Cuvitru
[Immune Globulin Subcutaneous (Human)] 20%

Authorized CUVITRU Specialty Pharmacy Providers

Your patients will receive CUVITRU [Immune Globulin Subcutaneous (Human)] 20% Solution from specialty pharmacy providers (SPPs). Work with your patients to determine which SPP might be right for them.

The following SPPs are currently authorized to dispense CUVITRU:

Last update as of June 2024

AcariaHealth	InfuCareRx
Accredo Specialty Pharmacy	Intramed Plus
Advanced Infusion Care	KabaFusion
AllianceRx Walgreens Pharmacy	Kroger Specialty Infusion
Amerita	Nufactor
AOM Infusion	Option Care Health
Avevo RX, LLC	Optum Infusion Pharmacy
Axiva Health Solutions	Paragon Healthcare
BioMatrix	Promptcare
BioPlus	Realo Specialty Care Pharmacy
BioTek Remedys	Soleo Health
Coastal Infusion Services	Superior Biologics
ContinuumRx	Twelvestone Health Partners
CSI Pharmacy	Upstate Homecare
CVS Health	Vital Care

Inquire with specific SPPs for current status.

***Click here* for more information on access and support for CUVITRU.**

INDICATION

CUVITRU is indicated as replacement therapy for primary humoral immunodeficiency (PI) in adult and pediatric patients ≥2 years. CUVITRU is for subcutaneous use only.

IMPORTANT SAFETY INFORMATION

WARNING: THROMBOSIS

- **Thrombosis may occur with immune globulin (IG) products, including CUVITRU. 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.**
- **For patients at risk of thrombosis, administer CUVITRU 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.

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IMPORTANT SAFETY INFORMATION (Continued)

Contraindications

- History of anaphylactic or severe systemic hypersensitivity reactions to subcutaneous administration of human IG.
- IgA-deficient patients with antibodies against IgA and a history of hypersensitivity to human IG.

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.

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 starting 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.

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.

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: CUVITRU 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.

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

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 clinical trials in ≥5% of patients were: local adverse reactions including mild or moderate pain, erythema, and pruritus, and systemic adverse reactions including headache, nausea, fatigue, diarrhea, 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 see additional Important Safety Information throughout and click here for Full Prescribing Information, including Boxed Warning regarding Thrombosis.
Colorado prescribers: Please click for pricing disclosure information for CUVITRU.

Takeda

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