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# Immunoglobulin product booklet

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**n** Intravenous  
**n** Subcutaneous

## Product name Asceniv

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|   |  |
|---|--|
| Manufacturer                                | ADMA Biologics   |
| Method of production                        | Modified classical Cohn Method 6 / Oncley Method 9 fractionation procedure. Contains 100 ± 10 mg/mL protein, of which not less than 96% is human immunoglobulin obtained from source human plasma. |
| Form  | Liquid   |
| Shelf-life/Storage requirement*             | Refrigerated 36 months. Room temperature 1 month.  |
| Available concentrations                    | 10% IgG  |
| Maximum number of SCIG infusion sites       | N/A  |
| Maximum recommended infusion rate/or volume | 8 mg/kg/min (0.08 mL/kg/min)   |
| Stabilizers and other ingredients           | 0.20-0.29M glycine<br>0.15–0.25% polysorbate 80  |
| Sugar content                               | No added sugars  |
| Sodium content                              | 0.100 - 0.140 M sodium chloride  |
| Osmolarity/ Osmolality                      | 370 - 510 mOsm/kg  |
| pH  | 4.0 - 4.6  |
| IgA content                                 | ≤ 200 µg/mL  |
| Approved method of administration           | <b>Intravenous</b>   |

\*Refrigerated temperatures considered 36-46° F (2-8°C) and room temperature is up to 77°F (up to 25°C). Do not use any product past its printed expiration date. DO NOT FREEZE any product and do not use product that has been frozen. Check the package insert for detailed information. Information for each of the products listed above has been provided directly to IDF by the manufacturer.

## Product name Bivigam

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|   |  |
|---|--|
| Manufacturer                                | ADMA Biologics   |
| Method of production                        | Modified classical Cohn Method 6 / Oncley Method 9 fractionation procedure. Contains 100 ± 10 mg/mL protein, of which not less than 96% is human immunoglobulin obtained from source human plasma. |
| Form  | Liquid   |
| Shelf-life/Storage requirement*             | Refrigerated until the expiration date.<br>Room temperature 1 month.   |
| Available concentrations                    | 10% IgG  |
| Maximum number of SCIG infusion sites       | N/A  |
| Maximum recommended infusion rate/or volume | 6 mg/kg/min (0.06 mL/kg/min)   |
| Stabilizers and other ingredients           | 0.20-0.29 M glycine<br>0.15-0.25% polysorbate 80   |
| Sugar content                               | No added sugars  |
| Sodium content                              | 0.100 - 0.140 M sodium chloride  |
| Osmolarity/ Osmolality                      | 370 - 510 mOsm/kg  |
| pH  | 4.0 - 4.6  |
| IgA content                                 | ≤ 200 µg/mL (average- 72 µg/mL)  |
| Approved method of administration           | <b>Intravenous</b>   |

\*Refrigerated temperatures considered 36-46° F (2-8°C) and room temperature is up to 77°F (up to 25°C). Do not use any product past its printed expiration date. DO NOT FREEZE any product and do not use product that has been frozen. Check the package insert for detailed information. Information for each of the products listed above has been provided directly to IDF by the manufacturer.

## Product name Cutaquig

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|   |   |
|---|---|
| Manufacturer                                | Octapharma  |
| Method of production                        | Cold ethanol fractionation process followed by ultrafiltration and chromatography. The manufacturing process includes treatment with an organic solvent detergent mixture composed of tri-n-butyl phosphate (TNBP) and Octoxynol. Process steps include pH 4 treatment. |
| Form  | Liquid  |
| Shelf-life/Storage requirement*             | Refrigerated up to 36 months from date of manufacture. Room temperature up to 6 months.   |
| Available concentrations                    | 16.50% IgG  |
| Maximum number of SCIG infusion sites       | up to 6, with at least 2 inches between sites   |
| Maximum recommended infusion rate/or volume | 40 mL/site at 52 mL/hour/site (for adults ≥17 years)<br>29 mL/site at 25 mL/hour/site (for ages 7-17 years)<br>15.5 mL/site at 25 mL/hour/site (for ages 2-6 years)   |
| Stablizers and other ingredients            | None  |
| Sugar content                               | 79 mg/mL maltose  |
| Sodium content                              | ≤30 mmol/L  |
| Osmolarity/ Osmolality                      | 310 - 380 mOsm/kg   |
| pH  | 5.0 - 5.5   |
| IgA content                                 | 206 µg/mL (average)   |
| Approved method of administration           | Subcutaneous  |

\*Refrigerated temperatures considered 36-46° F (2-8°C) and room temperature is up to 77°F (up to 25°C). Do not use any product past its printed expiration date. DO NOT FREEZE any product and do not use product that has been frozen. Check the package insert for detailed information. Information for each of the products listed above has been provided directly to IDF by the manufacturer.

## Product Name Cuvitru

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|   |  |
|---|--|
| Manufacturer                                | Takeda   |
| Method of production                        | Modified Cohn-Oncley cold ethanol fractionation, as well as cation and anion-exchange chromatography, solvent detergent treatment, 35 nm nanofiltration, low pH / elevated temperature incubation. |
| Form  | Liquid   |
| Shelf-life/Storage requirement*             | Refrigerated up to 36 months.<br>Room temperature for up to 24 months.   |
| Available concentrations                    | 20% IgG  |
| Maximum number of SCIG infusion sites       | up to 4, with at least 4 inches between sites  |
| Maximum recommended infusion rate/or volume | ≤60 mL/site at ≤60 mL/hour/site  |
| Stablizers and other ingredients            | 0.25M glycine  |
| Sugar content                               | No added sugars  |
| Sodium content                              | No added sodium  |
| Osmolarity/ Osmolality                      | 280 - 292 mOsm/kg  |
| pH  | 4.6 - 5.1  |
| IgA content                                 | 80 µg/mL (average)   |
| Approved method of administration           | Subcutaneous   |

\*Refrigerated temperatures considered 36-46° F (2-8°C) and room temperature is up to 77°F (up to 25°C). Do not use any product past its printed expiration date. DO NOT FREEZE any product and do not use product that has been frozen. Check the package insert for detailed information. Information for each of the products listed above has been provided directly to IDF by the manufacturer.

## Product name **Flebogamma DIF**

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|   |  |
|---|--|
| Manufacturer                                | Grifols  |
| Method of production                        | Cold ethanol fractionation, polyethylene glycol precipitation, ion exchange chromatography, low pH treatment, pasteurization, solvent detergent treatment, and Planova nanofiltration using 20 nanometer (nm) filters. |
| Form  | Liquid   |
| Shelf-life/Storage requirement*             | Room temperature for 24 months.  |
| Available concentrations                    | 5% IgG<br>10% IgG  |
| Maximum number of SCIG infusion sites       | N/A  |
| Maximum recommended infusion rate/or volume | 5 mg/kg/min (0.10 mL/kg/min)<br>8 mg/kg/min (0.08 mL/kg/min)   |
| Stablizers and other ingredients            | ≤ 3 mg/mL polyethylene glycol  |
| Sugar content                               | 50 mg/mL D-sorbitol  |
| Sodium content                              | Trace amounts  |
| Osmolarity/ Osmolality                      | 240-370 mOsm/kg  |
| pH  | 5.0 - 6.0  |
| IgA content                                 | <ul style="list-style-type: none"> <li>• &lt;50 µg/ mL</li> <li>• &lt;100 µg/ mL</li> </ul>  |
| Approved method of administration           | <b>Intravenous</b>   |

\*Refrigerated temperatures considered 36-46° F (2-8°C) and room temperature is up to 77°F (up to 25°C). Do not use any product past its printed expiration date. DO NOT FREEZE any product and do not use product that has been frozen. Check the package insert for detailed information. Information for each of the products listed above has been provided directly to IDF by the manufacturer.

## Product name Gammagard Liquid

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|   |  |
|---|--|
| Manufacturer                                | Takeda   |
| Method of production                        | Modified Cohn-Oncley cold ethanol fractionation, as well as cation and anion-exchange chromatography, solvent detergent treatment, 35 nm nanofiltration, low pH / elevated temperature incubation. |
| Form  | Liquid   |
| Shelf-life/Storage requirement*             | Refrigerated up to 36 months. Room temperature for up to 24 months.  |
| Available concentrations                    | 10% IgG  |
| Maximum number of SCIG infusion sites       | N/A<br>up to 8, with at least 2 inches between sites   |
| Maximum recommended infusion rate/or volume | 8 mg/kg/min (5 mL/kg/hr)<br>30 mL/site at 30mL/hour/site (≥40 kg body weight)<br>20 mL/site at 20 mL/hour/site (<40 kg body weight)  |
| Stablizers and other ingredients            | 0.25M glycine  |
| Sugar content                               | No added sugars  |
| Sodium content                              | No added sodium  |
| Osmolarity/ Osmolality                      | 240 - 300 mOsm/kg  |
| pH  | 4.6 - 5.1  |
| IgA content                                 | 37 µg/mL (average)   |
| Approved method of administration           | Intravenous, Subcutaneous  |

\*Refrigerated temperatures considered 36-46° F (2-8°C) and room temperature is up to 77°F (up to 25°C). Do not use any product past its printed expiration date. DO NOT FREEZE any product and do not use product that has been frozen. Check the package insert for detailed information. Information for each of the products listed above has been provided directly to IDF by the manufacturer.



## Product name Gammagard S/D

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|   |  |   |
|---|--|---|
| Manufacturer                                | Takeda   |   |
| Method of production                        | Cohn-Oncley cold ethanol fractionation process, as well as cation and anion exchange chromatography steps.   |   |
| Form  | Freeze-dried - Use within 2 hours if reconstitution is performed aseptically outside of a sterile laminar air flow hood or within 24 hours if performed aseptically inside of a sterile laminar flow hood and stored in the original glass container or pooled into ViaFlex bags under constant refrigeration. |   |
| Shelf-life/Storage requirement*             | Room temperature for up to 24 months   |   |
| Available concentrations                    | 5% IgG<br>10% IgG  |   |
| Maximum number of SCIG infusion sites       | N/A  |   |
| Maximum recommended infusion rate/or volume | 4 mL/kg/ hour<br>8 mL/kg/ hour   |   |
| Stablizers and other ingredients            | 3 mg/mL albumin<br>2 mg/mL polyethylene glycol (PEG)<br>1 µg/mL tri-n-butyl phosphate<br>Doubled for 10% IgG   | 22.5 mg/mL glycine<br>1 µg/mL octoxynol 9<br>100 µg/mL polysorbate 80 |
| Sugar content                               | 20 mg/mL glucose<br>40 mg/ml glucose   |   |
| Sodium content                              | 8.5 mg/mL sodium chloride<br>17 mg mL sodium chloride  |   |
| Osmolarity/ Osmolality                      | 636 mOsm/kg<br>1250 mOsm/L   |   |
| pH  | 6.8 ± 0.4  |   |
| IgA content                                 | ≤2.2 µg/mL ≤4.4µg/mL   |   |
| Approved method of admin                    | Intravenous  |   |

\*Refrigerated temperatures considered 36-46° F (2-8°C) and room temperature is up to 77°F (up to 25°C). Do not use any product past its printed expiration date. DO NOT FREEZE any product and do not use product that has been frozen. Check the package insert for detailed information. Information for each of the products listed above has been provided directly to IDF by the manufacturer.

## Product name Gammaked

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|   |  |
|---|--|
| Manufacturer                                | Kedrion  |
| Method of production                        | Combination of cold ethanol fractionation, caprylate precipitation and filtration, and anion-exchange chromatography. Isotonicity is achieved by the addition of glycine.                                    |
| Form  | Liquid   |
| Shelf-life/Storage requirement*             | Refrigerated for up to 36 months from the date of manufacture.<br>Room temperature for up to 6 months.   |
| Available concentrations                    | 10% IgG  |
| Maximum number of SCIG infusion sites       | <ul style="list-style-type: none"> <li>• N/A</li> <li>• up to 8, with at least 2 inches between sites (18+ years old)</li> <li>• up to 6, with at least 2 inches between sites (&lt;18 years old)</li> </ul> |
| Maximum recommended infusion rate/or volume | <p>8 mg/kg/min (0.08 mL/kg/min)</p> <p>20 mL/hour/site (≥25 kg body weight)</p> <p>10mL/hour/site (&lt;25 kg body weight)</p>  |
| Stabilizers and other ingredients           | 0.16–0.24 M glycine<br>≤ 1.3 mmol/L capylate   |
| Sugar content                               | No added sugars  |
| Sodium content                              | No added sodium  |
| Osmolarity/ Osmolality                      | 258 mOsm/kg  |
| pH  | 4.0 - 4.5  |
| IgA content                                 | 46 µg/mL (average)   |
| Approved method of administration           | Intravenous, Subcutaneous  |

\*Refrigerated temperatures considered 36-46° F (2-8°C) and room temperature is up to 77°F (up to 25°C). Do not use any product past its printed expiration date. DO NOT FREEZE any product and do not use product that has been frozen. Check the package insert for detailed information. Information for each of the products listed above has been provided directly to IDF by the manufacturer.

## Product name **Gammaplex**

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|   |  |
|---|--|
| Manufacturer                                | Kedrion  |
| Method of production                        | Cold ethanol fractionation and ion exchange chromatography.                                      |
| Form  | Liquid   |
| Shelf-life/Storage requirement*             | Room temperature for up to 36 months   |
| Available concentrations                    | 5% IgG<br>10% IgG  |
| Maximum number of SCIG infusion sites       | N/A<br>4 mg/kg/min (0.08 mL/kg/min)<br>8 mg/kg/min (0.08 mL/kg/min)                              |
| Maximum recommended infusion rate/or volume | 6 mg/mL glycine      50 µg/mL polysorbate 80<br>200-300 mM glycine    10-60 µg/mL polysorbate 80 |
| Stablizers and other ingredients            | 50 mg/mL D sorbitol<br>No added sugars   |
| Sugar content                               | 2 mg/mL sodium acetate<br>3 mg/mL sodium chloride  |
| Sodium content                              | <30 m acetate<br><30 m sodium chloride   |
| Osmolarity/ Osmolality                      | 460 - 500 mOsm/kg<br>240 - 280 mOsmol/kg   |
| pH  | 4.8 - 5.1                      4.9 - 5.2   |
| IgA content                                 | < 10 µ/mL                      < 20 µg/ml  |
| Approved method of administration           | <b>Intravenous</b>   |

\*Refrigerated temperatures considered 36-46° F (2-8°C) and room temperature is up to 77°F (up to 25°C). Do not use any product past its printed expiration date. DO NOT FREEZE any product and do not use product that has been frozen. Check the package insert for detailed information. Information for each of the products listed above has been provided directly to IDF by the manufacturer.

## Product name Gamunex - C

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|   |   |
|---|---|
| Manufacturer                                | Grifols   |
| Method of production                        | Combination of cold ethanol fractionation, caprylate precipitation and filtration, and anion-exchange chromatography. Isotonicity is achieved by the addition of glycine. |
| Form  | Liquid  |
| Shelf-life/Storage requirement*             | Refrigerated up to 36 months.<br>Room temperature up to 6 months.   |
| Available concentrations                    | 10% IgG   |
| Maximum number of SCIG infusion sites       | N/A<br>up to 8, with at least 2 inches between sites (18+ years old)<br>up to 6, with at least 2 inches between sites (<18 years old)                                     |
| Maximum recommended infusion rate/or volume | 8 mg/kg/min<br>20 mL/hour/site (≥25 kg body weight)<br>10mL/hour/site (<25 kg body weight)  |
| Stabilizers and other ingredients           | 0.16–0.24 M glycine<br>≤1.3 mmol/L caprylat e   |
| Sugar content                               | No added sugars   |
| Sodium content                              | No added sodium   |
| Osmolarity/ Osmolality                      | 258 mOsm/kg   |
| pH  | 4.0 - 4.5   |
| IgA content                                 | 46 µg/mL (average)  |
| Approved method of administration           | Intravenous, Subcutaneous   |

\*Refrigerated temperatures considered 36-46° F (2-8°C) and room temperature is up to 77°F (up to 25°C). Do not use any product past its printed expiration date. DO NOT FREEZE any product and do not use product that has been frozen. Check the package insert for detailed information. Information for each of the products listed above has been provided directly to IDF by the manufacturer.

## Product name Hizentra

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|   |  |
|---|--|
| Manufacturer                                | CSL Behring  |
| Method of production                        | Combination of cold alcohol fractionation, octanoic acid fractionation, and anion exchange chromatography. |
| Form  | Liquid   |
| Shelf-life/Storage requirement*             | Room temperature for up to 30 months   |
| Available concentrations                    | 20% IgG  |
| Maximum number of SCIG infusion sites       | up to 8, with at least 2 inches between sites  |
| Maximum recommended infusion rate/or volume | 25 mL/site at 25mL/hour/site   |
| Stablizers and other ingredients            | 210-290 mmol/L L-proline<br>8-30 mg/L polysorbate 80   |
| Sugar content                               | No added sugars  |
| Sodium content                              | Trace amounts  |
| Osmolarity/ Osmolality                      | 380 mOsmol/kg  |
| pH  | 4.6 - 5.2  |
| IgA content                                 | ≤50 µg/mL  |
| Approved method of administration           | Subcutaneous   |

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## Product name Hyqvia<sup>3</sup>

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|   |   |
|---|---|
| Manufacturer                                | Takeda  |
| Method of production                        | Modified Cohn-Oncley cold ethanol fractionation process, as well as cation and anion exchange chromatography.<br>Recombinant hyaluronidase produced from genetically engineered Chinese Hamster Ovary (CHO) cells containing a DNA plasmid encoding for a soluble fragment of human hyaluronidase PH20. |
| Form  | Liquid  |
| Shelf-life/Storage requirement*             | Refrigerated up to 36 months. Room temperature for up to 3 months in first 24 months after manufacturing date.  |
| Available concentrations                    | 10% IgG      160 U/mL recombinant human hyaluronidase   |
| Maximum number of SCIG infusion sites       | Up to 2, on opposite sides of the body  |
| Maximum recommended infusion rate/or volume | 600 mL/site at 300 mL/hour/site (≥40 kg body weight)<br>300 mL/site at 160 mL/hour/site (<40 kg body weight)  |
| Stabilizers and other ingredients           | 0.25M glycine<br>1.0 mg/mL human albumin<br>0.40 mg/mL calcium chloride dihydrate   |
| Sugar content                               | No added sugars   |
| Sodium content                              | No added sodium<br>8.5 mg/mL sodium chloride<br>1.78 mg/mL sodium phosphate dibasic dihydrate<br>1.0 mg/mL edentate disodium dihydrate<br>0.17 mg/mL sodium hydroxide   |
| Osmolarity/ Osmolality                      | 240-300 mOsm/kg<br>290-350 mOsm.kg  |
| pH  | 4.6-5.1      7.4  |
| IgA content                                 | 37 µg/mL (average)  |
| Approved method of administration           | Subcutaneous (facilitated)  |

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## Product name Octagam

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|   |  |
|---|--|
| Manufacturer                                | Octapharma   |
| Method of production                        | Cold ethanol fractionation process followed by ultrafiltration and chromatography. The manufacturing process includes treatment with an organic S/D mixture composed of tri-n-butyl phosphate (TNBP) and Triton X-100 (Octoxynol). Process steps include pH 4 treatment. |
| Form  | Liquid   |
| Shelf-life/Storage requirement*             | Refrigerated for up to 36 months from the date of manufacture.<br>Room temperature storage is okay within first 24 months<br>Refrigerated for up to 36 months from the date of manufacture.<br>Room temperature up to 9 months.  |
| Available concentrations <sup>^</sup>       | 5% IgG<br>10% IgG  |
| Maximum number of SCIG infusion sites       | N/A  |
| Maximum recommended infusion rate/or volume | <ul style="list-style-type: none"> <li>• 3.33 mg/kg/min (0.07 mL/kg/min)</li> <li>• 12.0 mg/kg/min (0.12 mL/kg/min)</li> </ul>   |
| Stablizers and other ingredients            | <5 µg/mL tri-n-butyl phosphate (TNBP)<br><1 µg/mL Triton X-100<br>None   |
| Sugar content                               | 100 mg/mL maltose<br>90 mg/mL maltose  |
| Sodium content                              | ≤30 mmol/L   |
| Osmolarity/ Osmolality                      | 310 - 380 mOsm/kg  |
| pH  | <ul style="list-style-type: none"> <li>• 5.1 - 6.0</li> <li>• 4.5 - 5.0</li> </ul>   |
| IgA content                                 | <ul style="list-style-type: none"> <li>• ≤ 200 µg/mL</li> <li>• 106 µg/mL (average)</li> </ul>   |
| Approved method of administration           | Intravenous  |

\*Refrigerated temperatures considered 36-46° F (2-8°C) and room temperature is up to 77°F (up to 25°C). Do not use any product past its printed expiration date. DO NOT FREEZE any product and do not use product that has been frozen.

<sup>^</sup> Octagam 10% is approved for chronic idiopathic thrombocytopenic purpura and dermatomyositis.

Check the package insert for detailed information.

## Product name Panzyga

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|   |   |
|---|---|
| Manufacturer                                | Octapharma  |
| Method of production                        | Cold ethanol fractionation process followed by purification methodologies, as well as S/D treatment and nanofiltration (20 nm). The S/D mixture used is composed of tri-n-butyl phosphate (TNBP, solvent) and Triton X-100 (Octoxynol, detergent). Process steps include ion-exchange chromatography. |
| Form  | Liquid  |
| Shelf-life/Storage requirement*             | Refrigerated for up to 36 months from the date of manufacture.<br>Room temperature for up to 12 months.   |
| Available concentrations                    | 10% IgG   |
| Maximum number of SCIG infusion sites       | N/A   |
| Maximum recommended infusion rate/or volume | 14 mg/kg/min (0.14 mL/kg/min)   |
| Stabilizers and other ingredients           | 15.0-19.5 mg/mL glycine   |
| Sugar content                               | No added sugars   |
| Sodium content                              | Trace amounts   |
| Osmolarity/ Osmolality                      | 240 - 310 mOsmol/kg   |
| pH  | 4.5 - 5.0   |
| IgA content                                 | 100 µ/mL (average)  |
| Approved method of administration           | <b>Intravenous</b>  |

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## Product name Privigen

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|   |   |
|---|---|
| Manufacturer                                | CSL Behring   |
| Method of production                        | Cold ethanol fractionation, octanoic acid fractionation, and anion exchange chromatography. The IgG proteins are not subjected to heating or to chemical or enzymatic modification. The manufacturing process includes immunoaffinity chromatography step to specifically reduce blood group A and B antibodies (isoagglutinins A and B). |
| Form  | Liquid  |
| Shelf-life/Storage requirement*             | Room temperature for up to 36 months.   |
| Available concentrations                    | 10% IgG   |
| Maximum number of SCIG infusion sites       | N/A   |
| Maximum recommended infusion rate/or volume | 8 mg/kg/min (0.08 mL/kg/min)  |
| Stabilizers and other ingredients           | 210 to 290 mmol/L L-proline   |
| Sugar content                               | No added sugars   |
| Sodium content                              | Trace amounts   |
| Osmolarity/ Osmolality                      | 240-440 mOsm/kg   |
| pH  | 4.6-5.0   |
| IgA content                                 | ≤25 µg/mL   |
| Approved method of administration           | <b>Intravenous</b>  |

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## Product name Xembify

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|   |  |
|---|--|
| Manufacturer                                | Grifols  |
| Method of production                        | Cold ethanol fractionation, caprylate precipitation and filtration, anion-exchange chromatography. Isotonicity is achieved by the addition of glycine. |
| Form  | Liquid   |
| Shelf-life/Storage requirement*             | Refrigerated storage until date of expiration.<br>Room temperature for up to 6 months.   |
| Available concentrations                    | 20% IgG  |
| Maximum number of SCIG infusion sites       | up to 6, with at least 2 inches between sites  |
| Maximum recommended infusion rate/or volume | 25 mL/hour at 25 mL/hour/site  |
| Stablizers and other ingredients            | 0.16 M - 0.26 M glycine<br>10 to 40 µg/mL polysorbate 80   |
| Sugar content                               | No added sugars  |
| Sodium content                              | No added sodium  |
| Osmolarity/ Osmolality                      | 280 - 404 mOsm/kg  |
| pH  | 4.1 - 4.8  |
| IgA content                                 | ≤70 µg/mL  |
| Approved method of administration           | Subcutaneous   |

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| Product          | Manufacturer  | Approved administration method | Method of production  | Form         |
|------------------|---|--------------------------------|---|--------------|
| Asceniv          | ADMA Biologics  | Intravenous                    | Modified classical Cohn Method 6 / Oncley Method 9 fractionation procedure. Contains 100 ± 10 mg/mL protein, of which not less than 96% is human immunoglobulin obtained from source human plasma.  | Liquid       |
| Bivigam          | ADMA Biologics  | Intravenous                    | Modified classical Cohn Method 6 / Oncley Method 9 fractionation procedure. Contains 100 ± 10 mg/mL protein, of which not less than 96% is human immunoglobulin obtained from source human plasma.  | Liquid       |
| Cutaquig         | Octapharma  | Subcutaneous                   | Cold ethanol fractionation process followed by ultrafiltration and chromatography. The manufacturing process includes treatment with an organic solvent detergent mixture composed of tri-n-butyl phosphate (TNBP) and Octoxynol. Process steps include pH 4 treatment.   | Liquid       |
| Cuvitru          | Takeda  | Subcutaneous                   | Modified Cohn-Oncley cold ethanol fractionation, as well as cation and anion-exchange chromatography, solvent detergent treatment, 35 nm nanofiltration, low pH / elevated temperature incubation.  | Liquid       |
| Flebogamma DIF   | Grifols   | Intravenous                    | Cold ethanol fractionation, polyethylene glycol precipitation, ion exchange chromatography, low pH treatment, pasteurization, solvent detergent treatment, and Planova nanofiltration using 20 nm filters.  | Liquid       |
| Gammagard Liquid | Takeda  | Intravenous                    | Modified Cohn-Oncley cold ethanol fractionation, as well as cation and anion-exchange chromatography, solvent detergent treatment, 35 nm nanofiltration, low pH / elevated temperature incubation.  | Liquid       |
|                  |   | Subcutaneous                   |   |              |
| Gammagard S/D    | Takeda  | Intravenous                    | Cohn-Oncley cold ethanol fractionation process, as well as cation and anion exchange chromatography steps.  | Freeze-dried |
| Gammaked         | Kedrion   | Intravenous                    | Combination of cold ethanol fractionation, caprylate precipitation and filtration, and anion-exchange chromatography. Isotonicity is achieved by the addition of glycine.   | Liquid       |
|                  |   | Subcutaneous                   |   |              |
| Gammaplex        | Kedrion   | Intravenous                    | Cold ethanol fractionation and ion exchange chromatography.   | Liquid       |
| Gamunex - C      | Grifols   | Intravenous                    | Combination of cold ethanol fractionation, caprylate precipitation and filtration, and anion-exchange chromatography. Isotonicity is achieved by the addition of glycine.   | Liquid       |
|                  |   | Subcutaneous                   |   |              |
| Hizentra         | CSL Behring   | Subcutaneous                   | Combination of cold alcohol fractionation, octanoic acid fractionation, and anion exchange chromatography.  | Liquid       |
| Hyqvia           | Takeda  | Subcutaneous (facilitated)     | Modified Cohn-Oncley cold ethanol fractionation process, as well as cation and anion exchange chromatography.   | Liquid       |
|                  |   |                                | Recombinant hyaluronidase produced from genetically engineered Chinese Hamster Ovary (CHO) cells containing a DNA plasmid encoding for a soluble fragment of human hyaluronidase PH20.  |              |
| Octagam          | Octapharma  | Intravenous                    | Cold ethanol fractionation process followed by ultrafiltration and chromatography. The manufacturing process includes treatment with an organic S/D mixture composed of tri-n-butyl phosphate (TNBP) and Triton X-100 (Octoxynol). Process steps include pH 4 treatment.  | Liquid       |
| Panzyga          | Octapharma  | Intravenous                    | Cold ethanol fractionation process followed by purification methodologies, as well as S/D treatment and nanofiltration (20 nm). The S/D mixture used is composed of tri-n-butyl phosphate (TNBP, solvent) and Triton X-100 (Octoxynol, detergent). Process steps include ion-exchange chromatography.                                     | Liquid       |
| Privigen         | CSL Behring   | Intravenous                    | Cold ethanol fractionation, octanoic acid fractionation, and anion exchange chromatography. The IgG proteins are not subjected to heating or to chemical or enzymatic modification. The manufacturing process includes immunoaffinity chromatography step to specifically reduce blood group A and B antibodies (isoagglutinins A and B). | Liquid       |
| Xembify          | Grifols   | Subcutaneous                   | Cold ethanol fractionation, caprylate precipitation and filtration, anion-exchange chromatography. Isotonicity is achieved by the addition of glycine.  | Liquid       |
| Notes:           | <p>*Refrigerated temperatures considered 36-46° F (2-8°C) and room temperature is up to 77°F (up to 25°C). Do not use any product past its printed expiration date. DO NOT FREEZE any product and do not use product that has been frozen.</p> <p>Check the package insert for detailed information.<br/>Information for each of the products listed above has been provided directly to IDF by the manufacturer.</p> |                                |   |              |

| Product          | Shelf-life/Storage requirement*  | Available concentrations                 | Maximum number of SCIG infusion sites  | Maximum recommended infusion rate and/or volume   |
|------------------|--|--|--|---|
| Asceniv          | Refrigerated for up to 36 months. Room temperature for up to 1 month.  | 10% IgG                                  | N/A  | 8 mg/kg/min (0.08 mL/kg/min)  |
| Bivigam          | Refrigerated until the expiration date. Room temperature up to 1 month.  | 10% IgG                                  | N/A  | 6 mg/kg/min (0.06 mL/kg/min)  |
| Cutaquig         | Refrigerated up to 36 months from date of manufacture. Room temperature up to 6 months.  | 16.5% IgG                                | up to 6, with at least 2 inches between sites  | 40 mL/site at 52 mL/hour/site (for adults ≥17 years)<br>29 mL/site at 25 mL/hour/site (for ages 7-17 years)<br>15.5 mL/site at 25 mL/hour/site (for ages 2-6 years) |
| Cuvitru          | Refrigerated up to 36 months. Room temperature for up to 24 months.  | 20% IgG                                  | up to 4, with at least 4 inches between sites  | ≤60 mL/site at ≤60 mL/hour/site   |
| Flebogamma DIF   | Room temperature for 24 months.  | 5% IgG                                   | N/A  | 5 mg/kg/min (0.10 mL/kg/min)  |
|                  |  | 10% IgG                                  |  | 8 mg/kg/min (0.08 mL/kg/min)  |
| Gammagard Liquid | Refrigerated up to 36 months. Room temperature for up to 24 months.  | 10% IgG                                  | N/A  | 8 mg/kg/min (5 mL/kg/hr)  |
|                  |  |  | up to 8, with at least 2 inches between sites  | 30 mL/site at 30mL/hour/site (≥40 kg body weight)<br>20 mL/site at 20 mL/hour/site (<40 kg body weight)   |
| Gammagard S/D    | Room temperature for up to 24 months.<br><br>Use within 2 hours if reconstitution is performed aseptically outside of a sterile laminar air flow hood or within 24 hours if performed aseptically inside of a sterile laminar flow hood and stored in the original glass container or pooled into ViaFlex bags under constant refrigeration. | 5% IgG                                   | N/A  | 4 mL/kg/hour  |
|                  |  | 10% IgG                                  |  | 8 mL/kg/hour  |
|                  | Refrigerated for up to 36 months from the date of manufacture. Room temperature for up to 6 months.  | 10% IgG                                  | N/A  | 8 mg/kg/min (0.08 mL/kg/min)  |
| Gammaked         | Room temperature for up to 36 months.  | 5% IgG                                   | N/A  | 4 mg/kg/min (0.08 mL/kg/min)  |
|                  |  | 10% IgG                                  |  | 8 mg/kg/min (0.08 mL/kg/min)  |
| Gammaplex        | Refrigerated up to 36 months. Room temperature up to 6 months.   | 10% IgG                                  | N/A  | 8 mg/kg/min   |
|                  |  |  | up to 8, with at least 2 inches between sites (18+ years old)<br>up to 6, with at least 2 inches between sites (<18 years old) | 20 mL/hour/site (≥25 kg body weight)<br>10mL/hour/site (<25 kg body weight)   |
| Gamunex - C      | Room temperature for up to 30 months.  | 20% IgG                                  | up to 8, with at least 2 inches between sites  | 25 mL/site at 25 mL/hour/site   |
| Hizentra         | Refrigerated up to 36 months. Room temperature for up to 3 months in first 24 months after manufacturing date.   | 10% IgG                                  | up to 2, on opposite sides of the body   | 600 mL/site at 300 mL/hour/site (≥40 kg body weight)<br>300 mL/site at 160 mL/hour/site (<40 kg body weight)  |
|                  |  | 160 U/mL recombinant human hyaluronidase |  |   |
| Hyqvia           | Refrigerated for up to 36 months from the date of manufacture. Room temperature storage is okay within first 24 months.  | 5% IgG                                   | N/A  | 3.33 mg/kg/min (0.07 mL/kg/min)   |
| Octagam          | Refrigerated for up to 36 months from the date of manufacture. Room temperature up to 9 months.  | 10% IgG <sup>^</sup>                     |  | 12.0 mg/kg/min (0.12 mL/kg/min) <sup>^</sup>  |
| Panzyga          | Refrigerated for up to 36 months from the date of manufacture. Room temperature for up to 12 months.   | 10% IgG                                  | N/A  | 14 mg/kg/min (0.14 mL/kg/min)   |
| Privigen         | Room temperature for up to 36 months.  | 10% IgG                                  | N/A  | 8 mg/kg/min (0.08 mL/kg/min)  |
| Xembify          | Refrigerated storage until date of expiration. Room temperature for up to 6 months.  | 20% IgG                                  | up to 6, with at least 2 inches between sites  | 25 mL/site at 25 mL/hour/site   |

| Product          | Stabilizers and other ingredients  | Sugar content       | Sodium content   | Osmolarity/ Osmolality | pH        | IgA content             |
|------------------|--|---------------------|--|------------------------|-----------|-------------------------|
| Asceniv          | 0.20-0.29 M glycine<br>0.15–0.25% polysorbate 80   | No added sugars     | 0.100-0.140 M sodium chloride  | 370 - 510 mOsm/kg      | 4.0 - 4.6 | <200 µg/mL              |
| Bivigam          | 0.20-0.29 M glycine<br>0.15–0.25% polysorbate 80   | No added sugars     | 0.100 - 0.140 M sodium chloride  | 370 - 510 mOsm/kg      | 4.0 - 4.6 | <200 µg/mL              |
| Cutaquig         | None   | 79 mg/mL maltose    | ≤30 mmol/L   | 310 - 380 mOsm/kg      | 5.0 - 5.5 | 206 µg/mL (average)     |
| Cuvitru          | 0.25 M glycine   | No added sugars     | No added sodium  | 280 - 292 mOsm/kg      | 4.6 - 5.1 | 80 µg/mL (average)      |
| Flebogamma DIF   | ≤ 3 mg/mL polyethylene glycol  | 50 mg/mL D-sorbitol | Trace amounts  | 240 - 370 mOsm/kg      | 5.0 - 6.0 | <50 µg/mL<br><100 µg/mL |
| Gammagard Liquid | 0.25 M glycine   | No added sugars     | No added sodium  | 240 - 300 mOsm/kg      | 4.6 - 5.1 | 37 µg/mL (average)      |
| Gammagard S/D    | 3 mg/mL albumin<br>22.5 mg/mL glycine<br>2 mg/mL polyethylene glycol (PEG)<br>1 µg/mL tri-n-butyl phosphate<br>1 µg/mL octoxynol 9<br>100 µg/mL polysorbate 80 | 20 mg/ml glucose    | 8.5 mg/mL sodium chloride  | 636 mOsm/kg            | 6.8 ± 0.4 | ≤2.2 µg/mL              |
|                  | 6 mg/mL albumin<br>45 mg/mL glycine<br>4 mg/mL polyethylene glycol (PEG)<br>2 µg/mL tri-n-butyl phosphate<br>2 µg/mL octoxynol 9<br>200 µg/mL polysorbate 80   | 40 mg/ml glucose    | 17 mg/mL sodium chloride   | 1250 mOsm/L            |           | ≤4.4 µg/mL              |
| Gammaked         | 0.16–0.24 M glycine<br>≤1.3 mmol/L caprylate   | No added sugars     | No added sodium  | 258 mOsm/kg            | 4.0 - 4.5 | 46 µg/mL (average)      |
| Gammaplex        | 6 mg/mL glycine<br>50 µg/mL polysorbate 80   | 50 mg/mL D-sorbitol | 2 mg/mL sodium acetate<br>3 mg/mL sodium chloride  | 460 - 500 mOsm/kg      | 4.8 - 5.1 | < 10 µg/mL              |
|                  | 200-300 mM glycine<br>10-60 µg/mL polysorbate 80   | No added sugars     | <30 mM acetate<br><30 mM sodium chloride   | 240-280 mOsm/kg        | 4.9 - 5.2 | < 20 µg/mL              |
| Gamunex - C      | 0.16–0.24 M glycine<br>≤1.3 mmol/L caprylate   | No added sugars     | No added sodium  | 258 mOsm/kg            | 4.0 - 4.5 | 46 µg/mL (average)      |
| Hizentra         | 210-290 mmol/L L-proline<br>8-30 mg/L polysorbate 80   | No added sugars     | Trace amounts  | 380 mOsm/kg            | 4.6 - 5.2 | ≤50 µg/mL               |
| Hyqvia           | 0.25 M glycine   | No added sugars     | No added sodium  | 240-300 mOsm/kg        | 4.6 - 5.1 | 37 µg/mL (average)      |
|                  | 1.0 mg/mL human albumin<br>0.40 mg/mL calcium chloride dihydrate   |                     | 8.5 mg/mL sodium chloride<br>1.78 mg/mL sodium phosphate dibasic dihydrate<br>1.0 mg/mL edentate disodium dihydrate<br>0.17 mg/mL sodium hydroxide | 290-350 mOsm/kg        | 7.4       |                         |
| Octagam          | <5 µg/mL tri-n-butyl phosphate (TNBP)<br><1 µg/mL Triton X-100   | 100 mg/mL maltose   | ≤30 mmol/L   | 310 - 380 mOsm/kg      | 5.1 - 6.0 | ≤ 200 µg/mL             |
|                  | None   | 90 mg/mL maltose    |  |                        | 4.5 - 5.0 | 106 µg/mL (average)     |
| Panzyga          | 15.0-19.5 mg/mL glycine  | No added sugars     | Trace amounts  | 240 - 310 mOsm/kg      | 4.5 - 5.0 | 100 µg/mL (average)     |
| Privigen         | 210-290 mmol/L L-proline   | No added sugars     | Trace amounts  | 240-440 mOsm/kg        | 4.6-5.0   | ≤25 µg/mL               |
| Xembify          | 0.16 M - 0.26 M glycine<br>10-40 µg/mL polysorbate 80  | No added sugars     | No added sodium  | 280 - 404 mOsm/kg      | 4.1 - 4.8 | ≤70 µg/mL               |