Self-Administration of HYQVIA [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase]

Administration Method:  □ Peristaltic infusion pump  □ Syringe driver pump

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<th>Infusion Number</th>
<th>Infusion Date</th>
<th>Name of Healthcare Professional</th>
<th>Site of Care</th>
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Complete the following checklists to document patient/caregiver competency in administering HYQVIA [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase]. The checklist is meant to aid in evaluation and is not to be used as a training tool. For the first 4 infusions, use the following ranking system to indicate the patient/caregiver level of knowledge and proficiency for each checklist item.

A. Proficient—highly skilled, very confident, no supervision necessary
B. Competent—correct, somewhat confident, indirect supervision necessary
C. Advanced Beginner—slow but accurate, starting to feel confident, continual supervision still required
D. Novice—uncomfortable, lacking in confidence, continual supervision and coaching required

After each infusion, use the drop down menus to select A, B, C, or D in the appropriate box below.

Knowledge/Skill | Infusion Number | Notes
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General Knowledge

Able to accurately describe the method of administering (eg, required supplies, 5 main steps, HY before IG, and order and timing of infusing the components)

Demonstrates awareness of preparation and handling instructions (eg, not mixing HYQVIA components together)

Receiving and Storing Supplies

Can state important considerations when receiving deliveries of medication and supplies (eg, tracking delivery dates, inspecting vials, and proper storage)

Please see the Full Prescribing Information, including Boxed Warning regarding Thrombosis, at www.HYQVIA.com.

[Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase]
STEP 4: INFUSE HYQVIA
Properly prepares the infusion site(s), inserts and secures the subcutaneous needle(s)
Properly confirms needle placement
Correctly infuses the HY first and then detaches the HY syringe from the needle set
To infuse the IG, properly attaches the same needle set to the pump tubing (if peristaltic infusion pump method) or to the IG syringe(s) (if syringe driver pump method)
Properly infuses the IG using the infusion pump

STEP 5: FINISH UP
Peristaltic infusion pump only: Properly uses saline infusion bag to flush the IG (if instructed to do so)*
Properly turns off the pump, removes the subcutaneous needle(s), and places a bandage over the infusion site(s)
Appropriately disposes of all supplies
Accurately records the infusion details in the infusion log

*If not applicable, record NA.

The undersigned acknowledge that the patient/caregiver has received suitable instruction from a healthcare professional regarding the HYQVIA [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase] infusion procedure and hereby confirm that the patient/caregiver is capable of performing infusions independently without direct supervision.

Patient/Caregiver ____________________________________________ Date ____________

Healthcare Professional _________________________________________ Date ____________

[Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase]
Indication and Important Safety Information

Indication and Usage
HYQVIA is an immune globulin with a Recombinant Human Hyaluronidase indicated for the treatment of primary humoral immunodeficiency (PI) in adults.

Limitation of Use:
Safety and efficacy of chronic use of Recombinant Human Hyaluronidase in HYQVIA have not been established in conditions other than PI.

HYQVIA is for subcutaneous use only.

Important Safety Information

BOXED WARNING: THROMBOSIS
Thrombosis may occur with immune globulin products, including HYQVIA. Risk factors may include advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors. For patients at risk of thrombosis, administer HYQVIA at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk of hyperviscosity.

CONTRAINDICATIONS
HYQVIA is contraindicated: in patients who have a history of anaphylactic or severe systemic hypersensitivity reactions to Human Immune Globulin (IgG); in IgA-deficient patients with antibodies against IgA and a history of hypersensitivity; in patients with known systemic hypersensitivity to hyaluronidase including Recombinant Human Hyaluronidase of HYQVIA; and in patients with known systemic hypersensitivity to human albumin (in the hyaluronidase solution).

WARNINGS and PRECAUTIONS

Hypersensitivity: Severe hypersensitivity reactions may occur, even in patients who have tolerated previous treatment with IgG. IgA-deficient patients with antibodies to IgA are at greater risk of developing potentially severe hypersensitivity and anaphylactic reactions.

Immunogenicity of Recombinant Human Hyaluronidase (rHuPH20): Non-neutralizing antibodies to the Recombinant Human Hyaluronidase component can develop. The potential exists for such antibodies to cross-react with endogenous PH20, which is known to be expressed in adult male testes, epididymis, and sperm. The clinical significance of these antibodies or whether they interfere with fertilization in humans is unknown.

Aseptic Meningitis Syndrome (AMS): Monitor for clinical signs and symptoms of AMS.

Hemolysis: Monitor for clinical signs and symptoms of hemolysis and delayed hemolytic anemia.

Renal Dysfunction/Failure: Monitor renal function and urine output and consider lower, more frequent dosing in patients who are at risk of developing renal dysfunction because of pre-existing renal insufficiency or predisposition to acute renal failure.

Spread of Localized Infection: Do not infuse HYQVIA into or around an infected area due to potential risk of spreading a localized infection.

Transfusion-Related Acute Lung Injury (TRALI): Monitor for pulmonary adverse reactions associated with TRALI.

Transmittable Infectious Agents: Because the Immune Globulin Infusion 10% (Human) of HYQVIA is made from human plasma, it may carry a risk of transmitting infectious agents, such as viruses and other pathogens. No cases of transmission of viral diseases or variant Creutzfeldt-Jakob disease (vCJD) have been associated with HYQVIA.

Interference with Laboratory Tests: False positive serological test results, with the potential for misleading interpretation, can occur as the result of passively transferred antibodies.

ADVERSE REACTIONS
The most common adverse reactions observed in > 5% of patients in the clinical trials were: local adverse reactions, headache, antibody formation against Recombinant Human Hyaluronidase (rHuPH20), fatigue, nausea, pyrexia, and vomiting.

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