

# HyQvia

Human Normal Immunoglobulin (10%)  
Recombinant Human Hyaluronidase

## Infusing HyQvia treatment directly from vials with a peristaltic infusion pump

A step-by-step guide for patients and caregivers

Additional information following training from your healthcare team

HyQvia is prescribed as replacement therapy to patients who do not have sufficient antibodies, including the following groups:

- Patients with an inborn inability or reduced ability to produce antibodies (primary immunodeficiencies)
- Patients with a certain kind of blood cancer (chronic lymphocytic leukaemia) which leads to a lack of antibody production and recurrent infections when preventative antibiotics have failed
- Patients with a specific cancer of the bone marrow (multiple myeloma) and lack of antibody production with recurrent infections who have failed to respond to a vaccine against certain bacteria (pneumococci)
- Patients with low antibody production prior and after transplantation of bone marrow cells from another person

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 of the Package Leaflet for how to report side effects.

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



## Introduction

### Infusion overview

Managing primary immunodeficiency presents many challenges. Treatment administration should not be one of them. This step-by-step guide is designed to help you learn how to administer **HyQvia** using a peristaltic infusion pump. Familiarise yourself with the 5 steps to help ensure that you have a comfortable and effective infusion experience with **HyQvia** and that it occurs in a safe manner. If you have any questions or concerns about how to administer **HyQvia** treatment, please discuss them with your healthcare professional.

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

Healthcare professional name and phone number:



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

## The 5 steps to infusing HyQvia treatment

### 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 pump tubing

### 4. Infuse HyQvia

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

### 5. Finish up

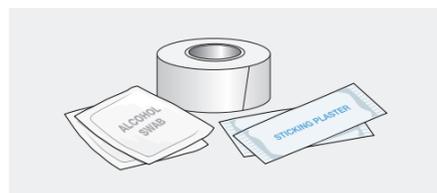
- Remove needle
- Log infusion

## What you'll need

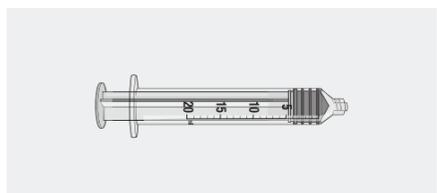
Below are the supplies you'll need to infuse **HyQvia** treatment. Your supplies may look slightly different.



HyQvia vial(s)



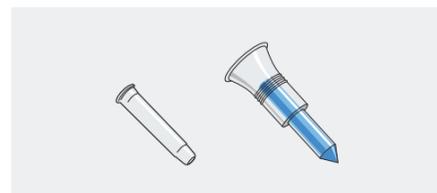
Alcohol swabs, tape and clean, sterile bandage\*



20 mL syringe(s)



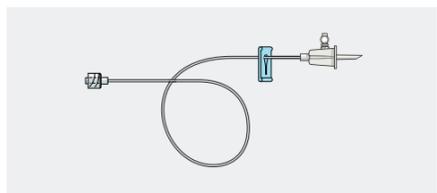
Optional: sterile tip caps (one per syringe)



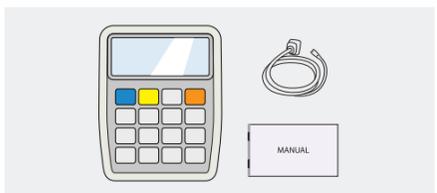
Non-vented device or needle (one per HY vial)



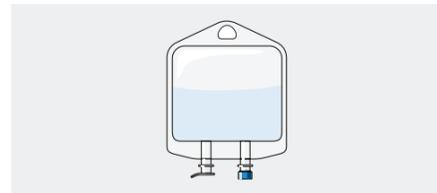
Subcutaneous needle set with a sterile dressing (one per infusion site)



Vented pump tubing



Peristaltic infusion pump, power supply and manual



Optional: saline infusion bag (if required by your healthcare professional)



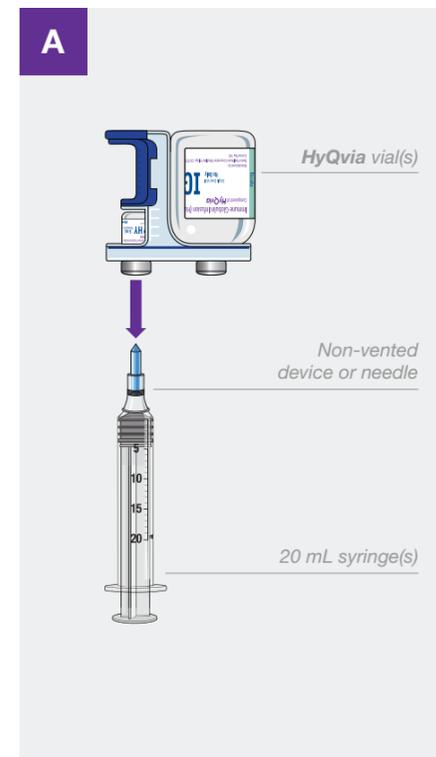
Sharps container



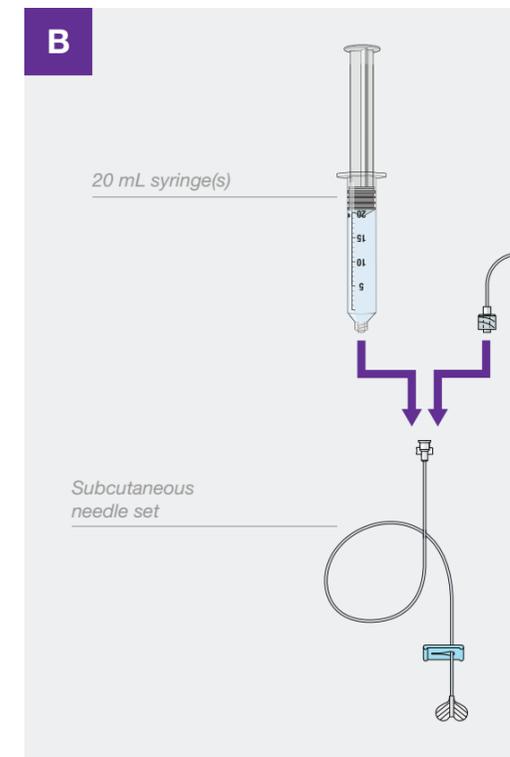
Log book

\*Wear gloves if instructed by your healthcare professional.

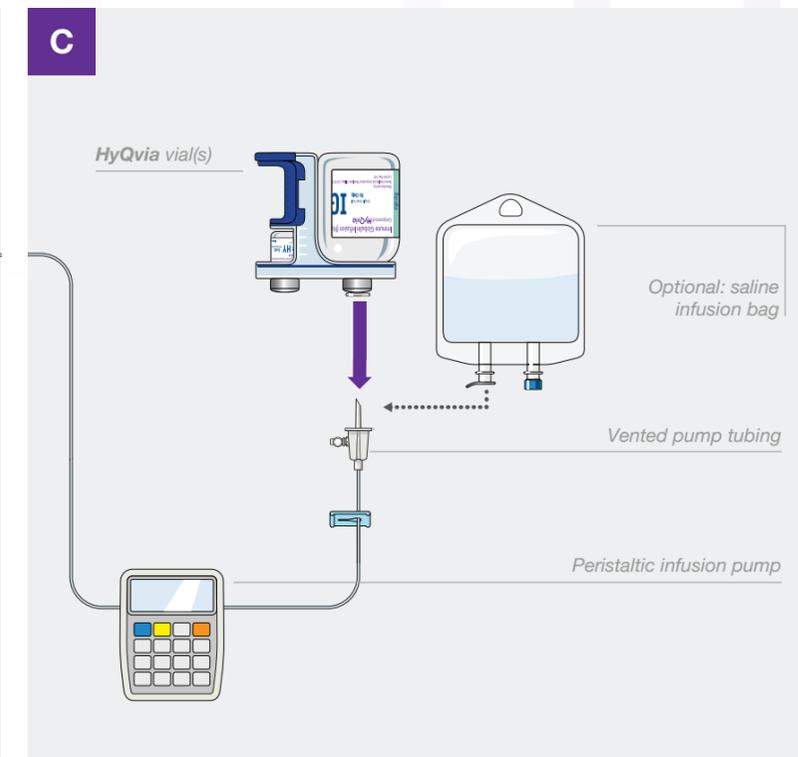
## How they fit together



Transfer the HY into the syringe(s).



Infuse the HY manually (first)



Infuse the IG using the peristaltic pump (second)

# STEP 1

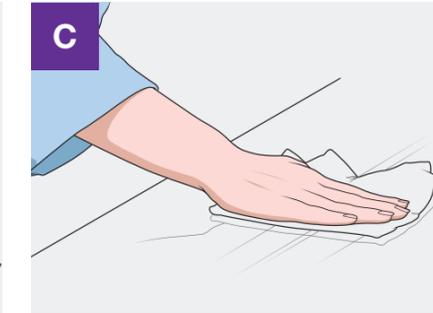
# Get ready



Remove **HyQvia** from the box and inspect it. Check the colour and expiry date. Make sure the liquid isn't cloudy and doesn't have particles in it. Allow **HyQvia** to reach room temperature (this may take up to 60 minutes). Do not use heating devices including microwaves. Do not shake **HyQvia**.



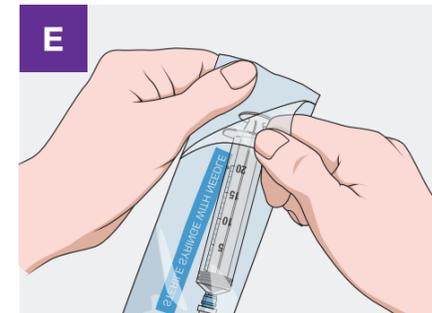
Gather your supplies.



Clean your work area.



Wash your hands thoroughly.



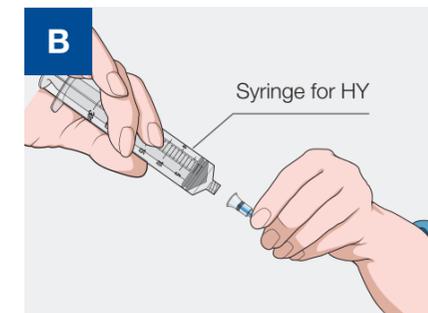
Open supplies as instructed by your healthcare professional.

# STEP 2

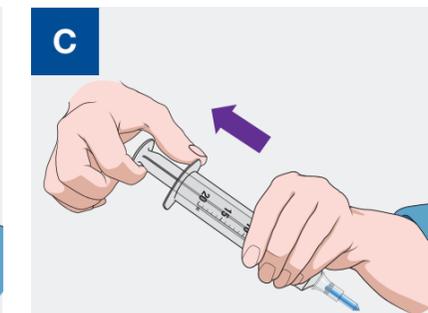
# Prepare the HY



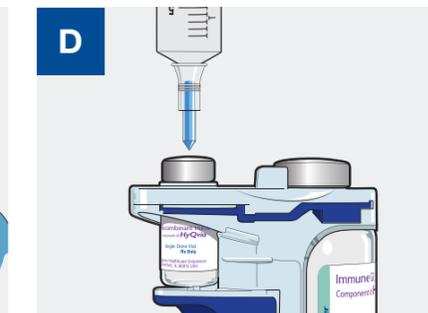
Remove the blue cap. Clean each vial of HY by wiping the stopper with an alcohol swab and allowing to dry for at least 30 seconds.



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



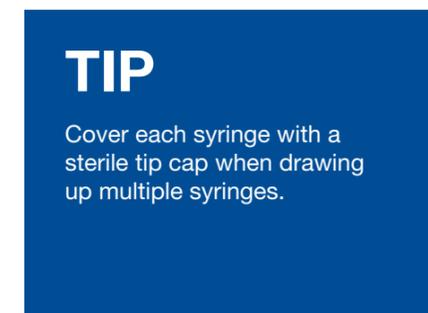
Pull back on the plunger to fill the syringe with air (an amount equal to the full amount of HY).



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

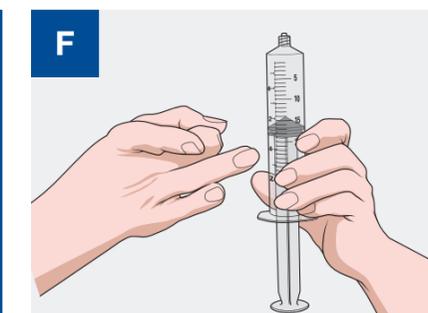


Turn the vial upside down. Pull back on the plunger to withdraw all of the HY into the syringe. Repeat steps C to E if more than one vial of HY is needed for your dose. **Use the same syringe, if possible.**

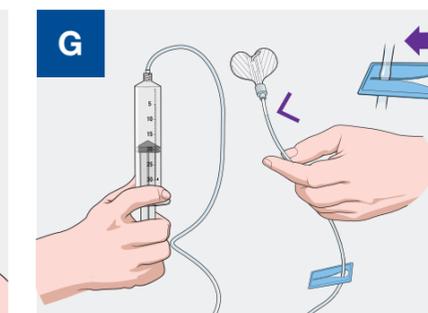


## TIP

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



When the full dose has been transferred into the syringe, hold the syringe upright and **gently tap it to remove air bubbles**. Then slowly push the plunger until the HY reaches the tip of the barrel.



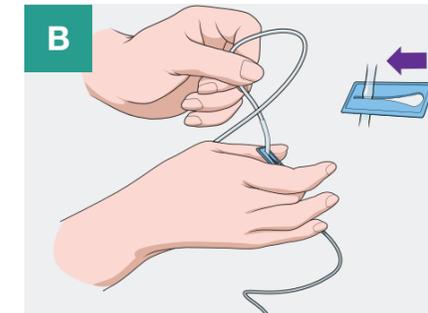
Attach the subcutaneous needle set to the HY syringe. Slowly push the plunger to fill the needle set tubing to the needle wings. Close the clamp on the needle set tubing. Label the syringe HY.

# STEP 3

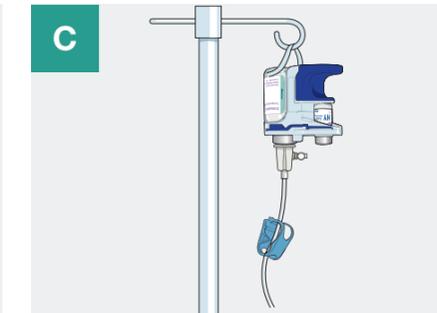
# Prepare the IG



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



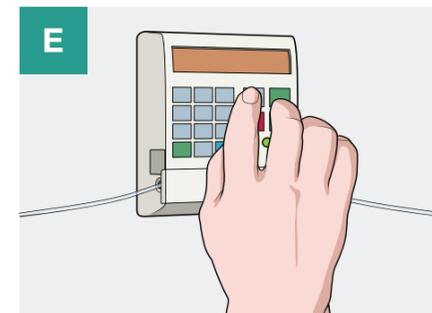
Close the clamp on the vented pump tubing.



Insert the spike of the vented pump tubing straight down into the IG vial stopper. Turn the vial upside down and hang it from an intravenous pole or hook.



Fill the vented pump tubing with IG as instructed by your healthcare professional.

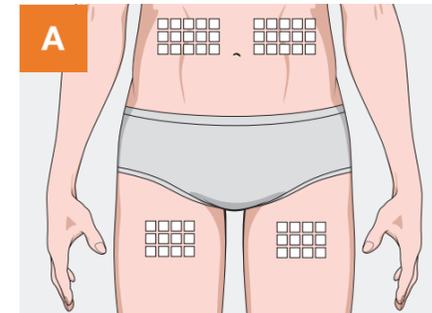


Following the manufacturer's instructions, programme the pump for the prescribed infusion flow rates. Turn off the pump.

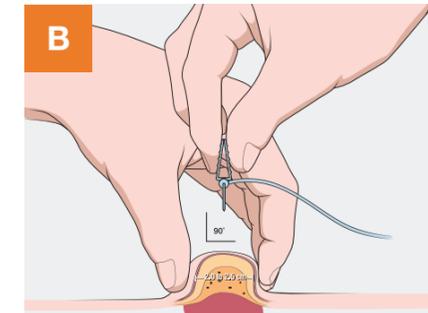
# STEP 4

## Infuse HyQvia

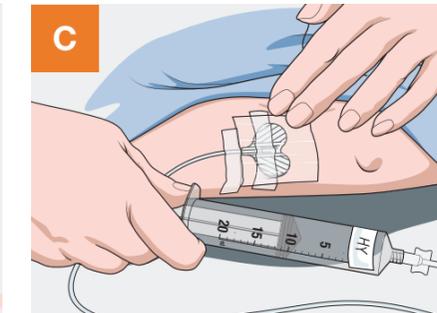
### Remember: HY before IG



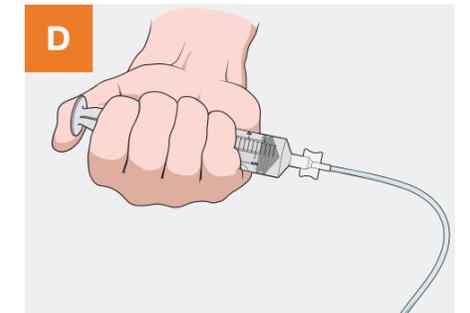
Choose an infusion site (or sites) in either the abdomen or thigh. Avoid bony areas, visible blood vessels, scars and any areas of inflammation or infection. Rotate your infusion sites to opposite sides of the body between infusions.\* **Clean the infusion site(s) with an alcohol swab**, if instructed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



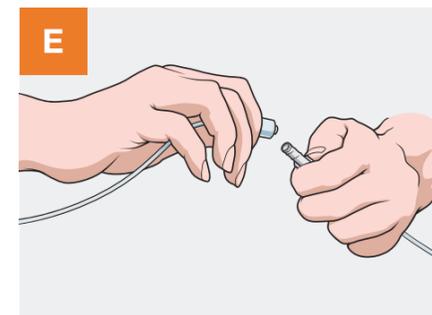
Remove the subcutaneous needle cover. Pinch at least 2.0 to 2.5 cm of your skin. Insert the needle with a rapid motion straight into the skin at a 90-degree angle. Open the needle set wings and secure the needle in place with a sterile dressing.



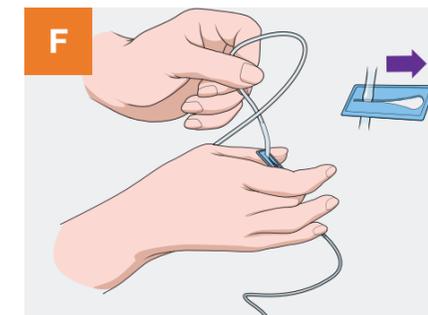
If more than one infusion site is used, repeat steps A through C. Open the clamp on the needle set. Check for proper needle placement before starting the infusion, as instructed by your healthcare professional.



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.



When all of the HY has been infused, remove the syringe and attach the same subcutaneous needle set to the vented pump tubing. Do not remove the needle from your infusion site(s).



Open the clamp on the vented pump tubing and start the pump to infuse the IG at the rate prescribed by your healthcare professional. The IG infusion should be started within 10 minutes after completing the HY infusion.

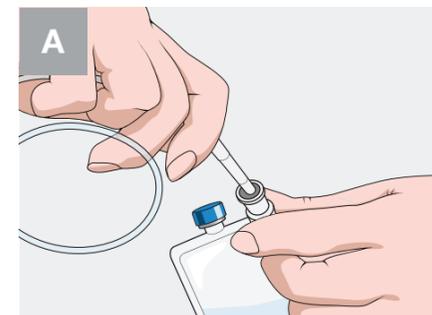


When the vial is empty, pause the pump and reprogramme if needed. Insert the spike of the vented pump tubing into the cleansed IG vial. Then restart the pump. Repeat for each remaining IG vial.

\*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 5

## Finish up



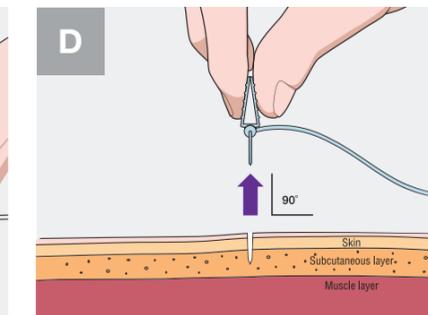
If instructed to do so by your healthcare professional, when the last IG vial is empty, remove it and attach the saline infusion bag to the vented pump tubing.



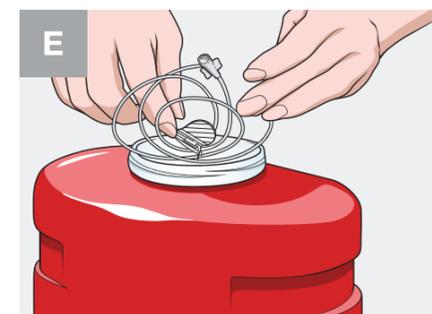
Restart the pump to flush the IG up to the needle wings.



Turn off the pump 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 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 log book.



Follow up with your healthcare professional as directed.

## What it looks like when you infuse HyQvia treatment

Following your infusion with **HyQvia**, you may experience swelling at the infusion site. Swelling should only last for a few days.

### Before, during and after HyQvia treatment

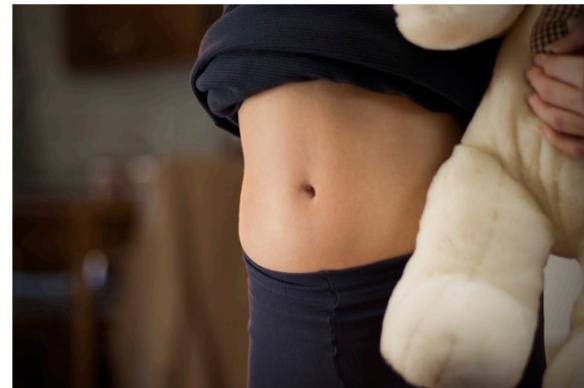
Example of a patient on **HyQvia**. Your body may react to your **HyQvia** infusion in the same way, or differently.



Before **HyQvia** infusion



Right after **HyQvia** infusion



24 hours after infusion

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

## 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.**

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.**

## 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. 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 log book 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 [\[insert local reporting list\]](#). By reporting side effects, you can help provide more information on the safety of this medicine.**





**Reference**

HyQvia [Region or Country] Summary of Product Characteristics, [Month Year].

**HyQvia**

**Human Normal Immunoglobulin (10%)  
Recombinant Human Hyaluronidase**

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