IMPORTANT SAFETY INFORMATION

INDICATIONS AND IMPORTANT SAFETY INFORMATION

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 can occur in predisposed patients with immune globulin intravenous (IGIV) products, including Carimune NF. Patients predisposed to renal dysfunction include those 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 risk of severe, immediate hypersensitivity reactions, including anaphylaxis.

Increases in creatinine and blood urea 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 hemolysis, 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, chills, fever, nausea, dizziness or other unusual response; stop infusion immediately if

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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 NF, including boxed warning on thrombosis and renal dysfunction/failure.