Know your IVIg options

Proven IgG therapy
Designed for stability

Please see full Important Safety Information for Privigen and Carimune NF on following pages and full prescribing information, including boxed warning, in pocket.
Proven effective, Privigen is the first and only IVIg designed with proline stabilization
- Privigen is approved for the treatment of PI, CIDP, and chronic ITP
- Low IgA content
- Convenient, ready-to-use 10% IVIg that can be stored at room temperature

Important Safety Information for Privigen
Privigen is indicated for the treatment of:
- Primary humoral immunodeficiency (PI)
- Chronic immune thrombocytopenic purpura (ITP) in patients age 15 years and older
- Chronic inflammatory demyelinating polyneuropathy (CIDP) in adults

– Limitation of use: maintenance therapy in CIDP has not been studied for periods longer than 6 months. Individualize duration of treatment beyond 6 months based on patient response.

Important Safety Information
Privigen is a convenient 10% liquid IVIg

Storage
- Privigen is ready to use
- No reconstitution or warming needed
- 36-month room-temperature storage

Vial Sizes
- Multiple vial sizes to minimize waste
- Includes the largest vial of IVIg available

5 g (50 mL) 10 g (100 mL) 20 g (200 mL) 40 g (400 mL)

Important Safety Information for Privigen
WARNING: THROMBOSIS, RENAL DYSFUNCTION AND ACUTE RENAL FAILURE
- Thrombosis may occur with immune globulin products, including Privigen. 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.
- Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur with immune globulin intravenous (IGIV) products in predisposed patients. Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products that contain sucrose. Privigen does not contain sucrose.
- For patients at risk of thrombosis, renal dysfunction or renal failure, administer Privigen 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 for hyperviscosity.

See full prescribing information for complete boxed warning.
Review your IVIg* options for PI, ITP, and CIDP

<table>
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<tr>
<th>Feature</th>
<th>Product Name</th>
<th>Details</th>
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<tr>
<td>Concentration/Volume</td>
<td>Immune Globulin Intravenous (Human), Langtrop®</td>
<td>1 g (20 mL), 2.5 g (50 mL), 5 g (100 mL), 10 g (200 mL), 20 g (400 mL)</td>
</tr>
<tr>
<td>Dosage Form</td>
<td>Immune Globulin Intravenous (Human), Langtrop®</td>
<td>5 g (100 mL), 10 g (200 mL), 25 g (500 mL), 50 g (1000 mL), 100 g (2000 mL)</td>
</tr>
<tr>
<td>Storage</td>
<td>Immune Globulin Intravenous (Human), Langtrop®</td>
<td>At temperatures not to exceed 30°C (86°F) until expiration. Do not freeze.</td>
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<tr>
<td>Maximum Dosage</td>
<td>Immune Globulin Intravenous (Human), Langtrop®</td>
<td>Reviews your IVIg* options for PI, ITP, and CIDP</td>
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*IVIg: Immune Globulin Intravenous (Human)
Important Safety Information for Privigen

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- Primary humoral immunodeficiency (PI)
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- Chronic inflammatory demyelinating polyneuropathy (CIDP) in adults

- Limited use: maintenance therapy in CIDP has not been studied for periods longer than 6 months. Individualize duration of treatment beyond 6 months based on patient response.

WARNING: THROMBOSIS, RENAL DYSFUNCTION or ACUTE RENAL FAILURE

- Thrombosis may occur with immune globulin products, including Privigen. 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.

- Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur with immune globulin intravenous (IGIV) products in predisposed patients. Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products that contain sucrose. Privigen does not contain sucrose.

- For patients at risk of thrombosis, renal dysfunction or renal failure, administer Privigen 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 for hyperviscosity. See full prescribing information for complete boxed warning.

Privigen is contraindicated in patients with history of anaphylactic or severe systemic reaction to human immune globulin, in patients with hypersensitivity, and in IgA-deficient patients with antibodies to IgA and a history of hypersensitivity. In patients at risk of developing acute renal failure, monitor urine output and renal function, including blood urea nitrogen and creatinine. Hypermobility, increased serum viscosity, or hyperviscotropism can occur with Privigen. Infrequently, aseptic meningitis syndrome (AMS) may occur—especially with high doses or rapid infusion.

Hemolysis, either intravascular or due to enhanced red blood cell sequestration, may occur. Risk factors include non-O blood group and high doses. Close monitoring patients for hemolysis and hemolytic anemia.

During and shortly following Privigen infusion, elevations of systolic and diastolic blood pressure (including cases of hypertensive urgency) have been observed. These elevations resolved or significantly improved within hours with oral anti-hypertensive therapy or observation alone. Check patients for a history of hypertension and monitor blood pressure during this period.

Consider relative risks and benefits before prescribing high-dose regimens for chronic ITP and CIDP in patients at increased risk of thrombosis, hemolysis, acute kidney injury or volume overload. Monitor patients for pulmonary adverse reactions (transfusion-related acute lung injury (TRALI)).

Privigen is derived from human plasma. The risk of transmission of infectious agents, including viruses and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent and its variant (vCJD), cannot be completely eliminated.

In clinical studies of patients with PI, the most common adverse reactions to Privigen, observed in >5% of subjects, were headache, fatigue, nausea, chills, vomiting, back pain, pain, elevated body temperature, abdominal pain, diarrhea, cough, stomach discomfort, chest pain, joint swelling/edema, influenza-like illness, pharyngolaryngeal pain, urticaria, and dizziness. Serious adverse reactions were hypersensitivity, chills, fatigue, dizziness, and increased body temperature.

In clinical studies of patients being treated for chronic ITP, the most common adverse reactions, seen in >5% of subjects, were laboratory findings consistent with hemolysis, headache, elevated body temperature, anemia, nausea, and vomiting. A serious adverse reaction was aseptic meningitis syndrome.

In clinical studies of patients being treated for CIDP, the most common reactions, observed in >5% of subjects, were headache, asthma, hypotension, nausea, pain in extremity, hemolysis, influenza-like illness, leukopenia, and rash. Serious adverse reactions were hemolysis, exaration of CIDP, acute rash, increased gastric blood pressure, hyperviscosity, pulmonary embolism, respiratory failure, and migraine.

Treatment with Privigen might interfere with a patient’s response to live virus vaccines and cause or exacerbate misinterpretation of serologic testing. In patients over 65 and those at risk of renal insufficiency, do not exceed recommended dose and infusion at the minimum rate practicable.

Please see full prescribing information for Privigen.

References:


2. References: 1. Gammagard Liquid [package insert]. Westlake Village, CA: Baxter Healthcare Corporation; 2016. 2. Carimune® NF, Nanofiltered Immune Globulin Intravenous (Human) is indicated for the maintenance treatment of patients with primary immunodeficiencies (PI), such as common variable immunodeficiency, X-linked agammaglobulinemia, and severe combined immunodeficiency, as well as for acute and chronic immune thrombocytopenic purpura (ITP). 

WARNING: THROMBOSIS, RENAL DYSFUNCTION or ACUTE RENAL FAILURE

- Thrombosis may occur with immune globulin products, including Carimune NF. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling central vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis might occur in absence of known risk factors.

- Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur in predisposed patients with immune globulin intravenous (IGIV) products, including Carimune NF. Patients predisposed to renal dysfunction develop with any degree of preexisting renal insufficiency, diabetes mellitus, age over 65, volume depletion, sepsis, paraproteinemia, and those receiving known nephrotoxic drugs. Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. Carimune NF contains sucrose.

- For patients at risk of thrombosis, renal dysfunction or acute renal failure, administer Carimune NF 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 for hyperviscosity.

- See full prescribing information for full boxed warning.

Carimune NF is contraindicated in patients who have had anaphylactic or severe systemic reactions to the administration of human immune globulin. Individuals with selective IgA deficiency who possess antibody to IgA should only receive Carimune NF with utmost caution due to the risk of severe reactions, including anaphylaxis. Increases in creatinine and urine nitrogen with progression to oliguria or anuria requiring dialysis have been observed as soon as one to two days following IGIV infusion. Severe renal adverse events have included acute renal failure, acute tubular nephrosis, proximal tubular nephropathy, and osmotic nephrosis.

Patients receiving Carimune NF should be monitored for clinical signs and symptoms of hypomoly, as well as pulmonary adverse reactions, including TRALI. An aseptic meningitis syndrome (AMS) has been reported to occur infrequently with IVIG—more frequently in association with high dose (2 g/kg) treatment.

Inflammatory adverse reactions have been observed; they may become apparent within 30 minutes to an hour after beginning infusion. Slow or temporarily stop infusion if patient experiences facial flushing, tightness in chest, fever, nausea, dizziness, and other unusual response; stop infusion immediately if anaphylaxis or severe reaction occurs. Headache, usually mild, is the most common adverse reaction; mild hemolysis, arthralgia, myalgia, and transient skin reactions have also been reported. Carimune NF is derived from human plasma. The risk of transmission of infectious agents, including viruses and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent and its variant (vCJD), cannot be completely eliminated.

Carimune NF should be given to a pregnant woman only if clearly needed. Please see full prescribing information for Carimune, including boxed warning on thrombosis and renal dysfunction/failure, in pocket.