Characteristics of Immunoglobulin Products Used to Treat Primary Immunodeficiencies (PI)

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Immunoglobulin Products Quick Links

Click on a product to learn more about its characteristics.

■ Intravenous
■ Subcutaneous

Product Name ASCENIV

Manufacturer	ADMA Biologics
Method of Production	Modified classical Cohn Method 6 / Oncley Method 9 fractionation procedure. Precipitation and removal of fraction III of the cold ethanol process, solvent/detergent treatment, 35 nm nanofiltration
Form	Liquid
Shelf-Life/Storage Requirement	Refrigerate between 2 to 8°C (36 to 46°F) until expiration date
Reconstitution Time	N/A
Available Concentrations	10% IgG (100 mg/mL)
Maximum Recommended Infusion Rate	4.8 mL/kg/hour
Time to Infuse 35 gms[1]	Time will vary depending upon volume and patient tolerability
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	**Intravenous**

[1] 0.5 gm/kg for a 70 kg adult = 35 gms; 5% Concentrations: 1g = 20 mL; 10% Concentrations: 1g = 10 mL.

The time to infuse is based on the maximal infusion rate. Check product label for storage temperatures, which vary among immunoglobulin products. Check package insert for detailed prescribing information. Information for each of the products listed above has been provided directly to IDF by the manufacturer of that product.

Product Name Bivigam

Manufacturer	ADMA Biologics
Method of Production	Modified classical Cohn Method 6 / Oncley Method 9 fractionation procedure. Precipitation and removal of fraction III of the cold ethanol process, solvent/detergent treatment, 35 nm nanofiltration
Form	Liquid
Shelf-Life/Storage Requirement	Refrigerate between 2 to 8°C (36 to 46°F) until expiration date
Reconstitution Time	N/A
Available Concentrations	10% IgG (100 mg/mL)
Maximum Recommended Infusion Rate	3.6 mL/kg/hour
Time to Infuse 35 gms[1]	Time will vary depending upon volume and patient tolerability
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	**Intravenous**

[1] 0.5 gm/kg for a 70 kg adult = 35 gms; 5% Concentrations: 1g = 20 mL; 10% Concentrations: 1g = 10 mL.
The time to infuse is based on the maximal infusion rate. Check product label for storage temperatures, which vary among immunoglobulin products. Check package insert for detailed prescribing information. Information for each of the products listed above has been provided directly to IDF by the manufacturer of that product.

Product Name Cutaquig

Manufacturer	Octapharma
Method of Production	Cohn-Oncley cold ethanol fractionation, ultrafiltration, chromatography, solvent/ detergent treatment, low pH incubation
Form	Liquid
Shelf-Life/Storage Requirement	24 Months (refrigerated) 6 Months (room temperature up to 25°C or 77°F)
Reconstitution Time	None (Liquid solution)
Available Concentrations	16.50%
Maximum Recommended Infusion Rate	Up to 100 mL/hr/ all sites combined. First 6 infusions: ≤ 20 mL/hr/site (30 mL/hr/all sites combined). Subsequent infusions: 25 mL/hr/site (Up to 100 mL/hr/all sites combined) Subsequent infusions may gradually increase to 50 mL, then to 80 mL; if well tolerated, use a max of 100 mL/hr/all sites combined
Time to Infuse 35 gms[1]	Time will vary based upon patient tolerability
Sugar Content	79 mg/mL Maltose
Sodium Content	≤30 mmol/L
Osmolarity/ Osmolality	310 - 380 mOsm/kg
PH	5.0 - 5.5
IgA Content	≤0.6 mg/mL of IgA
Approved Method of Administration	**Subcutaneous**

[1] 0.5 gm/kg for a 70 kg adult = 35 gms; 5% Concentrations: 1g = 20 mL; 10% Concentrations: 1g = 10 mL.

The time to infuse is based on the maximal infusion rate. Check product label for storage temperatures, which vary among immunoglobulin products. Check package insert for detailed prescribing information. Information for each of the products listed above has been provided directly to IDF by the manufacturer of that product.

Product Name Cuvitru

Manufacturer	Takeda
Method of Production	Cohn-Oncley fractionation, ion-exhange chromatograph solvent/ detergent treatment, 35nm nanofiltration, low pH/ elevated temperature incubation
Form	Liquid
Shelf-Life/Storage Requirement	12 Months (room temperature storage not to exceed 25°C or 77°F)
Reconstitution Time	None (Liquid solution)
Available Concentrations	20%
Maximum Recommended Infusion Rate	First 2 Infusions: 10 - 20 mL/hr/site Subsequent Infusions: ≤60 mL/hr/site
Time to Infuse 35 gms[1]	Time will vary based upon patient tolerability
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
Approved Method of Administration	**Subcutaneous**

[1] 0.5 gm/kg for a 70 kg adult = 35 gms; 5% Concentrations: 1g = 20 mL; 10% Concentrations: 1g = 10 mL.

The time to infuse is based on the maximal infusion rate. Check product label for storage temperatures, which vary among immunoglobulin products. Check package insert for detailed prescribing information. Information for each of the products listed above has been provided directly to IDF by the manufacturer of that product.

Product Name Flebogamma DIF

Manufacturer	Grifols
Method of Production	Cold alcohol fractionation, polyethylene glycol precipitation, ion exchange chromatography, pH 4 treatment, pasteurization, solvent detergent treatment, and double sequential nanofiltration through 35 and 20 nm filters
Form	Liquid
Shelf-Life/Storage Requirement	24 Months (room temperature storage)
Reconstitution Time	None (Liquid solution)
Available Concentrations	• 5% • 10%
Maximum Recommended Infusion Rate	• 6.0 mL/kg/ hour • 4.8 mL/kg/ hour
Time to Infuse 35 gms[1]	• 1.6 hours • 1 hour
Sugar Content	None
Sodium Content	Trace amounts
Osmolarity/ Osmolality	240 - 370 mOsm/kg
PH	5.0 - 6.0
IgA Content	• Average: < 3 mcg/mL • Average: < 3 mcg/mL (Specification value: < 100 mcg/mL)
Approved Method of Administration	Intravenous

[1] 0.5 gm/kg for a 70 kg adult = 35 gms; 5% Concentrations: 1g = 20 mL; 10% Concentrations: 1g = 10 mL.

The time to infuse is based on the maximal infusion rate. Check product label for storage temperatures, which vary among immunoglobulin products. Check package insert for detailed prescribing information. Information for each of the products listed above has been provided directly to IDF by the manufacturer of that product.

Product Name Gammagard Liquid

Manufacturer	Takeda
Method of Production	Cohn-Oncley fractionation, ion-exhange chromatography solvent/ detergent treatment, 35nm nanofiltration, low pH/ elevated temperature incubation
Form	Liquid
Shelf-Life/Storage Requirement	36 Months (refrigerated) 24 Months (room temperature storage not to exceed 25°C or 77°F) 12 Months (room temperature storage not to exceed 25°C or 77°F)
Reconstitution Time	None (Liquid solution)
Available Concentrations	10%
Maximum Recommended Infusion Rate	• **5 mL/kg/hr (IV)** • **≥40 kg BW: 30 mL/site at 20-30mL/hour site. <40 kg BW: 20 mL/site at 15-20 mL/hour/site (SC)**
Time to Infuse 35 gms[1]	Time will vary based on tolerability and route of administration
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
Approved Method of Administration	**Intravenous**, **Subcutaneous**

[1] 0.5 gm/kg for a 70 kg adult = 35 gms; 5% Concentrations: 1g = 20 mL; 10% Concentrations: 1g = 10 mL.
The time to infuse is based on the maximal infusion rate. Check product label for storage temperatures, which vary among immunoglobulin products. Check package insert for detailed prescribing information. Information for each of the products listed above has been provided directly to IDF by the manufacturer of that product.

Product Name Gammagard S/D

Manufacturer	Takeda
Method of Production	Cohn-Oncley fractionation, ion-exchange chromatography, solvent detergent treatment
Form	Lyophilized
Shelf-Life/Storage Requirement	24 Months (room temperature storage)
Reconstitution Time	N/A
Available Concentrations	• 5% • 10%
Maximum Recommended Infusion Rate	• 4 mL/kg/ hour • 8 mL/kg/ hour
Time to Infuse 35 gms[1]	Time will vary based on concentration and tolerability
Sugar Content	• 20 mg/ml glucose • 40 mg/ml glucose
Sodium Content	• 8.5 mg/mL sodium chloride • 17 mg mL sodium chloride
Osmolarity/ Osmolality	• 636 mOsm/kg • 1250 mOsm/L
PH	6.8 ± 0.4
IgA Content	• ≤ 1 µg/mL ≤ 2.2 µg/mL • N/A
Approved Method of Administration	Intravenous

[1] 0.5 gm/kg for a 70 kg adult = 35 gms; 5% Concentrations: 1g = 20 mL; 10% Concentrations: 1g = 10 mL.
The time to infuse is based on the maximal infusion rate. Check product label for storage temperatures, which vary among immunoglobulin products. Check package insert for detailed prescribing information. Information for each of the products listed above has been provided directly to IDF by the manufacturer of that product.

Product Name Gammaked

Manufacturer	Kedrion
Method of Production	Cohn-Oncley fractionation, caprylate/chromatography purification, cloth and depth filtration, final container low pH incubation
Form	Liquid
Shelf-Life/Storage Requirement	36 Months
Reconstitution Time	None (Liquid solution)
Available Concentrations	10%
Maximum Recommended Infusion Rate	• **4.8 mL/kg/ hour (IV)** • **20 mL per hour (SC)**
Time to Infuse 35 gms[1]	Time will vary depending on route of administration
Sugar Content	None
Sodium Content	Trace amounts
Osmolarity/ Osmolality	258 mOsm/kg
PH	4.0 - 4.5
IgA Content	46 µg/mL
Approved Method of Administration	**Intravenous**, **Subcutaneous**

[1] 0.5 gm/kg for a 70 kg adult = 35 gms; 5% Concentrations: 1g = 20 mL; 10% Concentrations: 1g = 10 mL.
The time to infuse is based on the maximal infusion rate. Check product label for storage temperatures, which vary among immunoglobulin products. Check package insert for detailed prescribing information. Information for each of the products listed above has been provided directly to IDF by the manufacturer of that product.

Product Name Gammaplex

Manufacturer	Bio Products Laboratory
Method of Production	Kistler & Nitschmann fractionation, DEAESephadex chromatography, Solvent/detergent, CM-Sepharose chromatography, Virus Filration (20 nm) Terminal low pH incubation
Form	Liquid
Shelf-Life/Storage Requirement	36 months (room temperature storage)
Reconstitution Time	None (Liquid solution)
Available Concentrations	• 5% • 10%
Maximum Recommended Infusion Rate	4.8 mL/kg/hour
Time to Infuse 35 gms[1]	• 35 grams for 70kg person, 2 hrs 40 minutes if infused according to PI • For 70 kg person, 1 hr 53 minutes if infused according to PI
Sugar Content	• 5% D-sorbitol (polyol) • None
Sodium Content	• 30 - 50 mmol/L • < 30 mM
Osmolarity/ Osmolality	• 460 - 500 mOsm/kg • Typically, 280 mOsmol/kg
PH	• 4.6 - 5.1 • 4.9 - 5.2
IgA Content	• Average: <4 mcg/mL • Specification value: < 20 mcg/ml
Approved Method of Administration	Intravenous

[1] 0.5 gm/kg for a 70 kg adult = 35 gms; 5% Concentrations: 1g = 20 mL; 10% Concentrations: 1g = 10 mL.
The time to infuse is based on the maximal infusion rate. Check product label for storage temperatures, which vary among immunoglobulin products. Check package insert for detailed prescribing information. Information for each of the products listed above has been provided directly to IDF by the manufacturer of that product.

Product Name Gamunex - C

Manufacturer	Grifols
Method of Production	Cold ethanol fractionation, anion-exchange chromatography, caprylate chromatography purified, low pH incubation
Form	Liquid
Shelf-Life/Storage Requirement	6 months (room temperature); 36 months (refrigerated)
Reconstitution Time	None (Liquid solution)
Available Concentrations	10%
Maximum Recommended Infusion Rate	• **4.8 mL/kg/ hour (IV)** • **20 mL/hour/site (SC)**
Time to Infuse 35 gms[1]	Time will vary depending on route of administration
Sugar Content	None
Sodium Content	Trace amounts
Osmolarity/ Osmolality	258 mOsm/kg
PH	4.0 - 4.5
IgA Content	Average: 46 µg/mL
Approved Method of Administration	**Intravenous**, **Subcutaneous**

[1] 0.5 gm/kg for a 70 kg adult = 35 gms; 5% Concentrations: 1g = 20 mL; 10% Concentrations: 1g = 10 mL.

The time to infuse is based on the maximal infusion rate. Check product label for storage temperatures, which vary among immunoglobulin products. Check package insert for detailed prescribing information. Information for each of the products listed above has been provided directly to IDF by the manufacturer of that product.

Product Name Hizentra

Manufacturer	CSL Behring
Method of Production	Cold alcohol fractionation, octanoic acid fractionation, anion exchange chromatography; pH 4 incubation, depth filtration, nanofiltration; TSE reduction steps include octanoic acid fractionation, depth filtration, and virus filtration
Form	Liquid
Shelf-Life/Storage Requirement	30 Months (room temperature storage)
Reconstitution Time	None (Ready-to-use liquid solution)
Available Concentrations	20% (200 mg/mL)
Maximum Recommended Infusion Rate	Up to 25 mL/hr/injection site (50 mL/hr for all sites combined)
Time to Infuse 35 gms[1]	Time will vary depending upon volume and tolerability
Sugar Content	None
Sodium Content	Trace amounts (≤10 mmol/L)
Osmolarity/ Osmolality	380 mOsmol/kg
PH	4.6 - 5.2
IgA Content	Average: ≤50 mcg/mL
Approved Method of Administration	**Subcutaneous**

[1] 0.5 gm/kg for a 70 kg adult = 35 gms; 5% Concentrations: 1g = 20 mL; 10% Concentrations: 1g = 10 mL.

The time to infuse is based on the maximal infusion rate. Check product label for storage temperatures, which vary among immunoglobulin products. Check package insert for detailed prescribing information. Information for each of the products listed above has been provided directly to IDF by the manufacturer of that product.

Product Name HYQVIA[3]

Manufacturer	Takeda
Method of Production	IG 10% (Human) of HYQVIA: Cohn-Oncley fractionation, ion-exhange chromatography solvent/detergent treatment, 35nm nanofiltration, low pH/elevated temperature incubation recombinant human 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	36 Months (refrigerated) 3 Months[4] (room temperature storage not to exceed 25°C or 77°F)
Reconstitution Time	None (Liquid solution)
Available Concentrations	10%
Maximum Recommended Infusion Rate	< 40kg BW: maximum 160 mL/site > 40kg BW: maximum 300 mL/site
Time to Infuse 35 gms[1]	Time will vary based on patient tolerability
Sugar Content	No added sugars
Sodium Content	8.5 mg/mL sodium chloride in recombinant human hyaluronidase, no added sodium in IG 10%
Osmolarity/ Osmolality	240 - 300 mOsm/kg
PH	4.6 - 5.2
IgA Content	Average: 37 µg/mL
Approved Method of Administration	**Subcutaneous**

[1] 0.5 gm/kg for a 70 kg adult = 35 gms; 5% Concentrations: 1g = 20 mL; 10% Concentrations: 1g = 10 mL.

[3] HYQVIA is a dual vial unit containing 10% IgG (100 mg/mL) and 160 U/mL recombinant human hyaluronidase.

[4] Shorter room temperature shelf life of HYQVIA (3 months) compared to Gammagard Liquid (24 months) is due to the recombinant human hyaluronidase component of HYQVIA.

The time to infuse is based on the maximal infusion rate. Check product label for storage temperatures, which vary among immunoglobulin products. Check package insert for detailed prescribing information. Information for each of the products listed above has been provided directly to IDF by the manufacturer of that product.

Product Name Octagam

Manufacturer	Octapharma
Method of Production	Cohn-Oncley cold ethanol fractionation, ultra-filtration, chromatography, solvent detergent treatment
Form	Liquid
Shelf-Life/Storage Requirement	24 Months
Reconstitution Time	None (Liquid solution)
Available Concentrations	• 5% • 10%
Maximum Recommended Infusion Rate	• <4.2 mL/kg/hour • <7.2 mL/kg/hour
Time to Infuse 35 gms[1]	• 2.5 hours. Time can vary based on patient tolerability • 1.44 hours. Time can vary based on patient tolerability
Sugar Content	• 100 mg/ml. maltose • 90 mg/ml. maltose
Sodium Content	≤30 mmol/L
Osmolarity/ Osmolality	310 - 380 mOsm/kg
PH	• 5.1 - 6.0 • 4.5 - 5.0
IgA Content	• <100 µg/mL • Average of 106 µg/mL of IgA
Approved Method of Administration	Intravenous

[1] 0.5 gm/kg for a 70 kg adult = 35 gms; 5% Concentrations: 1g = 20 mL; 10% Concentrations: 1g = 10 mL.
The time to infuse is based on the maximal infusion rate. Check product label for storage temperatures, which vary among immunoglobulin products. Check package insert for detailed prescribing information. Information for each of the products listed above has been provided directly to IDF by the manufacturer of that product.

Product Name Panzyga

Manufacturer	Octapharma
Method of Production	Cohn-Oncley cold ethanol fractionation, caprylic acid precipitation, solvent/detergent treatment, ion exchange chromatography, 20nm nanofiltration
Form	Liquid
Shelf-Life/Storage Requirement	24 Months (refrigerated); 9 Months (room temperature up to 25°C or 77°F)
Reconstitution Time	None (Liquid solution)
Available Concentrations	10%
Maximum Recommended Infusion Rate	For new patients: 4.8 mL/kg/hour; For experienced patients: up to 7.2 or 8.4 mL/kg/hour
Time to Infuse 35 gms[1]	For new patients: 2.1 hours; For experienced patients: 1.35 hours; Time can vary based on patient experience and tolerability
Sugar Content	None
Sodium Content	Trace amounts
Osmolarity/ Osmolality	240 - 310 mOsmol/kg
PH	4.5 - 5.0
IgA Content	Average: 100 µ/mL
Approved Method of Administration	**Intravenous**

[1] 0.5 gm/kg for a 70 kg adult = 35 gms; 5% Concentrations: 1g = 20 mL; 10% Concentrations: 1g = 10 mL.

The time to infuse is based on the maximal infusion rate. Check product label for storage temperatures, which vary among immunoglobulin products. Check package insert for detailed prescribing information. Information for each of the products listed above has been provided directly to IDF by the manufacturer of that product.

Product Name Privigen

Manufacturer	CSL Behring
Method of Production	Octanoic Acid Fractionation, CH9 Filtration, pH 4.0 incubation, Depth filtration, Chromatography, Nanofiltration, TSE Reduction Steps
Form	Liquid
Shelf-Life/Storage Requirement	36 Months (room temperature storage)
Reconstitution Time	None (Liquid solution)
Available Concentrations	10%
Maximum Recommended Infusion Rate	4.8mL/kg/hour
Time to Infuse 35 gms[1]	Variable based on patient tolerability
Sugar Content	None
Sodium Content	Trace amounts
Osmolarity/ Osmolality	Isotonic (320 mOsmol/kg)
PH	4.8
IgA Content	< or = 25mcg/mL
Approved Method of Administration	**Intravenous**

[1] 0.5 gm/kg for a 70 kg adult = 35 gms; 5% Concentrations: 1g = 20 mL; 10% Concentrations: 1g = 10 mL.

The time to infuse is based on the maximal infusion rate. Check product label for storage temperatures, which vary among immunoglobulin products. Check package insert for detailed prescribing information. Information for each of the products listed above has been provided directly to IDF by the manufacturer of that product.

Product Name Xembify

Manufacturer	Grifols
Method of Production	Cold ethanol fractionation, caprylate precipitation and filtration, anion-exchange chromatography
Form	Liquid
Shelf-Life/Storage Requirement	6 months (room temperature); 36 months (refrigerated)
Reconstitution Time	None (Liquid solution)
Available Concentrations	20%
Maximum Recommended Infusion Rate	25 mL/hour/site
Time to Infuse 35 gms[1]	Time will vary depending on rate of administration
Sugar Content	None
Sodium Content	Trace amounts
Osmolarity/ Osmolality	280 - 404 mOsm/kg
PH	4.1 - 4.8
IgA Content	≤0.07 mg/mL
Approved Method of Administration	**Subcutaneous**

[1] 0.5 gm/kg for a 70 kg adult = 35 gms; 5% Concentrations: 1g = 20 mL; 10% Concentrations: 1g = 10 mL.

The time to infuse is based on the maximal infusion rate. Check product label for storage temperatures, which vary among immunoglobulin products. Check package insert for detailed prescribing information. Information for each of the products listed above has been provided directly to IDF by the manufacturer of that product.