**Description**

Carimune® NF, Nanofiltered, Immune Globulin Intravenous (Human), is a sterile, highly purified polyclonal antibody product containing in concentrated form all the IgG antibodies which regularly occur in the donor population. This immunoglobulin preparation is produced by cold alcohol fractionation from the plasma of US donors. Part of the fractionation may be performed by another US-licensed manufacturer. Carimune® NF is made suitable for intravenous use by treatment at acid pH in the presence of trace amounts of pepsin. These studies provide reasonable assurance that low levels of CJD/vCJD agent infectivity, if present, would be removed.

**Nanofiltration**

Carimune® NF manufacturing process provides a significant virus reduction capacity as shown in in vitro studies. The results, summarized in Table 1, demonstrate virus clearance during Carimune® NF manufacturing using model viruses for lipid enveloped and non-enveloped viruses.

<table>
<thead>
<tr>
<th>Virus</th>
<th>HIV</th>
<th>BVDV</th>
<th>PRV</th>
<th>SV</th>
<th>BEV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genome</td>
<td>RNA</td>
<td>RNA</td>
<td>DNA</td>
<td>RNA</td>
<td>RNA</td>
</tr>
<tr>
<td>Envelope</td>
<td>Yes</td>
<td>Yes</td>
<td>DNA</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Size (nm)</td>
<td>80–100</td>
<td>40–60</td>
<td>120–200</td>
<td>50–70</td>
<td>50–70</td>
</tr>
<tr>
<td>Fractionation &amp;</td>
<td>15.5</td>
<td>nt</td>
<td>16.0</td>
<td>9.3</td>
<td>12.4</td>
</tr>
<tr>
<td>pH 4 / pepsin</td>
<td>≥ 6.1</td>
<td>≥ 4.4</td>
<td>≥ 5.3</td>
<td>≥ 6.8</td>
<td>nt</td>
</tr>
<tr>
<td>Nanofiltration</td>
<td>≥ 4.9</td>
<td>≥ 4.5</td>
<td>≥ 4.4</td>
<td>nt</td>
<td>≥ 7.5</td>
</tr>
<tr>
<td>Overall reduction</td>
<td>≥ 26</td>
<td>≥ 9</td>
<td>≥ 25</td>
<td>≥ 16</td>
<td>≥ 19</td>
</tr>
</tbody>
</table>

**Clinical Pharmacology**

Carimune® NF contains a broad spectrum of antibody specificities against bacterial, viral, parasitic, and mycoplasma antigens, that are capable of both opsonization and neutralization of microbes and toxins. The 3 week half-life of Carimune® NF corresponds to that of immune globulin (Human) for intramuscular use, although individual variations in half-life have been observed. Appropriate doses of Carimune® NF restore abnormally low immunoglobulin G levels to the normal range. One hundred percent of the infused dose of IgG-products is available in the recipient’s circulation immediately after infusion. After approximately 6 days, equilibrium is reached between the intra- and extravascular compartments, with immunoglobulin G being distributed approximately 50% intravascular and 50% extravascular.

**Warnings**

Severe immediate hypersensitivity reactions including anaphylaxis.
WARNINGS

Immune Globulin Intravenous (Human) (IGIV) products have been reported to be associated with renal dysfunction, acute renal failure, osmotic nephrosis, and death.31-36

Patients predisposed to acute renal failure include patients with:
1. any degree of pre-existing renal insufficiency
2. diabetes mellitus
3. age greater than 65
4. volume depletion
5. sepsis
6. paraproteinemia
7. patients receiving known nephrotoxic drugs

In such patients, IGIV products should be administered at the minimum concentration available and the minimum rate of infusion practicable. While these reports of renal dysfunction and acute renal failure have been associated with the use of many of the licensed IGIV products, those containing sucrose as a stabilizer accounted for a disproportionate share of the total number. See PRECAUTIONS and DOSAGE AND ADMINISTRATION sections for important information intended to reduce the risk of acute renal failure.

IgA deficient patients, especially those with known antibodies against IgA, are at greater risk of developing severe hypersensitivity and anaphylactic reactions. Carimune® NF is made from human plasma. Products made from human plasma may contain infectious agents, such as viruses, that can cause disease. The risk that such products will transmit an infectious agent has been reduced by screening plasma donors for prior exposure to certain viruses, by testing for the presence of certain current virus infections, and through the application of viral elimination/reduction steps such as alcohol fractionation in the presence of filter aids, nanofiltration and pH 4/pepsin treatment (see Table 1). Despite these measures, such products may carry a risk of transmitting infectious agents, e.g., viruses, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent. There is also the possibility that unknown infectious agents may be present in such products. All infections thought by a physician possibly to have been transmitted by this product should be reported to the physician or other healthcare provider to CSL Behring Pharmacovigilance at 1-866-915-6958. The physician should discuss the risks and benefits of this product with the patient.

Patients with aqama- or extreme hypogammaglobulinemia who have never before received immunoglobulin substitution treatment or whose time from last treatment is greater than 8 weeks, may be at risk of developing inflammatory reactions on rapid infusion (greater than 2 mg/kg/min) of Carimune® NF. These reactions are manifested by a rise in temperature, chills, nausea, and vomiting. The patient’s vital signs should be monitored continuously. The patient should be carefully observed throughout the infusion, since these reactions on rare occasions may lead to shock. Epinephrine and other appropriate resuscitative drugs and equipment should be available for treatment of an acute anaphylactic reaction.

PRECAUTIONS

Please see DOSAGE AND ADMINISTRATION below, for important information on Carimune® NF compatibility with other medications or fluids. Patients should not be volume depleted prior to the initiation of the infusion of IGIV. Periodic monitoring of renal function tests and urine output is particularly important in patients judged to have a potential increased risk for developing acute renal failure. Renal function, including measurement of blood urea nitrogen (BUN) and serum creatinine, should be assessed prior to the initial infusion of Carimune® NF and again at appropriate intervals thereafter. If renal function deteriorates, discontinuation of the product should be considered. For patients judged to be at risk for developing renal dysfunction, Carimune® NF should be infused at a rate less than 2 mg/kg/min.

Information for Patients

Patients should be instructed to immediately report symptoms of decreased urine output, sudden weight gain, fluid retention/edema, and/or shortness of breath (which may suggest kidney damage) to their physicians.

Laboratory Tests

IGIV recipients should be monitored for clinical signs and symptoms of hemolysis. IGIV recipients should be monitored for pulmonary adverse reactions. If Transfusion-Related Acute Lung Injury (TRALI) is suspected, appropriate tests should be performed for the presence of anti-neutrophil antibodies in both the product and patient serum. Baseline assessment of blood viscosity should be considered in patients at risk for hyperviscosity, including those with cryoglobulins, fasting chylomicronemia/markedly high triacylglycerols (triglycerides), or monoclonal gammapathies.

Pregnancy Category C

Animal reproduction studies have not been conducted with Carimune® NF. It is also not known whether Carimune® NF can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Carimune® NF should be given to a pregnant woman only if clearly needed.24 Intact immune globulins such as those contained in Carimune® NF cross the placenta from maternal circulation increasing after 30 weeks gestation.27,38 In cases of maternal ITP where Carimune® was administered to the mother prior to delivery, the platelet response and clinical effect were similar in the mother and neonate.30-36

Pediatric Use

High dose administration of Carimune® in pediatric patients with acute or chronic Immune Thrombocytopenic Purpura did not reveal any pediatric-specific hazards.33 Antibodies in Immune Globulin Intravenous (Human) may impair the efficacy of live attenuated viral vaccines such as measles, rubella, and mumps.9-13 Immunizing physicians should be informed of recent therapy with Immune Globulin Intravenous (Human) so that appropriate precautions may be taken.

Geriatric Use

Carimune® NF should be used with caution in patients over 65 years of age and judged to be at increased risk of developing renal insufficiency (see DOSAGE AND ADMINISTRATION). In the absence of prospective data, recommended doses should not be exceeded and the concentration and infusion rate selected should be the minimum practicable. The product should be infused at a rate less than 2 mg/kg/min.

Aseptic Meningitis Syndrome

An aseptic meningitis syndrome (AAMS) has been reported to occur infrequently in association with Immune Globulin Intravenous (Human) (IGIV) treatment. The syndrome usually begins within several hours to two days following IGIV treatment. It is characterized by symptoms and signs including severe headache, nuchal rigidity, drowsiness, fever, photophobia, painful eye movements, and nausea and vomiting. Cerebrospinal fluid (CSF) studies are frequently positive with pleocytosis. Patients exhibiting such symptoms and signs should receive thorough neurological examination, including CSF studies, to rule out other causes of meningitis. AAMS may occur more frequently in association with high dose (2 g/kg) IGIV treatment. Discontinuation of IGIV treatment has resulted in remission of AAMS within several days without sequelae.

Hemolysis

Immune Globulin Intravenous (Human) (IGIV) products can contain blood group antibodies which may act as hemolysins and induce in vivo coating of red blood cells with immunoglobulin, causing a positive direct antiglobulin reaction and, rarely, hemolysis.51-53 Hemolytic anemia can develop subsequent to IGIV therapy due to enhanced RBC sequestration (see ADVERSE REACTIONS). IGIV recipients should be monitored for clinical signs and symptoms of hemolysis (see PRECAUTIONS: Laboratory Tests).

Transfusion-Related Acute Lung Injury (TRALI)

There have been reports of cardiogenic pulmonary edema Transfusion-Related Acute Lung Injury (TRALI) in patients administered IGIV.50 TRALI is characterized by severe respiratory distress, pulmonary edema, hypoxemia, normal left ventricular function, and fever and typically occurs within 1-6 hours after transfusion. Patients with TRALI may be managed by using oxygen therapy with adequate ventilatory support. IGIV recipients should be monitored for pulmonary adverse reactions. If TRALI is suspected, appropriate tests should be performed for the presence of anti-neutrophil antibodies in both the product and patient serum (see PRECAUTIONS: Laboratory Tests).

Thrombotic Events

Thrombotic events have been reported in association with IGIV (see ADVERSE REACTIONS). Patients at risk may include those with a history of atherosclerosis, multiple cardiovascular risk factors, advanced age, impaired cardiac output, and/or known or suspected hyperviscosity. The potential risks and benefits of IGIV should be weighed against those of alternative therapies for all patients for whom IGIV administration is being considered. Baseline assessment of blood viscosity should be considered in patients at risk for hyperviscosity, including those with cryoglobulins, fasting chylomicronemia/markedly high triacylglycerols (triglycerides), or monoclonal gammapathies (see PRECAUTIONS: Laboratory Tests). For patients judged to be at increased risk of thromboembolic events, a maximum infusion rate of less than 2 mg/kg/min is recommended.

ADVERSE REACTIONS

Increases in creatinine and blood urea nitrogen (BUN) have been observed as soon as one to two days following infusion. Progression to oliguria or anuria, requiring dialysis has been observed. Types of severe renal adverse events that have been following IGIV therapy include: acute renal failure, acute tubular necrosis, proximal tubular nephropathy and osmotic nephrosis.11,12,16

Inflammatory adverse reactions have been described in agammaglobulinemic and hypogammaglobulinemic patients who have never received immunoglobulin substitution therapy before or in patients whose time from last treatment is greater than 8 weeks and whose initial infusion rate exceeds 2 mg/kg/min. This occurs in approximately 10% of such cases. Such reactions may also be observed in some patients during chronic substitution therapy. Reactions, which may become apparent only 30 minutes to 1 hour after the beginning of the infusion, are as follows: flushing of the face, feelings of tightness in the chest, chills, fever, dizziness, nausea, diarrhea, and hypotension or hypertension. In such cases, the infusion should be slowed or temporarily stopped until the symptoms subside. The infusion may then be resumed at a lower rate that is comfortable for the patient. If anaphylaxis or other severe reactions occur, the infusion should be stopped immediately.
Arthralgia, myalgia, and transient skin reactions (such as rash, erythema, pruritus, urticaria, eczema or dermatitis) have also been reported.

Immediate anaphylactoid and hypersensitivity reactions due to previous sensitization of the recipient to certain antigens, most commonly IgA, may be observed in exceptional cases, described under CONTRAINDICATIONS. In patients with ITP, who receive higher doses (0.4 g/kg/day or greater), 2.9% of infusions may result in adverse reactions. Headache, generally mild, is the most common symptom noted, occurring during or following 2% of infusions. A few cases of usually mild hemolysis have been reported after infusion of intravenous immunoglobulin products. These were attributed to transfusion of blood group (e.g., anti-D) antibodies.

Postmarketing
The following adverse reactions have been identified and reported during the post-approval use of IGIV products:

**Respiratory**
Apnea, Acute Respiratory Distress Syndrome (ARDS), Transfusion-Related Acute Lung Injury (TRALI), cyanosis, hypoxia, pulmonary edema, dyspnea, bronchospasm

**Cardiovascular**
Cardiac arrest, thromboembolism, vascular collapse, hypotension

**Neurological**
Coma, loss of consciousness, seizures, tremor

**Integumentary**
Stevens-Johnson syndrome, epidermolysis, erythema multiforme, bullous dermatitis

**Hematologic**
Pancytopenia, leukopenia, hemolysis, positive direct antiglobulin (Coombs) test

**General/Body as a Whole**
Pyrexia, rigors

**Musculoskeletal**
Back pain

**Gastrointestinal**
Hepatic dysfunction, abdominal pain

Because postmarketing reporting of these reactions is voluntary and the at-risk populations are of uncertain size, it is not always possible to reliably estimate the frequency of the reaction or establish a causal relationship to exposure to the product. Such is also the case with literature reports authored independently.

**DOSAGE AND ADMINISTRATION**

It is generally advisable not to dilute plasma derivatives with other infusible drugs. Carimune® NF should be given by a separate infusion line. No other medications or fluids should be mixed with Carimune® NF preparation.

Carimune® NF should be used with caution in patients with pre-existing renal insufficiency and in patients who are at increased risk of developing renal insufficiency (including, but not limited to those with diabetes mellitus, age greater than 65, volume depletion, paraproteinemia, sepis, and patients receiving known nephrotoxic drugs). In these cases especially it is important to assure that patients are not volume depleted prior to Carimune® NF infusion. No prospective data are presently available to identify a maximum safe dose, concentration, and rate of infusion in patients determined to be at increased risk of acute renal failure. In the absence of prospective data, recommended doses should not be exceeded and the concentration and infusion rate selected should be the minimum practicable. For patients judged to be at risk for developing renal dysfunction, Carimune NF® should be infused at a rate less than 2 mg/kg/min. 

For patients judged to be at an increased risk for thromboembolic events, a maximum infusion rate of less than 2 mg/kg/min for patients is recommended (see PRECAUTIONS: Thrombotic Events). If side effects occur, the infusion should be stopped or slowed until the symptoms subside.

**Adult and Child Substitution Therapy**

The recommended dose of Carimune® NF in primary immunodeficiency is 0.4 to 0.8 g/kg of body weight administered once every three to four weeks by intravenous infusion. The first infusion of Carimune® NF in previously untreated agammaglobulinemic and hypogammaglobulinemic patients must be given as a 3% immunoglobulin solution (see Reconstitution). Subsequent infusions may be administered at a higher concentration if the patient shows good tolerance.

An initial infusion rate of 0.5 mg/kg/min is recommended. If tolerated, after 30 minutes, the rate may be increased to 1 mg/kg/min for the next 30 minutes. Thereafter, the rate may be gradually increased in a stepwise manner up to a maximum of 3 mg/kg/min as tolerated. Refer to Table 3 for the corresponding infusion rates in mg/kg/min or mL/kg/min for all product concentrations.

The first infusion of Carimune® NF in previously untreated agammaglobulinemic and hypogammaglobulinemic patients may lead to systemic side effects. The nature of these effects has not been fully elucidated. Some of them may be due to the release of proinflammatory cytokines by activated macrophages in immunodeficient recipients. Subsequent administration of Carimune® NF to immunodeficient patients as well as to normal individuals usually does not cause further untoward side effects.

**Therapy of Idiopathic Thrombocytopenic Purpura (ITP)**

**Induction**
The recommended dose of Carimune® NF for the treatment of ITP is 0.4 g/kg of body weight on 2–5 consecutive days. An immunoglobulin solution of 6% (see Reconstitution) is recommended for use in ITP.

The recommended initial infusion rate for the treatment of ITP is 0.5 mg/kg/min. If tolerated, after 30 minutes, the rate may be increased to 1 mg/kg/min for the next 30 minutes. Thereafter, the rate may be gradually increased in a stepwise manner up to a maximum of 3 mg/kg/min as tolerated. Refer to Table 3 for the corresponding infusion rates in mg/kg/min or mL/kg/min for all product concentrations.

**Acute ITP – Childhood**

In acute ITP of childhood, if an initial platelet count response to the first two doses is inadequate (30–50,000/µL), therapy may be discontinued after the second day of the 5 day course.

**Maintenance – Chronic ITP**

In adults and children, if after induction therapy the platelet count falls to less than 30,000/µL and/or the patient manifests clinically significant bleeding, 0.4 g/kg of body weight may be given as a single infusion. If an adequate response does not result, the dose can be increased to 0.8–1 g/kg of body weight given as a single infusion.

**Reconstitution**

(see also pictures below)

1. Remove the protective plastic caps from the lyophilisate (LYO) and diluent (see also pictures below)
2a. and 2b. Remove the second protective cover from the other end of the transfer set. Grasp both bottles as shown in picture 2a, quickly plunge the diluent bottle onto the lyophilisate bottle and bring the bottles into an upright position. Only if this is done quickly and the bottles are immediately brought into an upright position can the vacuum in the lyophilisate bottle be maintained, thus speeding up reconstitution and facilitating the transfer. Allow the diluent to flow into the lyophilisate bottle (picture 2b).
3. Once the appropriate amount of diluent is transferred (see Table 4), lift the diluent bottle off the spike to release the vacuum (picture 3). This will reduce foaming and facilitate dissolution. Remove the spike.
4. Swirl vigorously but do not shake, otherwise a foam will form which is very slow to subside (picture 4). The lyophilisate dissolves within a few minutes.

**Table 3: Required Diluent Volume**

<table>
<thead>
<tr>
<th>Target Concentration</th>
<th>3 g Vial</th>
<th>5 g Vial</th>
<th>6 g Vial</th>
<th>12 g Vial</th>
</tr>
</thead>
<tbody>
<tr>
<td>3%</td>
<td>100 mL</td>
<td>200 mL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6%</td>
<td>50 mL</td>
<td>100 mL</td>
<td></td>
<td>200 mL</td>
</tr>
<tr>
<td>9%</td>
<td>33 mL</td>
<td>66 mL</td>
<td>132 mL</td>
<td></td>
</tr>
<tr>
<td>12%</td>
<td>25 mL</td>
<td>50 mL</td>
<td>100 mL</td>
<td></td>
</tr>
</tbody>
</table>

* In patients judged to be at increased risk of developing renal insufficiency and thromboembolic events, the concentration and infusion rate of Carimune® NF should be the minimum practicable.

**Table 4: Infusion Rates for Carimune® NF Concentrations**

<table>
<thead>
<tr>
<th>Concentration (%)</th>
<th>Initial Infusion Rate: 0.5 mg/kg/min</th>
<th>1 mg/kg/min</th>
<th>2 mg/kg/min*</th>
<th>Maximum Infusion Rate: 3 mg/kg/min</th>
</tr>
</thead>
<tbody>
<tr>
<td>3%</td>
<td>0.0167 mL/kg/min</td>
<td>0.033 mL/kg/min</td>
<td>0.067 mL/kg/min</td>
<td>0.10 mL/kg/min</td>
</tr>
<tr>
<td>6%</td>
<td>0.008 mL/kg/min</td>
<td>0.0167 mL/kg/min</td>
<td>0.033 mL/kg/min</td>
<td>0.050 mL/kg/min</td>
</tr>
<tr>
<td>9%</td>
<td>0.006 mL/kg/min</td>
<td>0.011 mL/kg/min</td>
<td>0.022 mL/kg/min</td>
<td>0.033 mL/kg/min</td>
</tr>
<tr>
<td>12%</td>
<td>0.004 mL/kg/min</td>
<td>0.008 mL/kg/min</td>
<td>0.016 mL/kg/min</td>
<td>0.025 mL/kg/min</td>
</tr>
</tbody>
</table>

* Maximum infusion rate for patients at risk of renal dysfunction or thromboembolic events.
† For patients not at risk of renal dysfunction or thromboembolic events.

**Table 5:  Required Diluent Volume**

<table>
<thead>
<tr>
<th>Target Concentration</th>
<th>3 g Vial</th>
<th>5 g Vial</th>
<th>6 g Vial</th>
<th>12 g Vial</th>
</tr>
</thead>
<tbody>
<tr>
<td>3%</td>
<td>100 mL</td>
<td>200 mL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6%</td>
<td>50 mL</td>
<td>100 mL</td>
<td></td>
<td>200 mL</td>
</tr>
<tr>
<td>9%</td>
<td>33 mL</td>
<td>66 mL</td>
<td>132 mL</td>
<td></td>
</tr>
<tr>
<td>12%</td>
<td>25 mL</td>
<td>50 mL</td>
<td>100 mL</td>
<td></td>
</tr>
</tbody>
</table>

* In patients judged to be at increased risk of developing renal insufficiency and thromboembolic events, the concentration and infusion rate of Carimune® NF should be the minimum practicable.

**Container not large enough to permit this concentration.**
If large doses of Carimune® NF are to be administered, several reconstituted vials of identical concentration and diluent may be pooled in an empty sterile glass or plastic i.v. infusion container using aseptic technique. Carimune® NF normally dissolves within a few minutes, though in exceptional cases it may take up to 20 minutes.

DO NOT SHAKE! Excessive shaking will cause foaming. Any undissolved particles should be carefully removed from the solution. Avoid contact with the solution. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Of Carimune® NF is acceptable but not required. Pore sizes of 15 microns or larger will be less likely to slow infusion, especially with higher Carimune® NF concentrations. Antibacterial filters (0.2 microns) may be used. When reconstitution of Carimune® NF occurs outside of refrigerated during that time. Do not freeze Carimune® NF solution.

Any undissolved particles should respond to careful rotation of the bottle. Avoid foaming. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Of Carimune® NF is acceptable but not required. Pore sizes of 15 microns or larger will be less likely to slow infusion, especially with higher Carimune® NF concentrations. Antibacterial filters (0.2 microns) may be used. When reconstitution of Carimune® NF occurs outside of refrigerated during that time. Do not freeze Carimune® NF solution.

Carimune® NF should be stored at room temperature not exceeding 30°C (86°F). The Store and Dispense HOW SUPPLIED

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63. Dalakas MC, Clark WM: Strokes, thromboembolic events, and IVig. Rare incidents blemish an excellent safety record. Neurology 2003; 60:1736–1737.


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