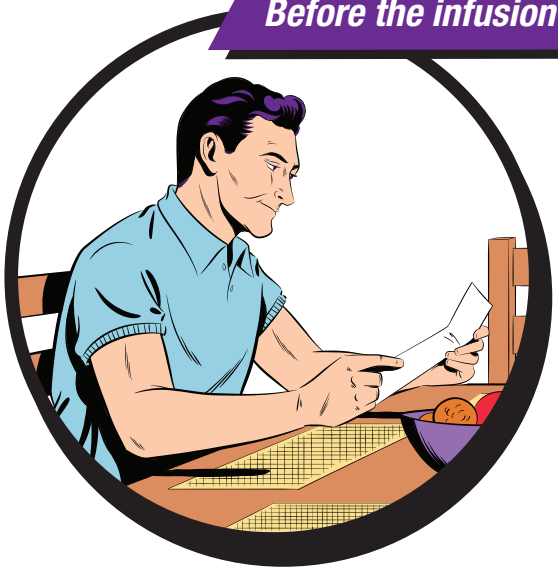
HyQvia

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

What you should know about self-infusing with HYQVIA[1]

Before the infusion



- Make sure you have received appropriate training from your healthcare professional on how to self-infuse HYQVIA [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase] and always follow his/her instructions, especially regarding the dose and schedule
- Ensure you're hydrated by drinking plenty of fluids before you infuse
- Choose a less busy day and plan ahead to avoid disruptions while infusing
- Set up your supplies in a clean area and carefully read the instructions provided to you
- Allow HYQVIA to reach room temperature (this may take up to 60 minutes)
- HYQVIA can be held at room temperature (up to 77°F [25°C]) for up to 3 months.* Be sure to keep it in the box to protect it from light

*During the first 24 months from the date of manufacturing.

Please see the Indication and Detailed Important Risk Information on back, and the Full Prescribing Information and Patient Product Information, including Boxed Warning.

During the infusion

- Get comfortable and try to relax during your infusion
- Local infusion-site reactions such as mild to moderate pain, temporary soft pancake-like swelling, itching, and skin redness are common with HYQVIA [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase]
  - » Flat, pancake-like swelling may last 1 to 3 days
  - » Other infusion-site reactions generally go away within a few hours
- In addition to local reactions, most common side effects may include headache, fatigue, nausea, fever, and vomiting
- If side effects increase in severity or persist for more than a few days, call your physician or hospital emergency services immediately
- Never infuse HYQVIA into or around an infected or red swollen area

After the infusion

- Continue drinking fluids to remain hydrated
- Record your infusion time, date, dose, infusion-site location, and any reactions you may experience in your infusion log
- Make sure to follow up with your physician routinely

Selected Important Risk Information

Before starting HYQVIA, tell your healthcare professional if you have or had any kidney, liver, or heart problems, a history of blood clots, are dehydrated, have any bruising, inflammation, irritation or infection of the skin, have IgA deficiency or a history of severe allergic reactions to IgG or other blood products, or are pregnant, trying to become pregnant or are breast feeding. Do not use HYQVIA if you have had a severe allergic reaction to IgG or other blood products, have had a severe allergic reaction to hyaluronidase, or have IgA deficiency with antibodies to IgA.

You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Women who become pregnant during HYQVIA treatment are encouraged to enroll in the HYQVIA Pregnancy Registry by calling 1-866-424-6724.

HyQvia

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

Important Risk Information

Indication and Usage

HYQVIA is an immune globulin with a recombinant human hyaluronidase indicated for the treatment of Primary Immunodeficiency (PI) in adults. This includes, but is not limited to, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Limitation of Use:
Safety and efficacy of chronic use of recombinant human hyaluronidase in HYQVIA have not been established in conditions other than PI.

Detailed Important Risk Information

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.

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.

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 Baxalta US Inc. 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.

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.

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.

Before starting HYQVIA, tell your healthcare professional if you have or had any kidney, liver, or heart problems, a history of blood clots, because HYQVIA can make these problems worse. Also tell your doctor if you have IgA deficiency or a history of severe allergic reactions to immune globulin (IgG) or other blood products, or are pregnant, trying to become pregnant or are breast feeding.

How should I take HYQVIA?

HYQVIA is infused under the skin (subcutaneously) up to once every 4 weeks. You can get HYQVIA at your healthcare professional's office, clinic, or hospital. You can use HYQVIA at home. You and your healthcare professional will decide if home self-infusion is right for you. Do not use HYQVIA at home until you get instructions and training from your healthcare professional.

Who should not take HYQVIA?

Do not take HYQVIA if you are allergic to IgG, hyaluronidase, or other blood products, or have IgA deficiency with antibodies to IgA.

Please see the accompanying Full Prescribing Information and Patient Product Information, including Boxed Warning.

To report suspected side effects, contact Baxalta US Inc. at 1-800-999-1785 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

References

1. HYQVIA [package insert]. Westlake Village, CA: Baxter Healthcare Corporation. September 2014

Baxalta

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