HyQvia

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

Looking for an alternative to IVIG with similar frequency?

Consider HYQVIA, the only once-a-month* subcutaneous IG (SCIG) therapy that can be administered in-center

Subcutaneous administration does not require venous access

IVIG=intravenous immune globulin.
*Every 3 or 4 weeks.

INDICATION AND LIMITATION OF USE

HYQVIA® [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase] Solution is indicated for the treatment of primary immunodeficiency (PI) in adults. HYQVIA is for subcutaneous use only. Safety and efficacy of chronic use of Recombinant Human Hyaluronidase in HYQVIA have not been established in conditions other than PI.

IMPORTANT SAFETY INFORMATION

WARNING: THROMBOSIS

- **Thrombosis may occur with immune globulin (IG) 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.**

Please see additional Important Safety Information throughout and click here for Full Prescribing Information.

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

**Infuse monthly.*[1]
Live daily.**

*Every 3 or 4 weeks.

For your IVIG patients, could a change in route of administration help improve their infusion experience?

With HYQVIA, monthly* dosing doesn't have to mean longer infusion times[1]

Up to
28 days
between infusions

~2 hour infusion time
Median infusion time was 2.08 h (0.83-4.68 h) in the clinical trial

Low rates of systemic adverse reactions (ARs) vs IVIG[1]

- 52% lower rates of systemic ARs with HYQVIA (0.20 per infusion, n=1129) vs IVIG (0.42 per infusion, n=365)
- ~99% of local ARs with HYQVIA were considered mild to moderate (observed at a rate of 0.21 per infusion)
- The most common ARs observed (in >5% of patients) were local ARs including pain, erythema, edema, and pruritus, and systemic ARs including headache, antibody formation against rHuPH20,† fatigue, nausea, pyrexia, and vomiting

Reliable protection against infection[1]

HYQVIA delivers reliable infection protection and steady-state Ig levels between infusions

- There were 0.025 ASBIs per patient-year with HYQVIA (upper 99% CL, 0.046, $P<0.0001$), significantly <1 ASBI per patient-year, in the clinical trial‡

The only once-a-month* SCIG that helps patients maximize time between infusions—whether infused in a center or at home[1]

*Every 3 or 4 weeks.
†Recombinant Human Hyaluronidase.
‡A prospective, open-label, non-controlled, multicenter clinical trial conducted to determine the efficacy, tolerability, and pharmacokinetics of HYQVIA in 83 patients with PI. The primary efficacy endpoint was the annualized rate of acute serious bacterial infections (ASBIs) per patient-year, measured over a median treatment duration of 366 days (range, 42-507 days).

IMPORTANT SAFETY INFORMATION (continued)

Contraindications

- History of anaphylactic or severe systemic hypersensitivity reactions to human IG
- IgA-deficient patients with antibodies to IgA and a history of hypersensitivity to human IG
- Known systemic hypersensitivity to hyaluronidase including Recombinant Human Hyaluronidase of HYQVIA
- Known systemic hypersensitivity to human albumin (in the hyaluronidase solution)

Please see additional Important Safety Information throughout, and click here for Full Prescribing Information, including Boxed Warning regarding Thrombosis.

OnePath® is here for your primary immunodeficiency (PI) patients and their caregivers, every step of the way

OnePath offers personalized, dedicated assistance to eligible* PI patients prescribed a Takeda product. This support includes:

- Facilitating an insurance benefits investigation
- Working with various sites of care (eg, hospital-owned specialty pharmacies/ home care, infusion centers) to coordinate treatment access for PI patients
- Directing PI patients and caregivers to educational resources available to them
- Arranging for PI patients and/or their caregivers to receive free, in-home, self-administration training with a specially trained nurse (if applicable)
- Enrolling eligible PI patients in the OnePath Co-Pay Assistance Program or providing information about additional financial assistance options

OnePath offers co-pay assistance to eligible PI patients

Up to 100% of qualified co-pay expenses may be covered*†

For eligible commercially insured OnePath PI patients, our co-pay assistance program covers out-of-pocket expenses related to treatment for which there is a co-pay such as deductibles, coinsurance, and certain infusion charges (if applicable), up to the program maximum.

Patient Support Managers are ready to assist your patients.

Patient Support Managers are available Monday through Friday, 8:30 AM to 8:00 PM ET. Call 1-866-888-0660 for more information or visit OnePath.com.

*At a minimum to be eligible, patients must be enrolled in OnePath and have commercial insurance. Other terms and conditions apply. Contact OnePath for more information.

†IMPORTANT NOTICE: The OnePath Co-pay Assistance Program (the Program) is not valid for prescriptions eligible to be reimbursed, in whole or in part, by Medicaid, Medicare (including Medicare Part D), Tricare, Medigap, VA, DoD, or other federal or state programs (including any medical or state prescription drug assistance programs). No claim for reimbursement of the out-of-pocket expense amount covered by the Program shall be submitted to any third party payer, whether public or private. The Program cannot be combined with any other rebate/coupon, free trial, or similar offer. Co-payment assistance under the Program is not transferable. The Program only applies in the United States, including Puerto Rico and other U.S. territories, and does not apply where prohibited by law, taxed, or restricted. This does not constitute health insurance. Void where use is prohibited by your insurance provider. If your insurance situation changes you must notify the Program immediately at 1-866-888-0660. Coverage of certain administration charges does not apply for patients residing in Massachusetts, Michigan, Minnesota, Rhode Island, and Vermont. Takeda reserves the right to rescind, revoke, or amend the Program at any time without notice.

myIgsource

MyIgSource is an educational resource where your patients can learn more about PI and connect with an individual who is living with PI or has a loved one with PI.

Have your patients connect at MyIgSource.com or call 1-855-250-5111.

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Contraindications

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- 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 human IG. If a hypersensitivity reaction occurs, discontinue infusion immediately and institute appropriate treatment. IgA-deficient patients with antibodies to IgA are at greater risk of developing potentially severe hypersensitivity reactions, including anaphylaxis.

Thrombosis: May occur following treatment with IG products and in the absence of known risk factors. In patients at risk, administer at the minimum dose and infusion rate practicable. Ensure adequate hydration before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.

Immunogenicity of Recombinant Human Hyaluronidase (rHuPH20): Non-neutralizing antibodies to the Recombinant Human Hyaluronidase component can develop. The clinical significance of these antibodies or whether they interfere with fertilization in humans is unknown.

Warnings and Precautions (continued)

Aseptic Meningitis Syndrome: Has been reported with use of IG and may occur more frequently in females. Conduct a thorough neurological exam on patients exhibiting signs and symptoms, to rule out other causes of meningitis. Discontinuing IG treatment has resulted in remission within several days without sequelae.

Hemolysis: HYQVIA contains blood group antibodies which may cause a positive direct antiglobulin reaction and hemolysis. Monitor patients for signs and symptoms of hemolysis and delayed hemolytic anemia and, if present, perform appropriate confirmatory lab testing.

Renal Dysfunction/Failure: Acute renal dysfunction/failure, acute tubular necrosis, proximal tubular nephropathy, osmotic nephrosis and death may occur with intravenous (IV) use of IG products, especially those containing sucrose. Ensure patients are not volume depleted prior to infusion. In patients at risk due to pre-existing renal insufficiency or predisposition to acute renal failure, assess renal function before initiation and throughout treatment, and consider lower, more frequent dosing. If renal function deteriorates, consider discontinuation.

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: Non-cardiogenic pulmonary edema may occur with IV administered IG. Monitor patients for pulmonary adverse reactions. If suspected, perform appropriate tests for presence of anti-neutrophil and anti-HLA antibodies in both product and patient serum. May be managed using oxygen therapy with adequate ventilatory support.

Transmittable Infectious Agents: Because HYQVIA is made from human plasma, it may carry a risk of transmitting infectious agents (e.g. viruses, other pathogens). No cases of transmission of viral diseases or variant Creutzfeldt-Jakob disease (vCJD) have been associated with HYQVIA.

Interference with Lab Tests: False positive serological test results and certain assay readings, with the potential for misleading interpretation, may 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 including pain, erythema, edema, and pruritus, and systemic adverse reactions including, headache, antibody formation against Recombinant Human Hyaluronidase (rHuPH20), fatigue, nausea, pyrexia, and vomiting.

Drug Interactions

Passive transfer of antibodies may transiently interfere with the immune responses to live attenuated virus vaccines (e.g., measles, mumps, rubella, and varicella).

Please click here for Full Prescribing Information.

Reference: 1. HYQVIA [Prescribing Information]. Lexington, MA: Baxalta US Inc.