



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

## Here's what you can expect when starting on HYQVIA<sup>1</sup>

Infusing HYQVIA [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase] may be different than what you're used to. If you and your doctor decide that self-administration at home is right for you, you will receive instruction from your infusion provider during the ramp-up period but will not begin self-administration until you feel comfortable enough to infuse on your own.

You'll also be provided with a training kit that will include the tools you'll need to infuse at home after adequate training. If you haven't received your HYQVIA Training Kit, please call **1-855-250-5111**.

### The ramp-up period<sup>1</sup>

To help you become comfortable with your treatment, you will receive the first dose of HYQVIA and will ramp up gradually. Your dose will eventually shift from 1 time a week to 1 time a month (every 3 to 4 weeks). Here is a typical schedule for starting HYQVIA regardless of whether you're new or switching from another Ig treatment.

Dose adjustment of HYQVIA [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase] may be necessary based on your clinical response.

**7 week HYQVIA ramp-up period for a 4-week treatment interval. Begins approximately 1 week after your last subQ Ig or IV Ig dose**

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Week 1					Infusion		
Week 2					Infusion		
Week 3							
Week 4					Infusion		
Week 5							
Week 6							
Week 7					Infusion		

**After Week 7, your HYQVIA personalized maintenance treatment schedule begins**

Ig = immune globulin, subQ = subcutaneous, IV = intravenous

Please see the Indication and Important Safety Information on page 2, and the [FDA-approved patient labeling](#).



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

### Indication and Important Safety Information

#### 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.

**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.

#### 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.**

**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](http://www.fda.gov/medwatch) or Shire Drug Safety at 1-800-999-1785.**

**The risk information provided here is not comprehensive. To learn more, talk about HYQVIA with your healthcare provider or pharmacist. Please click here for the [FDA-approved patient labeling](#), also available at [www.HYQVIA.com](http://www.HYQVIA.com).**

#### References

1. HYQVIA [prescribing information]. Westlake Village, CA: Baxalta US Inc.