



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

Authorized HYQVIA Specialty Pharmacy Providers

Your patients will receive HYQVIA® [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase] Solution from specialty pharmacy providers (SPPs). Work with each patient to determine which SPP might be right for him or her.

The following SPPs are currently authorized to dispense HYQVIA:

AcariaHealth	InfuCareRx
Accredo(incl. Cigna Tel-Drug)	KabaFusion
AIS	Kroger
AllianceRxWalgreens Prime	NuFACTOR
BioMatrix	Option Care (incl. BioScrip)
BriovaRx	OSO
CVS Specialty	Soleo
Diplomat	Superior Biologics
Humana RightSource	US Bioservices

Inquire with specific SP for current status.

INDICATION AND LIMITATION OF USE

HYQVIA 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 on the next page and click for [Full Prescribing Information](#)



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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)

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.

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.

Please see additional Important Safety Information on the next page and click for [Full Prescribing Information](#), including Boxed Warning regarding Thrombosis.

IMPORTANT SAFETY INFORMATION (Continued)

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 for [Full Prescribing Information](#) including Boxed Warning regarding Thrombosis.

