Characteristics of Immunoglobulin Products Used to Treat Primary Immunodeficiency Diseases
Licensed for Use in the United States

<table>
<thead>
<tr>
<th>PRODUCT NAME</th>
<th>Bivigam</th>
<th>Carimune NF</th>
<th>Cuvitru</th>
<th>Defregam GM</th>
<th>Gammagard Liquid</th>
<th>Gammagard S/D</th>
<th>Gammaked</th>
<th>Gammaplex</th>
<th>Gamunex - C</th>
<th>Hizentra</th>
<th>HYQVIA1</th>
<th>Octagam</th>
<th>Privigen</th>
</tr>
</thead>
<tbody>
<tr>
<td>MANUFACTURER</td>
<td>CSL Behring</td>
<td>CSL Behring</td>
<td>Shire</td>
<td>Grifols</td>
<td>Grifols</td>
<td>CSL Behring</td>
<td>CSL Behring</td>
<td>CSL Behring</td>
<td>CSL Behring</td>
<td>CSL Behring</td>
<td>CSL Behring</td>
<td>CSL Behring</td>
<td>CSL Behring</td>
</tr>
</tbody>
</table>

**METHOD OF PRODUCTION (INCLUDING VIRAL INACTIVATION)**
- Cohn-Ouchterlony fractionation, Anion exchange chromatography, Precipitation and removal of factor B: chelating column, solvent/detergent treatment, 20°C sodium acetate.
- Cohn-Ouchterlony fractionation, ion-exchange chromatography solvent/detergent treatment. Sodium nafion, low pH, pre-heated temperature incubation.
- Cohn-Ouchterlony fractionation, ion-exchange chromatography solvent/detergent treatment. Sodium nafion, low pH, pre-heated temperature incubation.
- Cohn-Ouchterlony fractionation, ion-exchange chromatography solvent/detergent treatment. Sodium nafion, low pH, pre-heated temperature incubation.
- Cohn-Ouchterlony fractionation, ion-exchange chromatography solvent/detergent treatment. Sodium nafion, low pH, pre-heated temperature incubation.
- Cohn-Ouchterlony fractionation, ion-exchange chromatography solvent/detergent treatment. Sodium nafion, low pH, pre-heated temperature incubation.
- Cohn-Ouchterlony fractionation, ion-exchange chromatography solvent/detergent treatment. Sodium nafion, low pH, pre-heated temperature incubation.
- Cohn-Ouchterlony fractionation, ion-exchange chromatography solvent/detergent treatment. Sodium nafion, low pH, pre-heated temperature incubation.
- Cohn-Ouchterlony fractionation, ion-exchange chromatography solvent/detergent treatment. Sodium nafion, low pH, pre-heated temperature incubation.
- Cohn-Ouchterlony fractionation, ion-exchange chromatography solvent/detergent treatment. Sodium nafion, low pH, pre-heated temperature incubation.

**SHELF-LIFE/STORAGE REQUIREMENT**
- 24 Months (reconstituted)
- 24 Months
- 12 Months (room temperature storage not to exceed 25°C/77°F)
- 24 Months (reconstituted)
- 24 Months (room temperature storage not to exceed 25°C/77°F)
- 24 Months
- 24 Months (room temperature storage)
- 24 Months (not refrigerated)
- 24 Months (room temperature storage not to exceed 32°C or 90°F)
- 24 Months (room temperature storage)

**RECONSTITUTION TIME**
- N/A
- Several minutes
- N/A
- N/A
- N/A
- N/A
- N/A
- N/A
- N/A
- N/A

**AVAILABLE CONCENTRATIONS**
- 10%
- 3 to 12%
- 30%
- 10%
- 10%
- 5%
- 10%
- 20%
- 5%
- 10%
- 20% (500 mg/mL)
- 5%
- 10%
- 10%

**MAXIMUM RECOMMENDED INFUSION RATE**
- 3.5 mL/hour
- Maximum 3 mg/kg/hour
- 2 mg/kg/hour
- First 2 infusions: 1.7 - 2.0 mL/kg/hour
- 5 mg/kg/hour
- 4 mL/kg/hour
- 5 mg/kg/hour
- 4 mL/kg/hour
- 5 mL/kg/hour
- 20 mL per hour (IV)
- Up to 25 mL/infusion site (50 mL/hr for all sites combined)
- > 48 kg: maximum 360 mL/hour
- > 48 kg: maximum 360 mL/hour
- > 4 kg: maximum 120 mL/hour
- > 4 kg: maximum 120 mL/hour
- 4 mL/kg/hour

**TIME TO INFUSE 30 grams**
- Time will vary based on patient tolerability. 45.5 L is based on recommended infusion rate.
- Time will vary based on patient tolerability. 1.6 hours
- Time will vary based on irritability and route of administration. 30 minutes
- Time will vary based on concentration and rate of administration. 12 hours
- Time will vary depending on route of administration.
- Time will vary depending on rate of administration.
- Time will vary depending on route of administration.
- Time will vary depending on route of administration.
- Time will vary depending on route of administration.
- Variable based on patient tolerability.

**SUGAR CONTENT**
- No added sugars
- 1.61 g per 1000 mg per gram of protein
- No added sugars
- No added sugars
- No added sugars
- No added sugars
- No added sugars
- No added sugars
- No added sugars
- 20 mg/g glucose
- 40 mg/g glucose
- No added sugars
- 5% D-sorbitol (polyol)
- No added sugars
- No added sugars
- 100 mg/mL glucose
- No added sugars
- No added sugars

**SODIUM CONTENT**
- 0.180 - 0.340 mEq/L sodium chloride
- <0.5 mg sodium chloride per gram of protein
- No added sodium
- Trace amounts
- No added sodium
- 85 mg/L sodium chloride
- 17 mg/L sodium chloride
- Trace amounts
- Trace amounts
- Trace amounts
- 30 - 50 mmol/L sodium chloride
- Trace amounts
- Trace amounts
- 6.3 mg/L sodium chloride in recombinant human TPA
- no added sodium
- ≤ 55 mg/L
- ≤ 55 mg/L
- Trace amounts

**OMOSOLARITY / OSMOLALITY**
- 250 - 305 mOsm/kg
- 280 - 315 mOsm/kg
- 240 - 300 mOsm/kg
- 130 mOsm/kg
- 125 mOsm/kg
- 258 mOsm/kg
- 460 - 500 mOsm/kg
- 310 - 380 mOsm/kg
- 340 - 360 mOsm/kg
- 310 - 380 mOsm/kg
- 180 - 200 mOsm/kg
- 180 - 200 mOsm/kg
- 310 - 380 mOsm/kg
- 180 - 200 mOsm/kg

**PH**
- 4.0 - 4.6
- 4.6 - 4.8
- 4.6 - 5.1
- 5.0 - 4.0
- 4.6 - 5.1
- 4.6 - 5.1
- 4.6 - 5.1
- 4.6 - 5.1
- 4.6 - 5.1
- 4.6 - 5.1
- 4.6 - 5.1
- 4.6 - 5.1
- 4.6 - 5.1
- 4.6 - 5.1

**IgA CONTENT**
- ≤ 300 µg/mL
- ≤ 300 µg/mL
- 80 µg/mL
- Average: ≤ 3 mg/mL (specification value: ≤ 5 mg/mL)
- Average: ≤ 3 mg/mL (specification value: ≤ 5 mg/mL)
- 37 µg/mL
- ≥ 4 µg/mL
- ≤ 150 µg/mL
- 46 µg/mL
- ≤ 150 µg/mL
- 46 µg/mL
- ≤ 150 µg/mL
- 46 µg/mL
- ≤ 150 µg/mL
- ≤ 150 µg/mL

**APPROVED METHOD OF ADMINISTRATION**
- Intravenous
- Intravenous
- Subcutaneous
- Intravenous
- Intravenous
- Intravenous
- Intravenous
- Intravenous
- Intravenous
- Intravenous
- Intravenous
- Intravenous
- Intravenous
- Intravenous
- Intravenous

**SODIUM CONTENT**
- 0.180 - 0.340 mEq/L sodium chloride
- <0.5 mg sodium chloride per gram of protein
- No added sodium
- Trace amounts
- No added sodium
- 85 mg/L sodium chloride
- 17 mg/L sodium chloride
- Trace amounts
- Trace amounts
- Trace amounts
- 30 - 50 mmol/L sodium chloride
- Trace amounts
- Trace amounts
- 6.3 mg/L sodium chloride in recombinant human TPA
- no added sodium
- ≤ 55 mg/L
- ≤ 55 mg/L
- Trace amounts

**OMOSOLARITY / OSMOLALITY**
- 250 - 305 mOsm/kg
- 280 - 315 mOsm/kg
- 240 - 300 mOsm/kg
- 130 mOsm/kg
- 125 mOsm/kg
- 258 mOsm/kg
- 460 - 500 mOsm/kg
- 310 - 380 mOsm/kg
- 340 - 360 mOsm/kg
- 310 - 380 mOsm/kg
- 180 - 200 mOsm/kg
- 180 - 200 mOsm/kg
- 310 - 380 mOsm/kg
- 180 - 200 mOsm/kg

**PH**
- 4.0 - 4.6
- 4.6 - 4.8
- 4.6 - 5.1
- 5.0 - 4.0
- 4.6 - 5.1
- 4.6 - 5.1
- 4.6 - 5.1
- 4.6 - 5.1
- 4.6 - 5.1
- 4.6 - 5.1
- 4.6 - 5.1
- 4.6 - 5.1
- 4.6 - 5.1

**IgA CONTENT**
- ≤ 300 µg/mL
- ≤ 300 µg/mL
- 80 µg/mL
- Average: < 3 mg/mL (specification value: ≤ 5 mg/mL)
- Average: < 3 mg/mL (specification value: ≤ 5 mg/mL)
- 37 µg/mL
- ≥ 4 µg/mL
- ≥ 25 µg/mL
- NA
- 40 µg/mL
- Average: < 4 mg/mL (specification value: < 18 mg/mL)
- 46 µg/mL
- ≤ 100 µg/mL
- ≤ 100 µg/mL
- ≤ 100 µg/mL

**APPROVED METHOD OF ADMINISTRATION**
- Intravenous
- Intravenous
- Subcutaneous
- Intravenous
- Intravenous
- Subcutaneous
- Intravenous
- Intravenous
- Intravenous
- Intravenous
- Intravenous
- Intravenous
- Intravenous
- Intravenous