of IG into the syringe

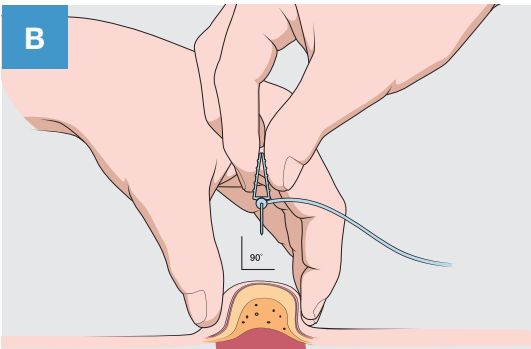
✓ Assess patient knowledge

Ask patients to explain 'Step 3: Prepare the IG' in their own words. Provide encouragement, and correct any misunderstandings before moving to the next step.

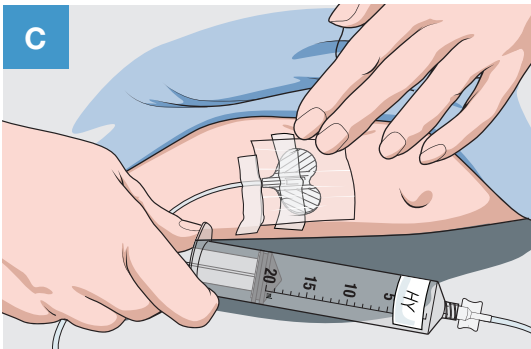
STEP 4 Infuse HyQvia



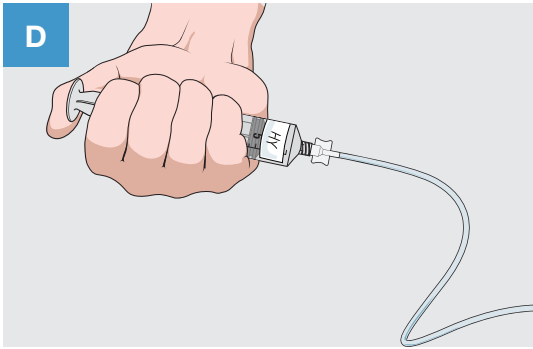
Choose an infusion site (or sites) in either the abdomen or thigh. Avoid bony areas, visible blood vessels, scars, and any areas of inflammation or infection. Rotate your infusion sites to opposite sides of the body between infusions.* **Clean the infusion site(s) with an alcohol swab**, as instructed by your healthcare professional. Allow to dry for at least 30 seconds.



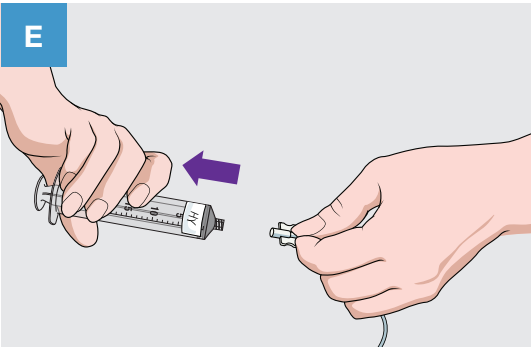
Remove the subcutaneous needle cover. Pinch at least 2.0 to 2.5 cm of your skin. Insert the needle with a rapid motion straight into the skin at a 90-degree angle. Open the needle set wings and secure the needle in place with a sterile dressing.



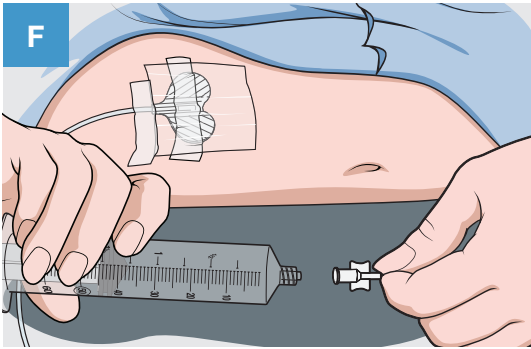
If more than one infusion site is used, repeat steps A to C. Open the clamp on the needle set. Check for proper needle placement before starting the infusion, as instructed by your healthcare professional.



Slowly push the plunger of the smaller syringe with the recombinant **HY** at an initial rate of 1 to 2 mL per minute and increase as tolerated. If more than one site is used, divide the **HY** equally between sites. Check infusion site(s) occasionally throughout the infusion for dislodgement or leaking.



When all of the **HY** has been infused, remove the syringe. Do not remove the needle from your infusion site(s).



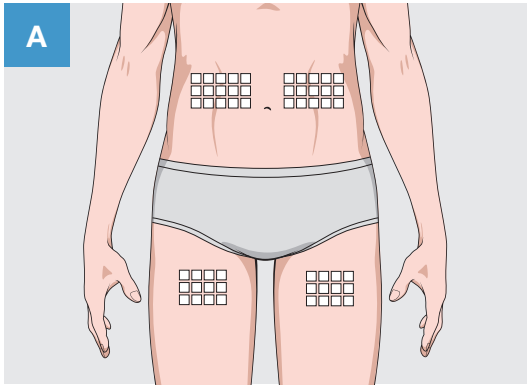
Attach the **IG** syringe to the same subcutaneous needle set.

*For patients with a body weight of <40kg, select sites on opposite sides of body if instructed to infuse in 2 sites for doses above 300 mL. For patients with a body weight of >40kg, select sites on opposite sides of body if instructed to infuse in 2 sites for doses above 600 mL.

STEP 4 continued

STEP 4 Infuse HyQvia

Train your patients and their caregivers on the steps below.
Also cover the ‘Points to emphasise’ in the grey boxes.



- Choose an infusion site (or sites) in either the abdomen or thigh
- Avoid bony areas, visible blood vessels, scars, and any areas of inflammation or infection
- Rotate your infusion sites to opposite sides of the body between infusions*
- **Clean the infusion site(s) with an alcohol swab**, as instructed by your healthcare professional
- Allow to dry for at least 30 seconds

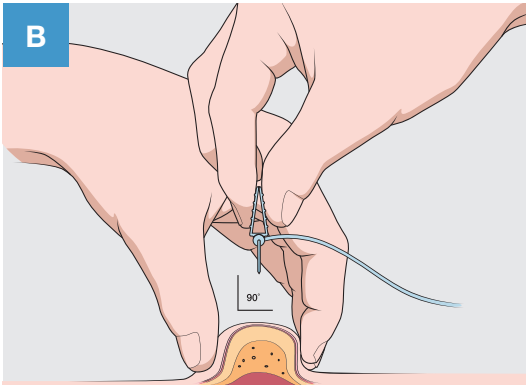
Points to emphasise

Remember: HY before IG.

Use opposite sides of the body if multiple infusion sites are required.

Avoid certain areas. HyQvia treatment should not be infused into or around an infected or red, swollen area due to potential risk of spreading a localised infection.

Clean the site. Start at the centre of the infusion site and work outward in a circular motion. Allow to dry for at least 30 seconds.

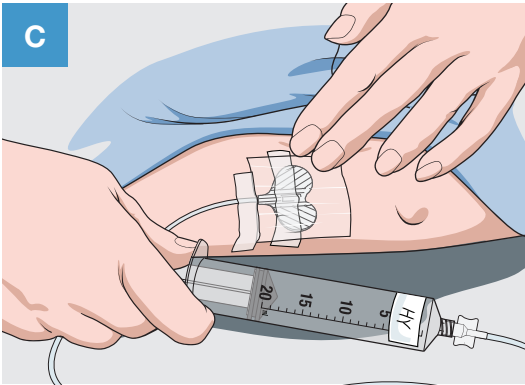


- Remove the subcutaneous needle cover
- Pinch at least 2.0 to 2.5 cm of your skin
- Insert the needle with a rapid motion straight into the skin at a 90-degree angle
- Open the needle set wings and secure the needle in place with a sterile dressing

Points to emphasise

Assess patient knowledge. Ask patients to demonstrate what 90 degrees means.

Point out the sterile tape. Show patients the sterile tape on the dressing that comes with the needle set.

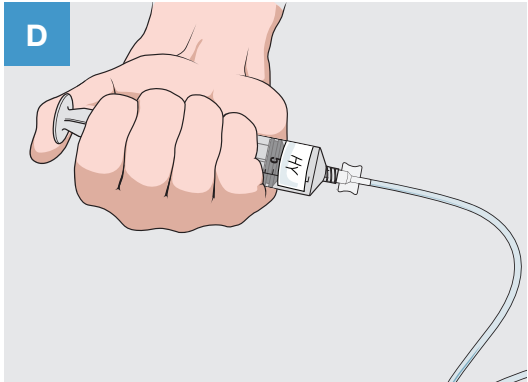


- If more than one infusion site is used, repeat steps A to C
- Open the clamp on the needle set
- Check for proper needle placement before starting the infusion, as instructed by your healthcare professional

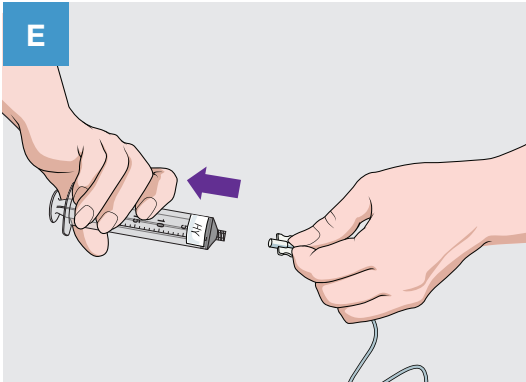
Points to emphasise

Repeat steps if needed. Remind patients to repeat steps A to C if they use more than one infusion site.

Show patients how to check for blood in the tubing and reinforce that the needle should be removed and replaced.



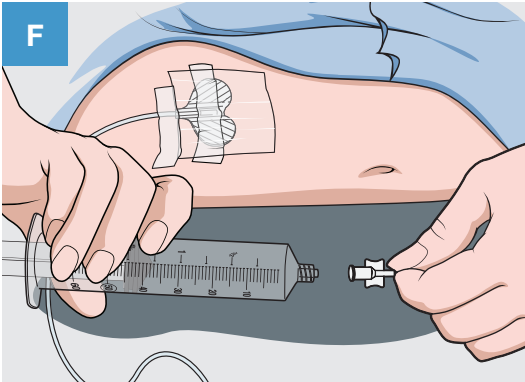
- Push the plunger on the **HY** syringe to infuse the **HY** at a rate of 1 to 2 mL per minute per infusion site
- If more than one site is used, divide the **HY** equally between sites
- Check infusion site(s) occasionally throughout the infusion for dislodgement or leaking



- When all of the **HY** has been infused, remove the syringe
- Do not remove the needle from your infusion site(s)

Points to emphasise

Leave the needle in. Emphasise that caregivers should not remove the needle from the infusion site after the **HY** infusion.



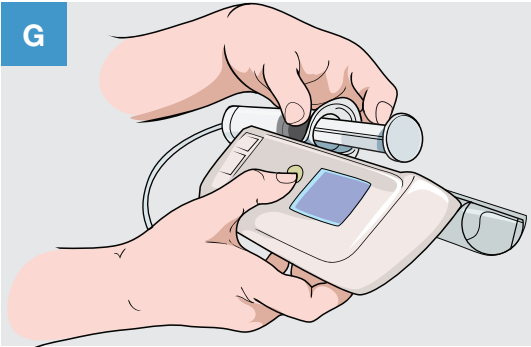
- Attach the **IG** syringe to the same subcutaneous needle set)

Points to emphasise

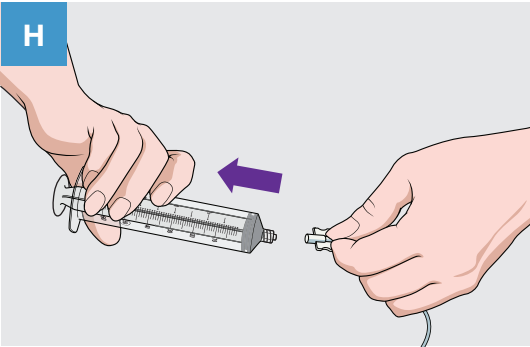
Reinforce that the tip of the syringe must remain sterile when changing syringes.

*For patients with a body weight of <40kg, select sites on opposite sides of body if instructed to infuse in 2 sites for doses above 300 mL.
For patients with a body weight of >40kg, select sites on opposite sides of body if instructed to infuse in 2 sites for doses above 600 mL.

STEP 4 Infuse HyQvia



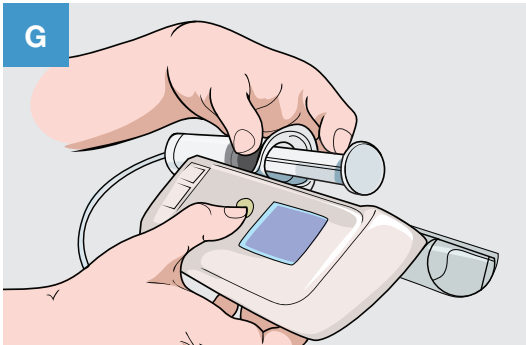
Insert the **IG** syringe into the pump and start the pump at the rate prescribed by your healthcare professional and following the manufacturer’s instructions for preparing the pump. **The IG infusion should be started within 10 minutes of completing the HY infusion.**



When the syringe is empty, remove the syringe from the pump and detach it from the subcutaneous needle set. Repeat steps F through H for each additional syringe of **IG**.

STEP 4: Infuse HyQvia

Train your patients and their caregivers on the steps below.
Also cover the 'Points to emphasise' in the grey boxes.



- Insert the **IG** syringe into the pump and start the pump at the rate prescribed by your healthcare professional and following the manufacturer's instructions for preparing the pump
- **The IG infusion should be started within 10 minutes of completing the HY infusion**

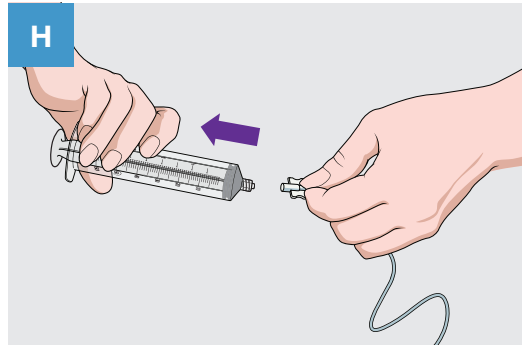
Points to emphasise

Discuss pump considerations. Refer caregivers to their pump manufacturer's guide or their pharmacy.

Take advantage of downtime during IG infusion. Discuss resources available. Reinforce when and how to use the emergency kit if prescribed. Assess caregivers' confidence with the infusion process and determine how to enhance the next infusion experience.

Check for leaking at the infusion site. If leaking occurs, direct caregivers to check if the needle is secured improperly, the needle length is too short, too much volume is being infused, or the needle is placed at an incorrect angle.

Reinforce HY before IG. Remind caregivers to start the **IG** infusion within 10 minutes after completing the **HY** infusion.



- When the syringe is empty, remove the syringe from the pump and detach it from the subcutaneous needle set
- Repeat steps F through H for each additional syringe of **IG**

Points to emphasise

Reinforce that the tip of the syringe must remain sterile when changing syringes.

Considerations for managing the infusion

Please check manufacturer's instructions, but for pump occlusion alarms, consider advising patients to:

- Verify that the occlusion alarm is set to maximum
- Confirm that the subcutaneous needle is 24 gauge and labeled for high flow rates
- Check that the pump is qualified for use with **HyQvia** treatment

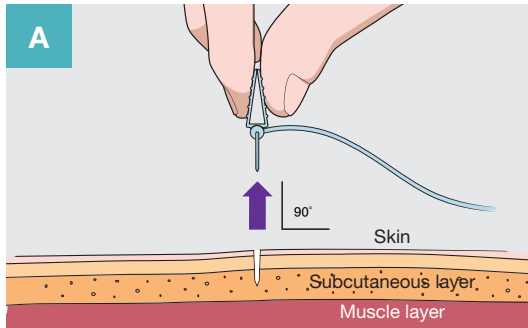
If the occlusion alarm persists, reduce the flow rate to complete the infusion.



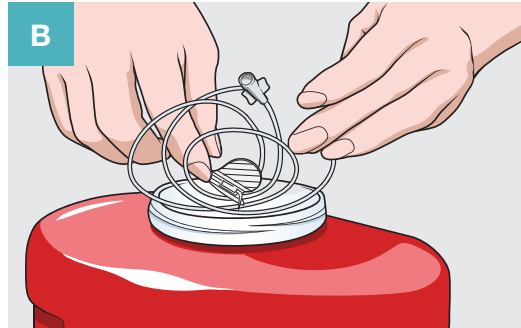
Assess patient knowledge

Ask patients to explain '**Step 4: Infuse HyQvia**' in their own words. Provide encouragement, and correct any misunderstandings before moving to the next step.

STEP 5 Finish up



When the infusion is complete, attach a syringe containing normal saline (0.9% Sodium Chloride [NaCl] solution) to the needle set to flush it and push the **IG** up to the needle wings, if instructed by your healthcare professional. Remove the subcutaneous needle set by loosening the sterile dressing on all edges. Pull the needle wings straight up and out. Gently place the clean sterile bandage over the infusion site.



Dispose of the needle set in the sharps container and throw away any unused product in the vial and disposable supplies, as recommended by your healthcare professional.



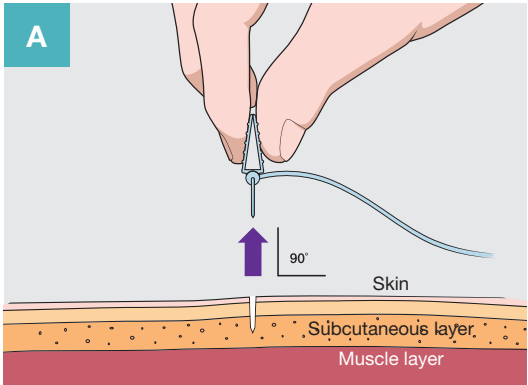
Record the infusion details in your logbook.

D

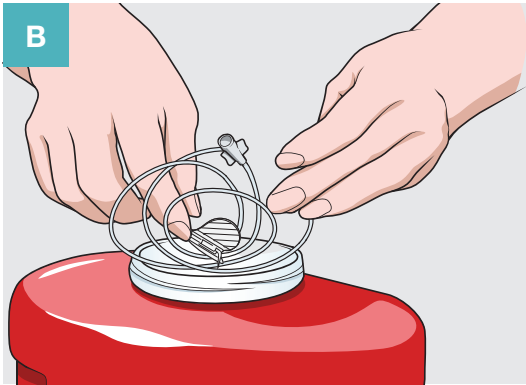
Follow up with your healthcare professional as directed.

STEP 5 Finish up

Train your patients and their caregivers on the steps below. Also cover the ‘Points to emphasise’ in the grey boxes.



- When the infusion is complete, attach a syringe containing normal saline (0.9% Sodium Chloride [NaCl] solution) to the needle set to flush it and push the **IG** up to the needle wings, if instructed by your healthcare professional
- Remove the subcutaneous needle set by loosening the sterile dressing on all edges
- Pull the needle wings straight up and out
- Gently place the clean sterile bandage over the infusion site



- Dispose of the needle set in the sharps container and throw away any unused product in the vial and disposable supplies, as recommended by your healthcare professional.



- Record the infusion details in your logbook

Points to emphasise

Explain proper needle handling. Use extra caution when handling an unprotected needle. Have a sharps container ready.

Points to emphasise

Review the logbook. Explain the importance of completing each section and recording the date, time, dose, site(s) of infusion, and any side effects.

Discuss how and where to attach the peel-off labels from the **HyQvia** vial(s) into the logbook.

D

- Follow up with your healthcare professional, as directed

Points to emphasise

Encourage and inform. Ask if caregivers have questions and discuss when to contact their healthcare professional.

Ensure supplies for the next infusion. Verify that patients understand how and when to reorder supplies.

✓ **Assess patient knowledge**

Ask patients to explain ‘**Step 5: Finish up**’ in their own words. Consider using the Patient Skills Checklist to document their training. Determine their comfort level with the infusion process.

What it looks like when you infuse HyQvia treatment

Following your infusion with **HyQvia**, you may experience swelling at the infusion site. This is due to the volume of fluid infused and should only last for a few days.

Before, during and after HyQvia treatment

Example of a patient on **HyQvia**. Your body may react to your **HyQvia** infusion in the same way, or differently.



Before **HyQvia** infusion



Right after **HyQvia** infusion

HyQvia infused: 235 mL (volume infused as per the healthcare professional's guidance based on this patient's specific clinical condition; it may be different for you).



24 hours after infusion

What are the possible side effects of HyQvia treatment?

Local site reactions occur at the infusion site. These reactions usually go away within a few days. The most common local side effects include: infusion site pain, including mild-to-moderate discomfort and tenderness, redness, swelling, itching, hardening and rash.

In clinical studies, there were no long-term changes to the skin. Any long-term inflammation, lumps (nodules), or inflammation that occurs at the infusion site and lasts more than a few days should be reported to your healthcare professional. Do not infuse **HyQvia** into or around an infected or red swollen area of skin because it may cause the infection to spread.

Generalised side effects are not limited to the infusion site and can occur throughout the body. The most common generalised side effects include: headache, tiredness, nausea, vomiting, diarrhoea, abdominal pain, muscle or joint pain, chest pain, fever and feeling weak or unwell.

Serious side effects

Infusions of medicines like **HyQvia** can occasionally result in serious, but rare, allergic reactions. You may experience a sudden fall in blood pressure and, in isolated cases, anaphylactic shock. Healthcare professionals are aware of these possible side effects and will monitor you during and after the initial infusions.

Typical signs or symptoms include: feeling light-headed, dizzy or faint, skin rash and itchiness, swelling in the mouth or throat, difficulty breathing, wheezing, abnormal heart rate, chest pain, blueness of lips or fingers and toes and blurred vision.

Tell your healthcare professional immediately if you notice any of these signs during the infusion. Please refer to the package leaflet for the full list of side effects associated with **HyQvia**.

What it looks like when you infuse HyQvia treatment

Train your patients and their caregivers on the information below. Also cover the ‘Points to emphasise.’

What it looks like when you infuse HyQvia treatment

Following your infusion with HyQvia, you may experience swelling at the infusion site. This is due to the volume of fluid infused and should only last for a few days.

Before, during and after HyQvia treatment

Example of a patient on HyQvia. Your body may react to your HyQvia infusion in the same way, or differently.



Before HyQvia infusion



Right after HyQvia infusion

HyQvia infused: 235 mL (volume infused as per the healthcare professional's guidance based on this patient's specific clinical condition; it may be different for you).



24 hours after infusion

What are the possible side effects of HyQvia treatment?

Local site reactions occur at the infusion site. These reactions usually go away within a few days. The most common local side effects include: infusion site pain, including mild-to-moderate discomfort and tenderness, redness, swelling, itching, hardening and rash.

In clinical studies, there were no long-term changes to the skin. Any long-term inflammation, lumps (nodules), or inflammation that occurs at the infusion site and lasts more than a few days should be reported to your healthcare professional. Do not infuse HyQvia into or around an infected or red swollen area of skin because it may cause the infection to spread.

Generalised side effects are not limited to the infusion site and can occur throughout the body. The most common generalised side effects include: headache, tiredness, nausea, vomiting, diarrhoea, abdominal pain, muscle or joint pain, chest pain, fever and feeling weak or unwell.

Serious side effects

Infusions of medicines like HyQvia can occasionally result in serious, but rare, allergic reactions. You may experience a sudden fall in blood pressure and, in isolated cases, anaphylactic shock. Healthcare professionals are aware of these possible side effects and will monitor you during and after the initial infusions.

Typical signs or symptoms include: feeling light-headed, dizzy or faint, skin rash and itchiness, swelling in the mouth or throat, difficulty breathing, wheezing, abnormal heart rate, chest pain, blueness of lips or fingers and toes and blurred vision.

Tell your healthcare professional immediately if you notice any of these signs during the infusion. Please refer to the package leaflet for the full list of side effects associated with HyQvia.

Points to emphasise

Explain why temporary swelling occurs at, or around, the infusion site.

Refer to the ‘Managing possible side effects of HyQvia treatment’ section for tips on managing local site reactions and other side effects.

Remind patients/caregivers to not infuse HyQvia into an infected or red swollen area of skin.

Please refer to the SmPC for a full list of side effects.



Assess patient knowledge

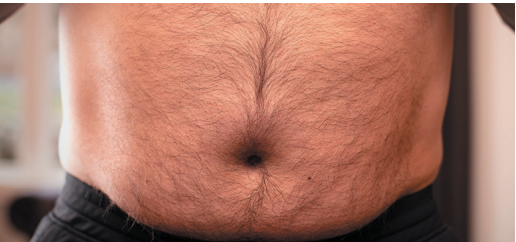
Ensure that patients have a general understanding of local site reactions that may occur with treatment.

What it looks like when you infuse HyQvia treatment

Following your infusion with HyQvia, you may experience swelling at the infusion site. This is due to the volume of fluid infused and should only last for a few days.

Before, during and after HyQvia treatment

Example of a patient on HyQvia. Your body may react to your HyQvia infusion in the same way, or differently.



Before HyQvia infusion



Right after HyQvia infusion

HyQvia infused: 235 mL (volume infused as per the healthcare professional's guidance based on this patient's specific clinical condition; it may be different for you).



24 hours after infusion

What are the possible side effects of HyQvia treatment?

Local site reactions occur at the infusion site. These reactions usually go away within a few days. The most common local side effects include: infusion site pain, including mild-to-moderate discomfort and tenderness, redness, swelling, itching, hardening and rash.

In clinical studies, there were no long-term changes to the skin. Any long-term inflammation, lumps (nodules), or inflammation that occurs at the infusion site and lasts more than a few days should be reported to your healthcare professional. Do not infuse HyQvia into or around an infected or red swollen area of skin because it may cause the infection to spread.

Generalised side effects are not limited to the infusion site and can occur throughout the body. The most common generalised side effects include: headache, tiredness, nausea, vomiting, diarrhoea, abdominal pain, muscle or joint pain, chest pain, fever and feeling weak or unwell.

Serious side effects

Infusions of medicines like HyQvia can occasionally result in serious, but rare, allergic reactions. You may experience a sudden fall in blood pressure and, in isolated cases, anaphylactic shock. Healthcare professionals are aware of these possible side effects and will monitor you during and after the initial infusions.

Typical signs or symptoms include: feeling light-headed, dizzy or faint, skin rash and itchiness, swelling in the mouth or throat, difficulty breathing, wheezing, abnormal heart rate, chest pain, blueness of lips or fingers and toes and blurred vision.

Tell your healthcare professional immediately if you notice any of these signs during the infusion. Please refer to the package leaflet for the full list of side effects associated with HyQvia.

Managing possible side effects of HyQvia treatment

Local side effects

The following local reactions may occur at the site of infusion and usually go away within a few days. You should be observed for at least 20 minutes after the administration. When **HyQvia** is given at home, support from another responsible person should be available for treating adverse reactions or to summon help should a serious side effect occur. Always contact your healthcare professional to find out how best to manage any local reaction that increases in severity or persists for more than a few days.

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

- Remove the needle because it may be in your muscle
- Contact your healthcare professional if severe pain does not fade when you remove the needle or if it happens each time you infuse
- Talk to your healthcare professional or speciality pharmacy about changing the length of your needle; it may be too long for you. The thickness of subcutaneous tissue can be different from person to person depending on age, gender, body mass index, and the site of infusion
- Note in your logbook that this site may not work for you

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

- Please talk to your healthcare professional, who may slow or stop the infusion
- Place a clean, warm or cold washcloth as directed by your healthcare professional for short periods (no longer than 10 minutes) on your irritated site
- Talk to your healthcare professional about a possible allergy to your tape or dressing or the possible use of a mild pain reliever

Swelling at or around the infusion site

After **HyQvia** infusion, a temporary swelling can occur due to the volume of fluid infused.

- Place a clean, warm washcloth for short periods (no longer than 5 to 10 minutes) on the swelling
- Your healthcare professional may advise you to walk around or gently massage the swelling

Itching or rash at or around the infusion site

- Slow or stop the infusion
- Place a clean, cold washcloth for short periods (no longer than 10 minutes) on your itchy site
- When priming the subcutaneous needle, avoid coating the needle with drops of the **HyQvia** treatment
- Talk to your healthcare professional about the possible use of an antihistamine, if recommended
- If you experience uncontrollable itching or rash/hives, stop your infusion immediately and contact your healthcare professional or emergency services; these could be signs of a serious allergic reaction

Generalised (systemic) side effects

Generalised side effects affect the whole body rather than a specific part. The most common generalised side effects include:

Headache

- Talk to your healthcare professional about using an over-the-counter pain reliever
- Contact your healthcare professional if the headache persists or worsens

Tiredness

- Rest quietly after the infusion
- Go to bed early the day of the infusion

Fever

- Talk to your healthcare professional about using an over-the-counter medicine to reduce the fever
- Contact your healthcare professional if the fever persists or worsens

Other less frequent side effects are listed in the **HyQvia** package leaflet including serious but rare allergic reactions. It's also possible that you may experience side effects that are not discussed in the **HyQvia** package leaflet. Please talk to your healthcare professional if you experience any side effects, particularly those that are not listed in the package leaflet, are severe, or last longer than a couple of days.

Please note: the suggestions above should not replace your healthcare professional's direction/advice.

You can also report side effects directly via HPRA Pharmacovigilance, website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

Managing possible side effects of HyQvia treatment

Train your patients and their caregivers on the information below. Also cover the ‘Points to emphasise.’

Managing possible side effects of HyQvia treatment

Local side effects

The following local reactions may occur at the site of infusion and usually go away within a few days. You should be observed for at least 20 minutes after the administration. When **HyQvia** is given at home, support from another responsible person should be available for treating adverse reactions or to summon help should a serious side effect occur. Always contact your healthcare professional to find out how best to manage any local reaction that increases in severity or persists for more than a few days.

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

- Remove the needle because it may be in your muscle
- Contact your healthcare professional if severe pain does not fade when you remove the needle or if it happens each time you infuse
- Talk to your healthcare professional or speciality pharmacy about changing the length of your needle; it may be too long for you. The thickness of subcutaneous tissue can be different from person to person depending on age, gender, body mass index, and the site of infusion
- Note in your logbook that this site may not work for you

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

- Please talk to your healthcare professional, who may slow or stop the infusion
- Place a clean, warm or cold washcloth as directed by your healthcare professional for short periods (no longer than 10 minutes) on your irritated site
- Talk to your healthcare professional about a possible allergy to your tape or dressing or the possible use of a mild pain reliever

Swelling at or around the infusion site

After **HyQvia** infusion, a temporary swelling can occur due to the volume of fluid infused.

- Place a clean, warm washcloth for short periods (no longer than 5 to 10 minutes) on the swelling
- Your healthcare professional may advise you to walk around or gently massage the swelling

Itching or rash at or around the infusion site

- Slow or stop the infusion
- Place a clean, cold washcloth for short periods (no longer than 10 minutes) on your itchy site
- When priming the subcutaneous needle, avoid coating the needle with drops of the **HyQvia** treatment
- Talk to your healthcare professional about the possible use of an antihistamine, if recommended
- If you experience uncontrollable itching or rash/hives, stop your infusion immediately and contact your healthcare professional or emergency services; these could be signs of a serious allergic reaction

Generalised (systemic) side effects

Generalised side effects affect the whole body rather than a specific part. The most common generalised side effects include:

Headache

- Talk to your healthcare professional about using an over-the-counter pain reliever
- Contact your healthcare professional if the headache persists or worsens

Tiredness

- Rest quietly after the infusion
- Go to bed early the day of the infusion

Fever

- Talk to your healthcare professional about using an over-the-counter medicine to reduce the fever
- Contact your healthcare professional if the fever persists or worsens

Other less frequent side effects are listed in the **HyQvia** package leaflet including serious but rare allergic reactions. It's also possible that you may experience side effects that are not discussed in the **HyQvia** package leaflet. Please talk to your healthcare professional if you experience any side effects, particularly those that are not listed in the package leaflet, are severe, or last longer than a couple of days.

Please note: the suggestions above should not replace your healthcare professional's direction/advice.

You can also report side effects directly via HPRA Pharmacovigilance, website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

Points to emphasise



Consider reading this page with your patients to help ensure they have a broad understanding of potential local and generalised side effects.



Assess patient knowledge

Ensure that patients have a broad understanding of potential local and generalised side effects.

What it looks like when you infuse HyQvia treatment

Local side effects

The following local reactions may occur at the site of infusion and usually go away within a few days. You should be observed for at least 20 minutes after the administration. When **HyQvia** is given at home, support from another responsible person should be available for treating adverse reactions or to summon help should a serious side effect occur. Always contact your healthcare professional to find out how best to manage any local reaction that increases in severity or persists for more than a few days.

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

- Remove the needle because it may be in your muscle
- Contact your healthcare professional if severe pain does not fade when you remove the needle or if it happens each time you infuse
- Talk to your healthcare professional or speciality pharmacy about changing the length of your needle; it may be too long for you. The thickness of subcutaneous tissue can be different from person to person depending on age, gender, body mass index, and the site of infusion.
- Note in your logbook that this site may not work for you

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

- Please talk to your healthcare professional, who may slow or stop the infusion
- Place a clean, warm or cold washcloth as directed by your healthcare professional for short periods (no longer than 10 minutes) on your irritated site
- Talk to your healthcare professional about a possible allergy to your tape or dressing or the possible use of a mild pain reliever

Swelling at or around the infusion site

After **HyQvia** infusion, a temporary swelling can occur due to the volume of fluid infused.

- Place a clean, warm washcloth for short periods (no longer than 5 to 10 minutes) on the swelling
- Your healthcare professional may advise you to walk around or gently massage the swelling

Itching or rash at or around the infusion site

- Slow or stop the infusion
- Place a clean, cold washcloth for short periods (no longer than 10 minutes) on your itchy site
- When priming the subcutaneous needle, avoid coating the needle with drops of the **HyQvia** treatment
- Talk to your healthcare professional about the possible use of an antihistamine, if recommended
- If you experience uncontrollable itching or rash/hives, stop your infusion immediately and contact your healthcare professional or emergency services; these could be signs of a serious allergic reaction

Generalised (systemic) side effects

Generalised side effects affect the whole body rather than a specific part. The most common generalised side effects include:

Headache

- Talk to your healthcare professional about using an over-the-counter pain reliever
- Contact your healthcare professional if the headache persists or worsens

Tiredness

- Rest quietly after the infusion
- Go to bed early the day of the infusion

Fever

- Talk to your healthcare professional about using an over-the-counter medicine to reduce the fever
- Contact your healthcare professional if the fever persists or worsens

Other less frequent side effects are listed in the **HyQvia** package leaflet including serious but rare allergic reactions. It's also possible that you may experience side effects that are not discussed in the **HyQvia** package leaflet. Please talk to your healthcare professional if you experience any side effects, particularly those that are not listed in the package leaflet, are severe, or last longer than a couple of days.

Please note: the suggestions above should not replace your healthcare professional's direction/advice.

You can also report side effects directly via HPRA Pharmacovigilance, website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

Resources

Helpful PID communities and support organisations

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

International Patient Organisation for Primary Immunodeficiencies (IPOPI)

<http://www.ipopi.org/>

Jeffrey Modell Foundation

<http://info4pi.org/>

European Society for Immunodeficiencies (ESID)

<http://esid.org/>

Helpful CIDP communities and support organisations

<http://gbs-cidp.org/>

Helpful PID communities and support organisations

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

International Patient Organisation for Primary Immunodeficiencies (IPOPI)

<http://www.ipopi.org/>

Jeffrey Modell Foundation

<http://info4pi.org/>

European Society for Immunodeficiencies (ESID)

<http://esid.org/>

Helpful CIDP communities and support organisations

<http://gbs-cidp.org/>

