



HyQvia

[Immune Globulin Infusion 10% (Human)
with Recombinant Human Hyaluronidase]

How to Infuse HYQVIA With a Peristaltic Infusion Pump

Your Step-by-Step Guide

This guide is intended for use only as a supplement to in-person training from your healthcare professional.

What is HYQVIA?

- HYQVIA is a liquid medicine containing immune globulin and Recombinant Human Hyaluronidase. HYQVIA contains IgG antibodies, collected from human plasma donated by healthy people. The antibodies help your body to fight off bacterial and viral infections. The hyaluronidase part of HYQVIA helps more of the immune globulin get absorbed into the body to fight infection.
- HYQVIA is indicated for the treatment of Primary Immunodeficiency (PI) involving the humoral immune system in adults.
- Safety and efficacy of chronic use of Recombinant Human Hyaluronidase in HYQVIA have not been established in conditions other than PI.
- HYQVIA is infused under the skin (subcutaneous).
- If you and your healthcare professional decide that home self-infusion of HYQVIA is right for you, then be sure you get instructions and training from your healthcare professional before using HYQVIA at home.

Important Safety Information

What is the most important information that I should know about HYQVIA?

- **HYQVIA can cause blood clots.**
- **Call your healthcare professional if you have pain, swelling, warmth, redness, or a lump in your legs or arms, other than at the infusion site(s), unexplained shortness of breath, chest pain or discomfort that worsens on deep breathing, unexplained rapid pulse, numbness or weakness on one side of the body.**
- Your healthcare professional may perform blood tests regularly to check your IgG level.
- With your consent, your healthcare professional may provide blood samples to Shire plc, to test for antibodies that may form against the hyaluronidase part of HYQVIA.
- Do not infuse HYQVIA into or around an infected or red swollen area because it can cause infection to spread.
- Talk to your healthcare professional if you become pregnant. Women who become pregnant during HYQVIA treatment are encouraged to enroll in the HYQVIA Pregnancy Registry by calling Medical Information at 1-866-424-6724.

Please scroll for additional Important Safety Information, and click for [Information for Patients](#), and discuss with your healthcare provider.

Shire



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THE 5 STAGES TO INFUSE HYQVIA

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

- Transfer IG into pooling bag
- Attach pump tubing to pooling bag

4 INFUSE HYQVIA

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

5 FINISH UP

- Remove needle(s)
- Log infusion

Infusion Overview

This guide is designed to help you infuse HYQVIA [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase] Solution using a peristaltic infusion pump, but is not meant as stand-alone instructions. Please refer to your Information for Patients for a complete list of steps.

Infuse HYQVIA only after you have been trained by your healthcare professional, have the Information for Patients, and are comfortable that you can perform all the steps on your own.

Important Safety Information (continued)

Who should not take HYQVIA?

Do not take HYQVIA if you:

- Are allergic to IgG, hyaluronidase, other blood products, or human albumin (in the hyaluronidase solution).
- Have IgA deficiency with antibodies to IgA.

Please scroll for additional Important Safety Information, and click for [Information for Patients](#), including [Warning about Blood Clots](#), and discuss with your healthcare provider.

HyQvia = HY + IG

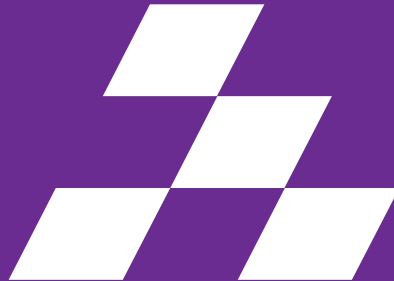
HY 1st

IG 2nd

HY=Recombinant Human Hyaluronidase.
IG=Immune Globulin Infusion 10% (Human).



If you have any questions about your HYQVIA infusion, contact a Nurse Advocate at **1-855-250-5111**.



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WHAT YOU'LL NEED

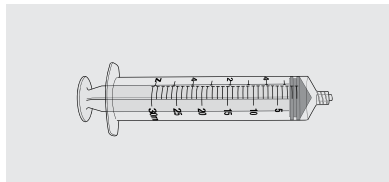
Below are the supplies you will need to infuse HYQVIA [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase] Solution. The supplies you receive from your pharmacy may look different.



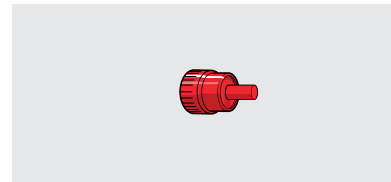
| HYQVIA vial(s)



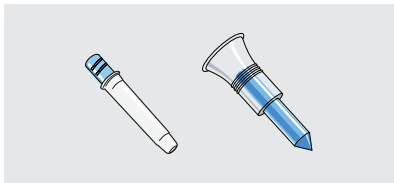
| Alcohol swabs, antibacterial cleaner, soap, tape, and bandages. Gloves can be used if recommended by your healthcare professional



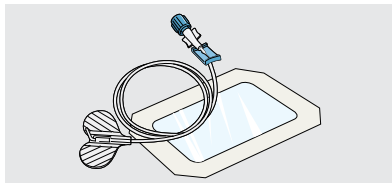
| Syringe(s)



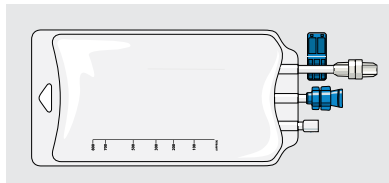
| Sterile tip caps—1 per syringe



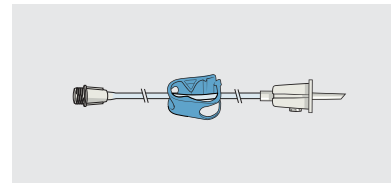
| Needle or needle-less transfer device*—1 per HY vial



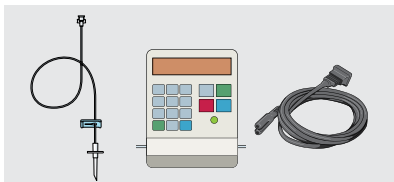
| Subcutaneous needle set with a clear dressing—1 per infusion site



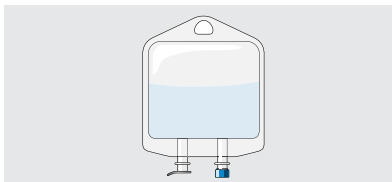
| Pooling bag



| Gravity fill set with vented spike and sterile cap



| Peristaltic infusion pump, pump tubing, power supply, and manual



| **Optional:** Saline infusion bag (if required by your healthcare professional)

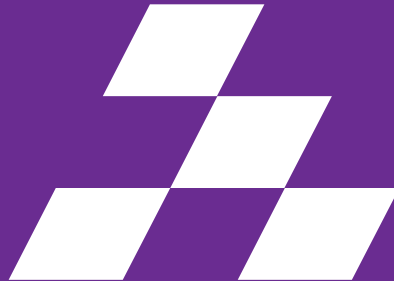


| Sharps container and trash can



| Infusion log

*Use an 18-22 gauge sterile needle to draw from the 1.25 mL vial of HY.



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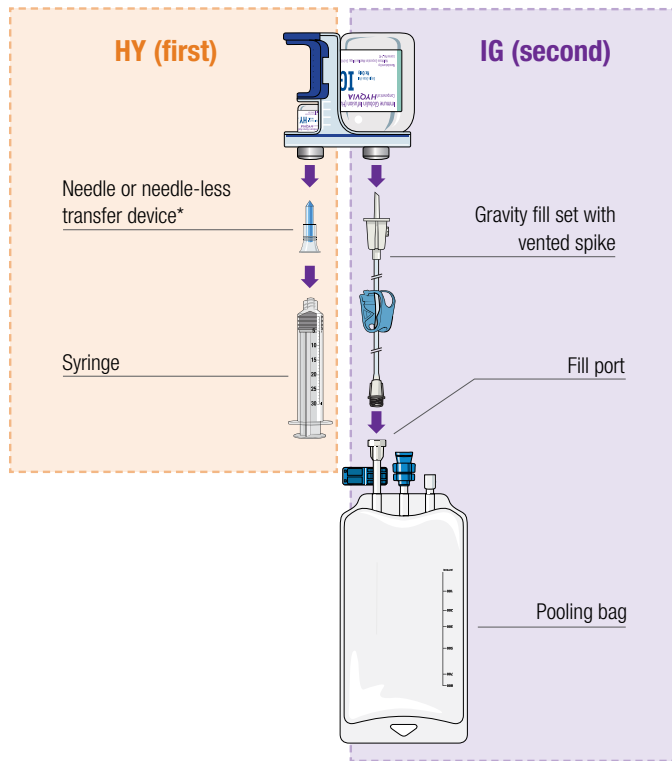


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with Recombinant Human Hyaluronidase]

ADMINISTRATION AT A GLANCE

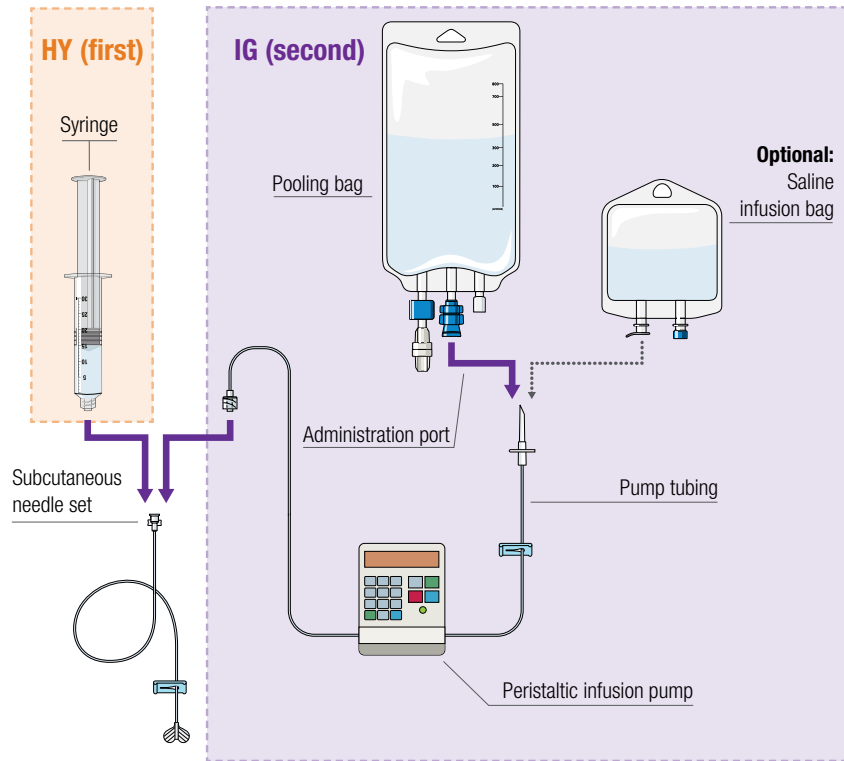
Prepare

- Transfer HY into syringe(s) (first)
- Transfer IG into pooling bag (second)



Infuse

- Infuse HY manually (first)
- Infuse IG using peristaltic infusion pump (second)



*Use an 18-22 gauge sterile needle to draw from the 1.25 mL vial of HY.

STAGE 1

Get Ready

- Inspect vials
- Gather supplies
- Wash hands



Important Safety Information (continued)

HYQVIA can cause serious side effects. Call your healthcare professional or go to your emergency department right away if you get:

- Hives, swelling in the mouth or throat, itching, trouble breathing, wheezing, fainting or dizziness. These could be signs of a serious allergic reaction.
- Bad headache with nausea, vomiting, stiff neck, fever, and sensitivity to light. These could be signs of swelling in your brain.
- Reduced urination, sudden weight gain, or swelling in your legs. These could be signs of a kidney problem.
- Pain, swelling, warmth, redness, or a lump in your legs or arms, other than at the infusion site(s). These could be signs of a blood clot.
- Brown or red urine, fast heart rate, yellow skin or eyes. These could be signs of a liver or blood problem.
- Chest pain or trouble breathing, blue lips or extremities. These could be signs of a lung problem.

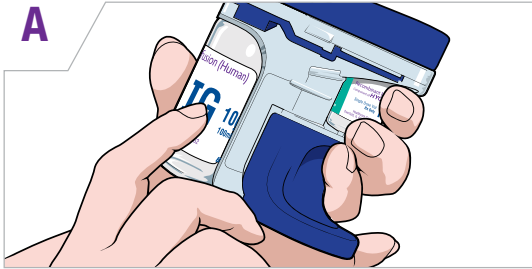
Please scroll for additional Important Safety Information, and click for [Information for Patients](#), including Warning about Blood Clots, and discuss with your healthcare provider.

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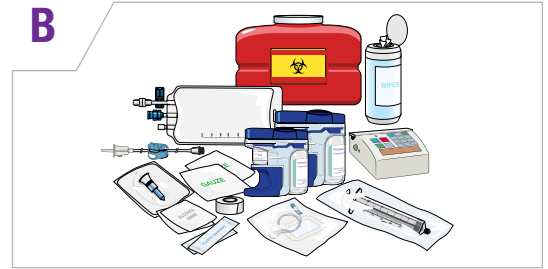
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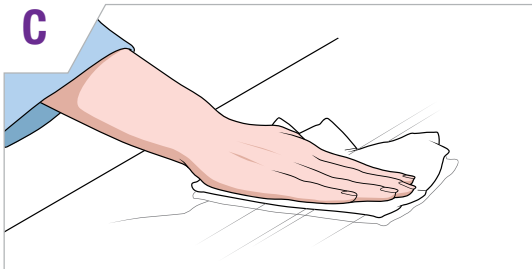
[Immune Globulin Infusion 10% (Human)
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- Take HYQVIA out of the box and allow to reach room temperature. This may take up to 60 minutes. Do not apply heat or place in the microwave.
- Do not return HYQVIA back to the refrigerator if you take it out to room temperature.*
- Do not shake HYQVIA.
- Do not use HYQVIA after the expiration date.
- Do not use HYQVIA if the vials are missing a protective cap, or are broken.
- Check the vials for color—the HY should be clear and colorless and the IG should be clear and colorless or pale yellow. Do not use HYQVIA if the liquid is cloudy or contains particles.



I Gather your supplies.



Clean your work area with an antibacterial cleaner. If you have an infusion mat or antibacterial towel, lay it out.



Wash your hands with antibacterial soap. If instructed by your healthcare professional, put gloves on when your hands are dry.



Open your supplies. Keep them in their packages and place near the clean work area.

*HYQVIA can be stored in the refrigerator (36°F-46°F [2°C-8°C]) for up to 36 months, or at room temperature (up to 77°F [25°C]) for up to 3 months during the first 24 months from the date of manufacturing. Do not freeze HYQVIA. To protect from light, store HYQVIA in its original box.

You're ready for **Stage 2!** >>>

1 GET READY

2 PREPARE HY

3 PREPARE IG

4 INFUSE HYQVIA

5 FINISH UP

STAGE 2

Prepare the HY

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



Important Safety Information (continued)

What are the possible or reasonably likely side effects of HYQVIA?

- After HYQVIA infusion a temporary, soft swelling may occur around the infusion site, which may last 1 to 3 days, due to the volume of fluid infused. Mild or moderate pain, redness, swelling, or itching may occur at the site of infusion and generally go away in a few hours. Local reactions are less likely after the first few infusions.
- The most common side effects of HYQVIA are headache, fatigue, nausea, fever, and vomiting.
- Antibodies to the hyaluronidase component of HYQVIA were formed in some patients taking HYQVIA. It is not known if there is any long term effect. In theory, these antibodies could react with your body's own PH20. PH20 is present in the male reproductive tract. So far, these antibodies have not been associated with increased or new side effects.

These are not all the possible side effects with HYQVIA. Talk to your healthcare professional about any side effects that bother you or that don't go away.

Please scroll for additional Important Safety Information, and click for [Information for Patients](#), including [Warning about Blood Clots](#), and discuss with your healthcare provider.

HyQvia

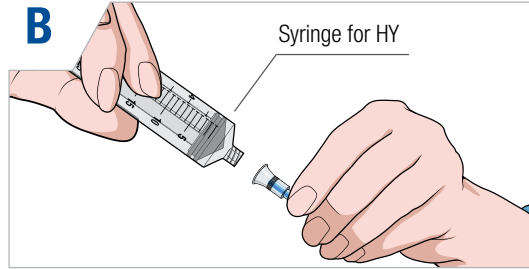
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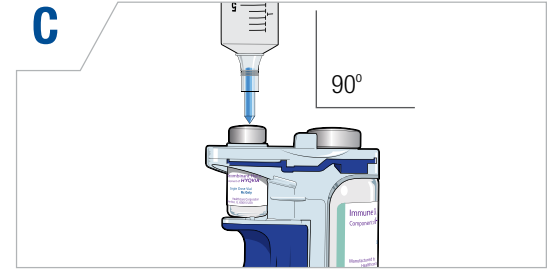
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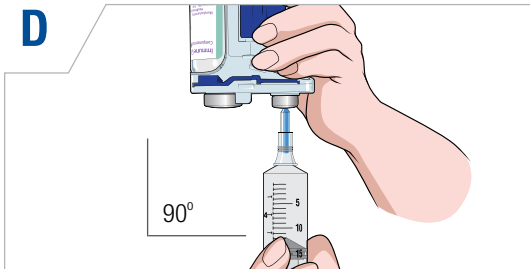
Take the cap off of the dual-vial unit(s). Without shaking the vials, clean each vial of HY by wiping the stopper with an alcohol swab and let it dry.



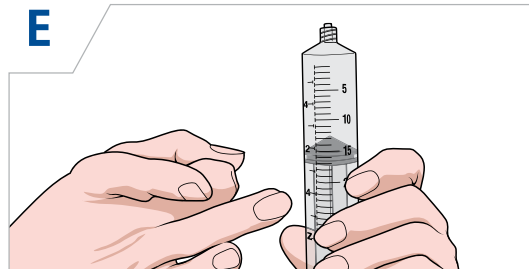
Remove a sterile syringe from the package. Attach a needle/needle-less transfer device* to the syringe. Pull back on the plunger to fill the syringe with air (the amount of air should equal the amount of HY in the vial). Remove the cap from the needle/needle-less transfer device.



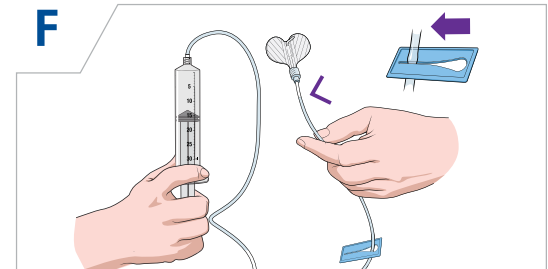
Insert the needle/needle-less transfer device into the center of the HY vial stopper at a 90-degree angle. Push the air into the vial.



Turn the vial upside down. Pull back on the plunger to withdraw the full amount of HY. Remove the needle/needle-less transfer device from the HY vial. Re-cap the needle/needle-less transfer device.[†] Remove it from the HY syringe and discard it in the sharps container. Repeat steps C and D for each HY vial, using the same syringe, if possible.



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



Remove the cap from the subcutaneous needle set. Attach the needle set to the HY syringe. *Slowly* push the plunger to fill the needle set. Stop when the HY reaches the needle hub. Lay the syringe down on the clean work surface. Clamp the needle set tubing.

*Use an 18-22 gauge sterile needle to draw from the 1.25 mL vial of HY.

[†]Re-cap the needle/needle-less transfer device with a one-handed scooping technique as demonstrated by your healthcare professional.

You're ready for **Stage 3!** >>>

3 PREPARE IG

4 INFUSE HYQVIA

5 FINISH UP

2 PREPARE HY

STAGE 3

Prepare the IG

- Transfer IG into pooling bag
- Attach pump tubing to pooling bag

Important Safety Information (continued)

Before starting HYQVIA, tell your healthcare professional if you:

- Have or had any kidney, liver, or heart problems or history of blood clots because HYQVIA can make these problems worse.
- Have IgA deficiency or a history of severe allergic reactions to IgG or other blood products.
- Are pregnant, trying to become pregnant or are breast feeding.

Please scroll for additional Important Safety Information, and click for [Information for Patients](#), including Warning about Blood Clots, and discuss with your healthcare provider.

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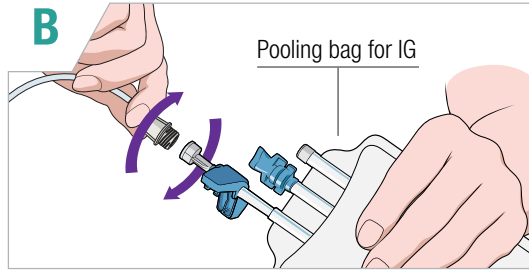
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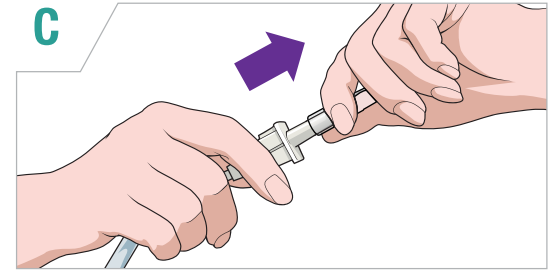
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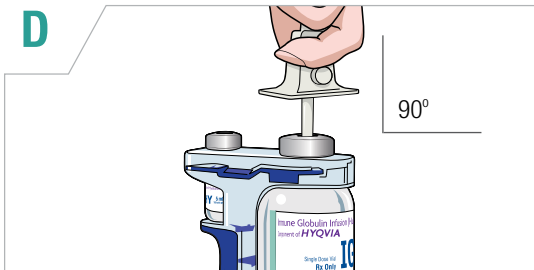
Without shaking the vials, clean each vial of IG you will use by wiping the stopper with an alcohol swab and let it dry.



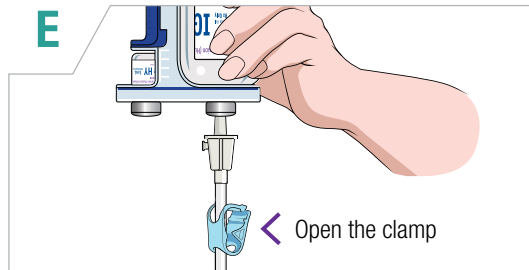
Remove the caps on the gravity fill set and the fill port of the pooling bag. Twist the gravity fill set onto the fill port of the pooling bag. Close the clamp on the gravity fill set tubing.



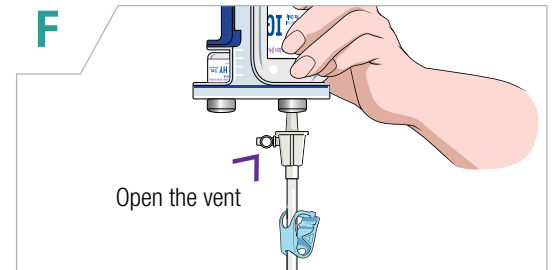
Remove the cap from the spike on the gravity fill set.



Insert the spike straight down into the center of the IG vial stopper at a 90-degree angle. The tip of the spike should be all the way inside the stopper.



Turn the IG vial upside down. Unclamp the gravity fill set tubing.



Continue to hold the IG vial upside down. Open the vent on the spike to transfer the IG into the pooling bag. You may need to tap the gravity fill set to float air bubbles to the top of the vial.

STAGE 3 CONTINUED

4 INFUSE HYQVIA

5 FINISH UP

3 PREPARE IG

STAGE 3

Prepare the IG (*continued*)

- Transfer IG into pooling bag
- Attach pump tubing to pooling bag

Important Safety Information

What is the most important information that I should know about HYQVIA?

- HYQVIA can cause blood clots.
- Call your healthcare professional if you have pain, swelling, warmth, redness, or a lump in your legs or arms, other than at the infusion site(s), unexplained shortness of breath, chest pain or discomfort that worsens on deep breathing, unexplained rapid pulse, numbness or weakness on one side of the body.
- Your healthcare professional may perform blood tests regularly to check your IgG level.
- With your consent, your healthcare professional may provide blood samples to Shire plc, to test for antibodies that may form against the hyaluronidase part of HYQVIA.
- Do not infuse HYQVIA into or around an infected or red swollen area because it can cause infection to spread.
- Talk to your healthcare professional if you become pregnant. Women who become pregnant during HYQVIA treatment are encouraged to enroll in the HYQVIA Pregnancy Registry by calling Medical Information at 1-866-424-6724.

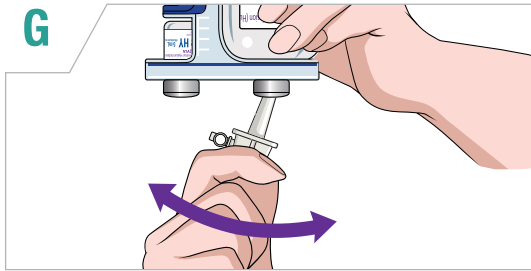
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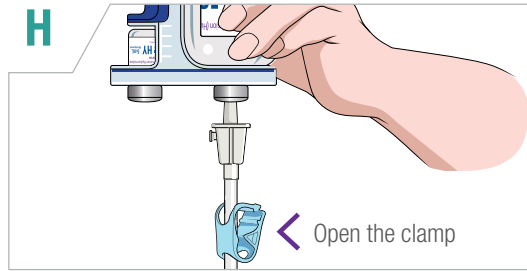
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Gently wiggle the spike back and forth to make sure you transfer all the IG. Close the clamp and the vent on the gravity fill set tubing. Remove the spike from the IG vial. Repeat steps D through G for each additional IG vial needed to infuse your prescribed dose.

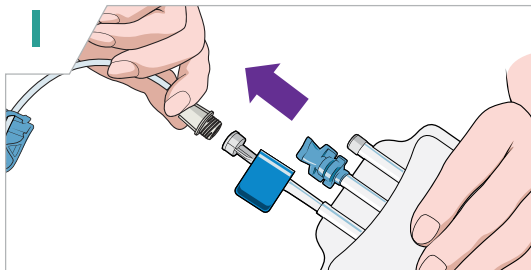


When you finish with the last vial, hold the gravity fill set tubing upright. Open the clamp and tap the gravity fill set tubing to get the last drops of IG into the pooling bag. Re-cap the spike.

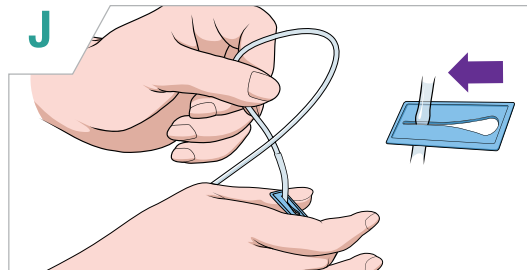
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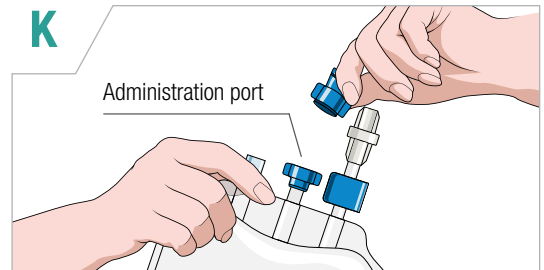
If you want to remove the air from the bag, gently push air out of the pooling bag through the fill port.



Close the clamp on the fill port and detach the gravity fill set from the pooling bag. Re-cap the end of the fill port.



Then, with the pump tubing, use two hands to close the clamp on the pump tubing.



Remove the cap from the administration port on the pooling bag.

STAGE 3 CONTINUED

STAGE 3

Prepare the IG (*continued*)

- Transfer IG into pooling bag
- Attach pump tubing to pooling bag



Important Safety Information (continued)

Who should not take HYQVIA?

Do not take HYQVIA if you:

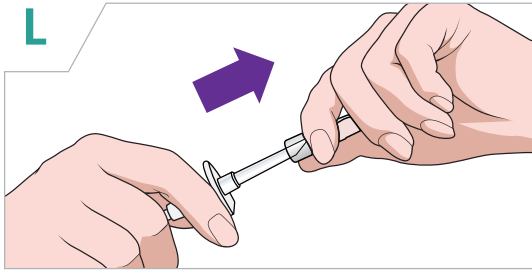
- Are allergic to IgG, hyaluronidase, other blood products, or human albumin (in the hyaluronidase solution).
- Have IgA deficiency with antibodies to IgA.

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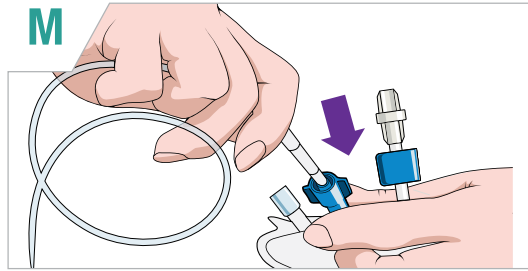
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Remove the cap from the spike on the pump tubing. Set down the cap, but continue to hold the spike.



Insert the spike into the administration port on the pooling bag.



Insert the pump tubing into the pump and fill the pump tubing per the pump manufacturer's guide.

You're ready for **Stage 4!** >>>

3 PREPARE IG

4 INFUSE HYQVIA

5 FINISH UP

STAGE 4

Infuse HYQVIA

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

Important Safety Information (continued)

HYQVIA can cause serious side effects. Call your healthcare professional or go to your emergency department right away if you get:

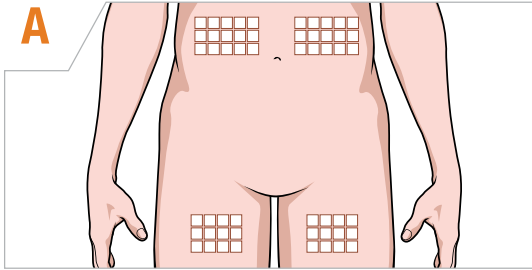
- Hives, swelling in the mouth or throat, itching, trouble breathing, wheezing, fainting or dizziness. These could be signs of a serious allergic reaction.
- Bad headache with nausea, vomiting, stiff neck, fever, and sensitivity to light. These could be signs of swelling in your brain.
- Reduced urination, sudden weight gain, or swelling in your legs. These could be signs of a kidney problem.
- Pain, swelling, warmth, redness, or a lump in your legs or arms, other than at the infusion site(s). These could be signs of a blood clot.
- Brown or red urine, fast heart rate, yellow skin or eyes. These could be signs of a liver or blood problem.
- Chest pain or trouble breathing, blue lips or extremities. These could be signs of a lung problem.

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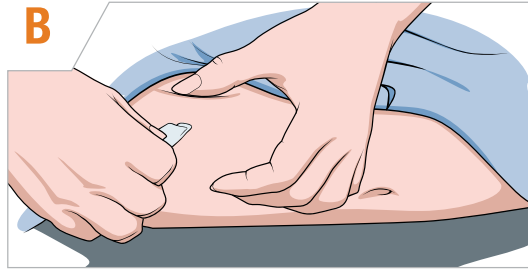
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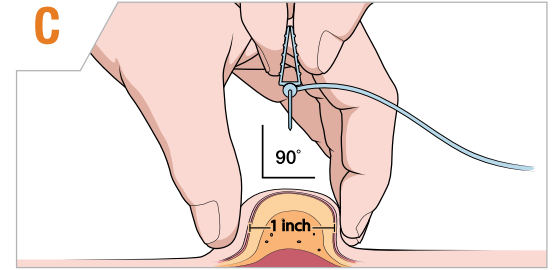
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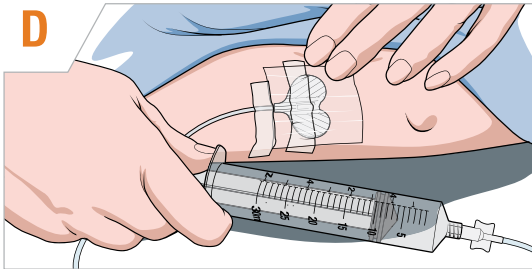
Choose an infusion site (or sites) in either the middle or upper abdomen or thigh. Avoid bony areas, visible blood vessels, scars, and any areas of inflammation, irritation, or infection. Rotate your sites by choosing opposite sides of the body for each infusion.



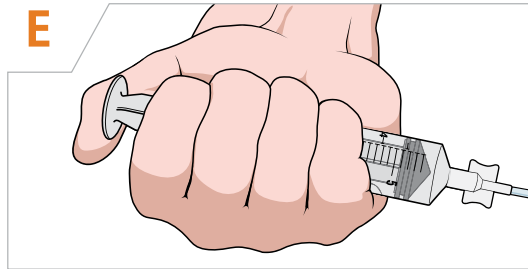
Wash your hands with antibacterial soap. Wipe each infusion site with a sterile alcohol wipe (beginning at the center of the site and moving outward in a circular motion) and let dry (at least 30 seconds).



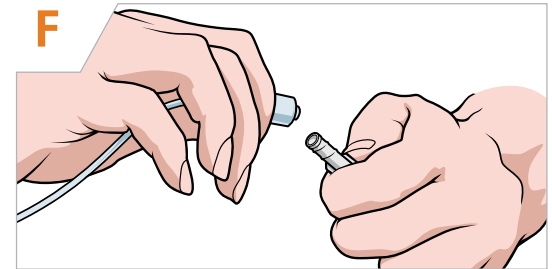
Remove the subcutaneous needle cover. Firmly grasp and pinch at least 1 inch of skin. Insert the needle with a rapid motion straight into the skin at a 90-degree angle. Secure the needle in place with sterile tape. Repeat this step for additional infusion sites.



Check for proper needle placement. Open the clamp on the needle set and gently pull back on the syringe plunger. Make sure there is no blood in the tubing. Secure the needle set in place by applying a clear dressing over the site. If blood is seen in the tubing, remove and discard the subcutaneous needle and repeat steps 2A-2F and 4A-4C with a new needle and infusion site.



Administer the HY at a rate of 1 to 2 mL per minute per infusion site. (For example, infusing 15 mL of HY should take about 7.5 to 15 minutes for a 30 gram HYQVIA dose). Divide the contents equally between sites, if more than one site is used. **REMEMBER: HY before IG.**



When all the HY has been infused, remove the empty syringe from the needle set, but do not remove the subcutaneous needle(s) from your infusion site(s). Attach the pump tubing to the same needle set. Open the clamp on the pump tubing.

STAGE 4 CONTINUED

5 FINISH UP

4 INFUSE HYQVIA

STAGE 4

Infuse HYQVIA (continued)

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

Important Safety Information (continued)

What are the possible or reasonably likely side effects of HYQVIA?

- After HYQVIA infusion a temporary, soft swelling may occur around the infusion site, which may last 1 to 3 days, due to the volume of fluid infused. Mild or moderate pain, redness, swelling, or itching may occur at the site of infusion and generally go away in a few hours. Local reactions are less likely after the first few infusions.
- The most common side effects of HYQVIA are headache, fatigue, nausea, fever, and vomiting.
- Antibodies to the hyaluronidase component of HYQVIA were formed in some patients taking HYQVIA. It is not known if there is any long term effect. In theory, these antibodies could react with your body's own PH20. PH20 is present in the male reproductive tract. So far, these antibodies have not been associated with increased or new side effects.

These are not all the possible side effects with HYQVIA. Talk to your healthcare professional about any side effects that bother you or that don't go away.

Please scroll for additional Important Safety Information, and click for [Information for Patients](#), including [Warning about Blood Clots](#), and discuss with your healthcare provider.

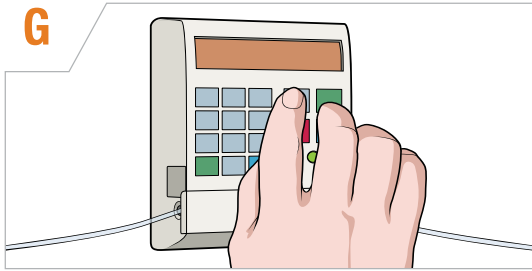
HyQvia

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HyQvia

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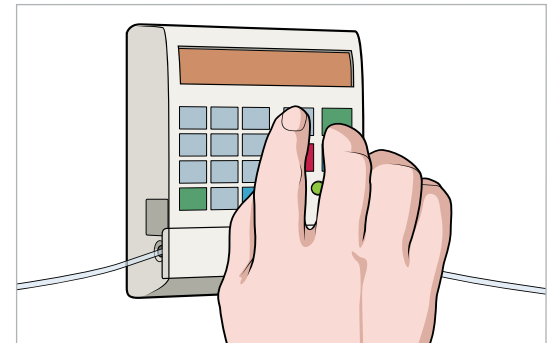
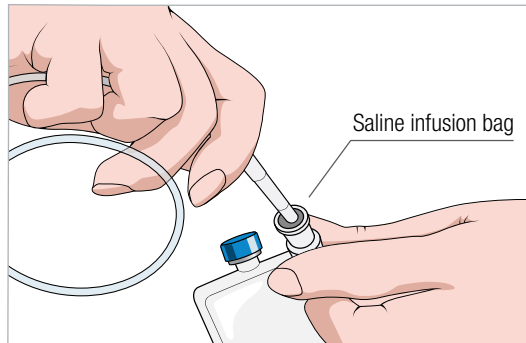
G



Start the pump to infuse the IG at the rates prescribed by your healthcare professional. Start the IG infusion **right after** the HY infusion is complete (within approximately 10 minutes).

If recommended by your healthcare professional OPTIONAL: SALINE FLUSH

- When the IG infusion is complete, remove the pump tubing spike from the pooling bag administration port.
- Pull the tab off the saline bag administration port.
- Insert the pump tubing spike into the administration port.
- Restart the pump to flush the remaining IG from the pump tubing at the rate prescribed by your healthcare professional.



You're almost done! >>>

4 INFUSE HYQVIA

5 FINISH UP

STAGE 5

Finish Up

- Remove needle(s)
- Log infusion

Important Safety Information (continued)

Before starting HYQVIA, tell your healthcare professional if you:

- Have or had any kidney, liver, or heart problems or history of blood clots because HYQVIA can make these problems worse.
- Have IgA deficiency or a history of severe allergic reactions to IgG or other blood products.
- Are pregnant, trying to become pregnant or are breast feeding.

You are encouraged to report suspected side effects by contacting FDA at 1-800-FDA-1088 or www.fda.gov/medwatch or Shire Drug Safety at 1-800-999-1785.

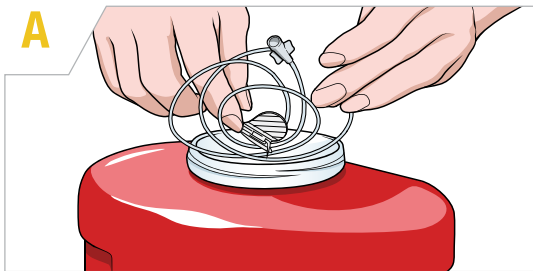
Please scroll for additional Important Safety Information, and click for [Information for Patients](#), including [Warning about Blood Clots](#), and discuss with your healthcare provider.

HyQvia

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HyQvia

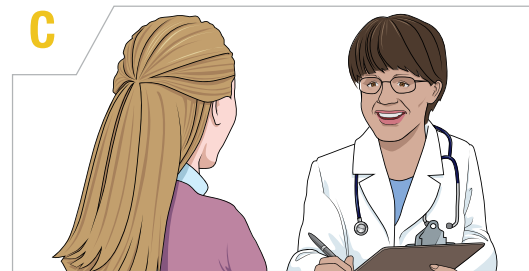
[Immune Globulin Infusion 10% (Human)
with Recombinant Human Hyaluronidase]



Loosen the clear dressing and pull the subcutaneous needle wings straight up and out. Place a bandage over the site. Dispose of the needle set in the sharps container. Check with your specialty pharmacy to learn how to dispose of your sharps container.



Record the infusion details as instructed by your healthcare professional and as outlined in your infusion log.



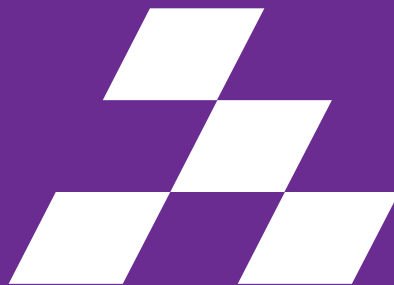
Follow up with your healthcare professional as directed.



Congratulations!

Your infusion with **HYQVIA**
[Immune Globulin Infusion 10% (Human) with
Recombinant Human Hyaluronidase] Solution is complete!

If you have any questions about infusing HYQVIA, contact a Nurse Advocate at 1-855-250-5111 or your healthcare provider, or visit www.HYQVIA.com



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WHAT IT LOOKS LIKE WHEN YOU INFUSE HYQVIA

What to expect

Pre-Infusion



HYQVIA Infused: 500 mL

Post-Infusion



24 Hours After Infusion



Following your infusion with HYQVIA [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase] Solution, it's common to experience a temporary soft swelling at the infusion site. This is due to the volume of fluid infused and may last 1 to 3 days after your infusion. The volume you'll infuse will be based on your doctor's guidance and your specific clinical condition; it may be different from the volumes shown here.



HYQVIA Infused: 235 mL



Mild local site reactions

Local infusion-site reactions such as mild or moderate pain, swelling, redness, and itching may also occur and generally go away within a few hours. Local reactions are less likely to occur after the first few infusions.

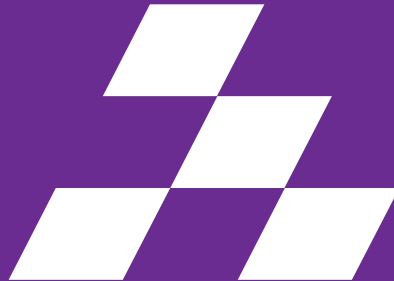
Pre-Infusion



Post-Infusion



HYQVIA Infused: 494 mL



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What to Do If You Experience a Local Reaction

After HYQVIA infusion a temporary, soft swelling may occur around the infusion site, which may last 1 to 3 days, due to the volume of fluid infused. Mild or moderate pain, redness, swelling, or itching may occur at the site of infusion and generally go away in a few hours. Local reactions are less likely after the first few infusions. Contact your healthcare professional if a local site reaction increases in severity or persists for more than a few days.^{1,2}

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

- Remove the needle because it may be in your muscle.³
- 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 specialty pharmacy about changing the length of your needle; it may be too long for you.²
- Note in your infusion log that this site may not work for you.

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

- Slow or stop the infusion.³
- Place a clean, warm or cold compress (post-infusion) as directed by your healthcare provider on your irritated site.^{2,3}
- Talk to your healthcare professional about a possible allergy to your tape or dressing or the possible use of a mild pain reliever, if recommended.^{2,3}

Itching or rash at or around the infusion site

- Place a clean, cold compress as directed by your healthcare professional, on your itchy site. Do not apply cold pack directly to skin.³
- When priming the subcutaneous needle, avoid coating the needle with drops of HYQVIA [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase] Solution.^{2,3}
- Talk to your healthcare professional about the possible use of an over-the-counter antihistamine, if recommended.³
- If you experience hives, swelling in the mouth or throat, itching, trouble breathing, wheezing, fainting or dizziness, stop your infusion immediately and contact your healthcare professional or emergency services; these could be signs of a serious allergic reaction.³

What to Do If You Experience a General (Systemic) Reaction

In addition to local reactions, the most common side effects of HYQVIA are headache, fatigue, nausea, fever, and vomiting.¹

Call your healthcare professional or go to your emergency department right away if you get:

- Bad headache with nausea, vomiting, stiff neck, fever, and sensitivity to light. These could be signs of swelling in your brain.
- Reduced urination, sudden weight gain, or swelling in your legs. These could be signs of a kidney problem.
- Pain, swelling, warmth, redness, or a lump in your legs or arms, other than at the infusion site(s). These could be signs of a blood clot.
- Brown or red urine, fast heart rate, yellow skin or eyes. These could be signs of a liver or blood problem.
- Chest pain or trouble breathing, blue lips or extremities. These could be signs of a lung problem.

Talk to your healthcare professional about any side effects that bother you or that don't go away.¹

Whenever giving yourself treatments at home, consider having another responsible person present to help treat side effects or get help if a serious adverse reaction occurs. Ask your healthcare professional whether you should have rescue medications, such as antihistamines or epinephrine available.³

References: **1.** HYQVIA [Prescribing Information]. Westlake Village, CA: Baxalta US Inc. **2.** Murphy E, Burton J, Riley P. Nursing approaches to a novel subcutaneous therapy: a look at 4 patients during transition from IVIg to SCIg. *Infusion*. 2007;13(4)(suppl):1-8. **3.** Younger MEM, ed. *IDF Guide for Nurses on Immune Globulin Therapy for Primary Immunodeficiency Diseases*. 3rd ed. Towson, MD: Immune Deficiency Foundation; 2012.


[Immune Globulin Infusion 10% (Human)
with Recombinant Human Hyaluronidase]



[Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase]

What is HYQVIA?

- HYQVIA is a liquid medicine containing immune globulin and Recombinant Human Hyaluronidase. HYQVIA contains IgG antibodies, collected from human plasma donated by healthy people. The antibodies help your body to fight off bacterial and viral infections. The hyaluronidase part of HYQVIA helps more of the immune globulin get absorbed into the body to fight infection.
- HYQVIA is indicated for the treatment of Primary Immunodeficiency (PI) involving the humoral immune system in adults.
- Safety and efficacy of chronic use of Recombinant Human Hyaluronidase in HYQVIA have not been established in conditions other than PI.
- HYQVIA is infused under the skin (subcutaneous).
- If you and your healthcare professional decide that home self-infusion of HYQVIA is right for you, then be sure you get instructions and training from your healthcare professional before using HYQVIA at home.

Important Safety Information

What is the most important information that I should know about HYQVIA?

- **HYQVIA can cause blood clots.**
- **Call your healthcare professional if you have pain, swelling, warmth, redness, or a lump in your legs or arms, other than at the infusion site(s), unexplained shortness of breath, chest pain or discomfort that worsens on deep breathing, unexplained rapid pulse, numbness or weakness on one side of the body.**
- Your healthcare professional may perform blood tests regularly to check your IgG level.
- With your consent, your healthcare professional may provide blood samples to Shire plc, to test for antibodies that may form against the hyaluronidase part of HYQVIA.
- Do not infuse HYQVIA into or around an infected or red swollen area because it can cause infection to spread.
- Talk to your healthcare professional if you become pregnant. Women who become pregnant during HYQVIA treatment are encouraged to enroll in the HYQVIA Pregnancy Registry by calling Medical Information at 1-866-424-6724.

Who should not take HYQVIA?

Do not take HYQVIA if you:

- Are allergic to IgG, hyaluronidase, other blood products, or human albumin (in the hyaluronidase solution).
- Have IgA deficiency with antibodies to IgA.

Please scroll for additional Important Safety Information, and click for [Information for Patients](#), and discuss with your healthcare provider.



[Immune Globulin Infusion 10% (Human)
with Recombinant Human Hyaluronidase]

Important Safety Information (continued)

HYQVIA can cause serious side effects. Call your healthcare professional or go to your emergency department right away if you get:

- Hives, swelling in the mouth or throat, itching, trouble breathing, wheezing, fainting or dizziness. These could be signs of a serious allergic reaction.
- Bad headache with nausea, vomiting, stiff neck, fever, and sensitivity to light. These could be signs of swelling in your brain.
- Reduced urination, sudden weight gain, or swelling in your legs. These could be signs of a kidney problem.
- Pain, swelling, warmth, redness, or a lump in your legs or arms, other than at the infusion site(s). These could be signs of a blood clot.
- Brown or red urine, fast heart rate, yellow skin or eyes. These could be signs of a liver or blood problem.
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What are the possible or reasonably likely side effects of HYQVIA?

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You are encouraged to report suspected side effects by contacting FDA at 1-800-FDA-1088 or www.fda.gov/medwatch or Shire Drug Safety at 1-800-999-1785.

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