panzyga®
Human Normal Immunoglobulin (IVIg)

Dose & infusion calculator

Panzyga® 10% (human normal immunoglobulin) solution for intravenous infusion. Solution for infusion containing 100 mg/mL protein of which >95% is human normal IgG. IgA content < 0.3 mg/mL.[1]

Panzyga® is indicated for replacement therapy in patients with primary and secondary immunodeficiencies and as immunomodulation therapy in specific autoimmune and neurological disorders.[1] Please review your local prescribing information before using the calculator.

This dose & infusion calculator is provided as general guidance only and is based on the European SmPC at the time of creation. Approved indications, infusion rates and recommendations for dosing and infusion procedures can vary and may be different for individual patients, hospitals and countries. Please refer to and check your local registration/approvals and any specific local recommendations or guidance including hospital, infusion centre or physician advice for individual patients.

Dosing recommendations

The dose and dose regimen are dependent on the indication and may need to be individualised for each patient based on the clinical response.[1]

The posology in children and adolescents (0–18 years) is not different to that of adults as the posology for each indication is given by body weight and adjusted to the clinical outcome.[1]

Storage conditions

The product should be brought to room or body temperature before use.[1]

- 3 years at +2°C to +8°C. Do not freeze. Protect from light.
- 12 months at room temperature (above +8°C and below +25°C). Once removed from refrigeration, product should be discarded if not used after 12 months.

Contraindications

Panzyga® is contraindicated in patients who are hypersensitive to the active ingredient or to any of the excipients in the formulation, and in patients with selective IgA deficiency who developed antibodies to IgA.[1]

Special warnings and precautions for use

Record the name and the batch number for each infusion. Do not exceed the recommended infusion rate. Adverse reactions may occur more frequently if administered at a high rate of infusion, in patients new to human normal immunoglobulin, in patients switching product or when there has been a long interval since the previous infusion or if patients have untreated infection or underlying chronic inflammation. In case of adverse reaction, either decrease rate of administration or stop the infusion.[1] Adverse events should be reported to safetyreporting@octapharma.com

Select the indication below

- ○ Primary immunodeficiency syndrome
- ○ Secondary immunodeficiency
- ○ Primary immune thrombocytopenia
- ○ Chronic inflammatory demyelinating polyneuropathy

Please refer to your local panzyga® Summary of Product Characteristics for full prescribing and safety information. Adverse events should be reported to safetyreporting@octapharma.com

1. Panzyga® Summary of Product Characteristics.

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PRIMARY IMMUNODEFICIENCY SYNDROME (PID)

Starting dose[1]	Maintenance dose[1]	Frequency[1]
0.4–0.8 g/kg	0.2–0.8 g/kg	Every 3–4 weeks

Patients should be observed for at least 20 minutes after administration.

Please select the weight of your patient and the dose

Patient's weight ____ kg

Dose ____ g/kg

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Total dose ____ g

Total infusion volume ____ mL

Minimum infusion time ____ min

1. Infuse intravenously at an initial rate of 0.6 mL/kg/hr (0.01 mL/kg/min) for 30 min.[1]
2. If well tolerated, gradually increase rate to a maximum of 4.8 mL/kg/hr (0.08 mL/kg/min).[1]
3. In PID patients the rate can be increased to 8.4 mL/kg/hr (0.14 mL/kg/min) if well tolerated.[1]

Infusion rate chart for your patient

Infusion interval (min)	Infusion rate (mL/kg/hr)	Potential infusion volume per hour (mL/hr)	Infusion volume in interval (mL)
0–30	0.6		
30–45	1.2		
45–60	2.4		
60–75	4.8		
Until completion of infusion (in 15 minute intervals)	8.4		

Comparison of infusion ramp up protocols

Infusion ramp up protocol	Approximate minimum total infusion time (min)
Rate increases every 15 minutes	
Rate increases every 30 minutes	

1 g	2.5 g	5 g	10 g	20 g	30 g

*It is recommended to start with smallest vials first, then move to larger vials once the infusion has commenced. Please note that not all vial sizes are available in all markets. Please refer to your local panzyga® Summary of Product Characteristics for full prescribing and safety information. Adverse events should be reported to safetyreporting@octapharma.com

1. Panzyga® Summary of Product Characteristics.

SECONDARY IMMUNODEFICIENCY (SID)

Recommended dose[1]	Frequency[1]
0.2–0.4 g/kg	Every 3–4 weeks

Patients should be observed for at least 20 minutes after administration.

Please select the weight of your patient and the dose

Patient's weight		kg
Dose		g/kg

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Total dose		g
Total infusion volume		mL
Minimum infusion time		min

1. Infuse intravenously at an initial rate of 0.6 mL/kg/hr (0.01 mL/kg/min) for 30 min.[1]
2. If well tolerated gradually increase rate to a maximum of 4.8 mL/kg/hr (0.08 mL/kg/min).[1]

Infusion rate chart for your patient

Infusion interval (min)	Infusion rate (mL/kg/hr)	Potential infusion volume per hour (mL/hr)	Infusion volume in interval (mL)
0–30	0.6		
30–45	1.2		
45–60	2.4		
60–75	4.8		
Until completion of infusion (in 15 minute intervals)	4.8		

Comparison of infusion ramp up protocols

Infusion ramp up protocol	Approximate minimum total infusion time (min)
Rate increases every 15 minutes	
Rate increases every 30 minutes	

1 g	2.5 g	5 g	10 g	20 g	30 g

*It is recommended to start with smallest vials first, then move to larger vials once the infusion has commenced. Please note that not all vial sizes are available in all markets. Please refer to your local panzyga® Summary of Product Characteristics for full prescribing and safety information. Adverse events should be reported to safetyreporting@octapharma.com

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PRIMARY IMMUNE THROMBOCYTOPENIA (ITP)

Recommended dose[1]	Frequency[1]
0.8–1.0 g/kg	On day 1, possibly repeated once within 3 days
OR	
0.4 g/kg/d	for 2–5 days

Patients should be observed for at least 20 minutes after administration.

Please select the weight of your patient and the dose

Patient's weight ____ kg

Dose ____ g/kg

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Total dose ____ g

Total infusion volume ____ mL

Minimum infusion time ____ min

1. Infuse intravenously at an initial rate of 0.6 mL/kg/hr (0.01 mL/kg/min) for 30 min.[1]
2. If well tolerated gradually increase rate to a maximum of 4.8 mL/kg/hr (0.08 mL/kg/min).[1]

Infusion rate chart for your patient

Infusion interval (min)	Infusion rate (mL/kg/hr)	Potential infusion volume per hour (mL/hr)	Infusion volume in interval (mL)
0–30	0.6		
30–45	1.2		
45–60	2.4		
60–75	4.8		
Until completion of infusion (in 15 minute intervals)	4.8		

Comparison of infusion ramp up protocols

Infusion ramp up protocol	Approximate minimum total infusion time (min)
Rate increases every 15 minutes	
Rate increases every 30 minutes	

1 g	2.5 g	5 g	10 g	20 g	30 g

*It is recommended to start with smallest vials first, then move to larger vials once the infusion has commenced. Please note that not all vial sizes are available in all markets. Please refer to your local panzyga® Summary of Product Characteristics for full prescribing and safety information. Adverse events should be reported to safetyreporting@octapharma.com

1. Panzyga® Summary of Product Characteristics.

CHRONIC INFLAMMATORY DEMYELINATING POLYNEUROPATHY (CIDP)

Starting dose[1]	Frequency[1]	Maintenance dose[1]	Frequency[1]
2.0 g/kg	divided over 2-5 consecutive days	1.0 g/kg	over 1–2 consecutive days every 3 weeks

Patients should be observed for at least 20 minutes after administration.

Please select the weight of your patient and the dose (initial or maintenance)

Patient's weight		kg
Dose		g/kg

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Total dose		g
Total infusion volume		mL
Minimum infusion time		min

1. Infuse intravenously at an initial rate of 0.6 mL/kg/hr (0.01 mL/kg/min) for 30 min.[1]
2. If well tolerated gradually increase rate to a maximum of 4.8 mL/kg/hr (0.08 mL/kg/min).[1]

Infusion rate chart for your patient

Infusion interval (min)	Infusion rate (mL/kg/hr)	Potential infusion volume per hour (mL/hr)	Infusion volume in interval (mL)
0–30	0.6		
30–45	1.2		
45–60	2.4		
60–75	4.8		
Until completion of infusion (in 15 minute intervals)	4.8		

Comparison of infusion ramp up protocols

(Infusion rate and duration will vary depending on the division of doses).

Infusion ramp up protocol	Approximate minimum total infusion time (min)
Rate increases every 15 minutes	
Rate increases every 30 minutes	

1 g	2.5 g	5 g	10 g	20 g	30 g

*It is recommended to start with smallest vials first, then move to larger vials once the infusion has commenced. Please note that not all vial sizes are available in all markets. Please refer to your local panzyga® Summary of Product Characteristics for full prescribing and safety information. Adverse events should be reported to safetyreporting@octapharma.com

1. Panzyga® Summary of Product Characteristics.

PRESCRIBING INFORMATION

Abbreviated prescribing information for panzyga®10% (Human Normal Immunoglobulin)

This information is designed for international use and may deviate from the product information valid in your country. Please refer to your national Summary of Product Characteristics (SmPC) before prescribing.

Presentation: Solution for infusion containing 100 mg/ml protein of which ≥95% is human normal immunoglobulin G (IgG). IgA content ≤ 0.3 mg/ml.

Indications: *Replacement therapy* in adults, and children and adolescents (0-18 years) with: - Primary immunodeficiency syndromes (PID) with impaired antibody production. - Secondary immunodeficiencies (SID) in patients who suffer from severe or recurrent infections, ineffective antimicrobial treatment and either proven specific antibody failure (PSAF) or serum IgG level of <4g/l. *Immunomodulation* in adults, and children and adolescents (0-18 years) with: Primary immune thrombocytopenia (ITP), in patients at high risk of bleeding or prior to surgery to correct the platelet count; Guillain Barré syndrome; Kawasaki disease (in conjunction with acetylsalicylic acid); Chronic inflammatory demyelinating polyradiculoneuropathy (CIDP); Multifocal motor neuropathy (MMN)

Dosage and Method of Administration: The dose is dependent on the indication: Replacement therapy in PID: Starting dose is 0.4 - 0.8 g/kg, maintenance dose 0.2 – 0.8 g/kg every 3 - 4 weeks. Replacement therapy in secondary immunodeficiencies (SID): 0.2 - 0.4 g/kg every 3 - 4 weeks. Immunmodulation in: ITP: for acute episodes 0.8 – 1 g/kg on day 1, may be repeated once within 3 days, or 0.4 g/kg daily for 2 - 5 days. Guillain Barré syndrome: 0.4 g/kg/day on 5 consecutive days. Kawasaki Disease: 2.0 g/kg as a single dose in association with acetylsalicylic acid. CIDP: Starting dose: 2 g/kg divided over 2-5 consecutive days. Maintenance dose: 1 g/kg divided over 1-2 consecutive days every 3 weeks. MMN: Starting dose: 2 g/kg divided over 2-5 consecutive days. Maintenance dose: 1 g/kg every 2 to 4 weeks or 2 g/kg divided over 2-5 consecutive days every 4 to 8 weeks. Infuse intravenously at an initial rate of 0.6 ml/kg/hr for 30 min. If well tolerated gradually increase to a maximum of 4.8 ml/kg/hr. In PID patients this can be increased to 8.4mL/kg/hr if well tolerated.

Contraindications: Hypersensitivity to the active substance or to any of the excipients. Patients with selective IgA deficiency who developed antibodies to IgA.

Special warnings and precautions for use: Record the name and the batch number for each infusion. Do not exceed the recommended infusion rate. Adverse reactions may occur more frequently if administered at a high rate of infusion, in patients new to human normal immunoglobulin, in patients switching product or when there has been a long interval since the previous infusion or if patients have untreated infection or underlying chronic inflammation. In case of adverse reaction, either decrease rate of administration or stop the infusion. Additional treatment depends on the nature and severity of the adverse reaction. In all patients, IVIg administration requires adequate hydration prior to the infusion, monitoring of urine output, monitoring of serum creatinine levels, avoidance of concomitant use of loop diuretics. Hypersensitivity reactions are rare. Anaphylaxis can develop in patients with undetectable IgA who have anti-IgA antibodies or in patients who had tolerated previous treatment with human normal immunoglobulin. In case of shock, standard medical treatment for shock should be implemented. There is clinical evidence of an association between IVIg administration and thromboembolic events such as myocardial infarction, cerebral vascular accident (including stroke), pulmonary embolism and deep vein thromboses. Risk patients are obese patients and patients with pre-existing risk factors for thrombotic events (e.g. advanced age, hypertension, diabetes mellitus, a history of vascular disease or thrombotic episodes, patients with acquired or inherited thrombophilic disorders or with prolonged periods of immobilisation, severely hypovolaemic patients, patients with diseases which increase blood viscosity). There is clinical evidence of association between IVIg and acute renal failure. Patients with risk factors (e.g. pre-existing renal insufficiency, diabetes mellitus, hypovolaemia, overweight, concomitant nephrotoxic medicinal products or age over 65) should be closely monitored. In patients at risk for thromboembolic or renal adverse reactions, IVIG products should be administered at the minimum rate and dose practicable. Aseptic meningitis syndrome (AMS) has been reported in connection with IVIg treatment. IVIg products can contain blood group antibodies, which may act as haemolysins and may induce a positive direct antiglobulin reaction (Coombs' test) and, rarely, haemolysis. Monitor for clinical signs and symptoms of haemolysis. Transient decreases in neutrophil count have been reported. There have been rare reports of transfusion related acute lung injury (TRALI) in connection with IVIG administration. Infusions must be immediately stopped in case of pulmonary adverse reactions. The transitory rise of passively transferred antibodies during/after IVIG infusion may result in misleading positive results in serological testing. When medicinal products prepared from human blood or plasma are administered, the possibility of transmitting infective agents cannot be totally excluded. This also applies to unknown or emerging viruses and other pathogens. This medicinal product contains 69 mg sodium per 100 ml.

Interaction with other medicinal products and other forms of interactions: IVIG administration may impair for a period of at least 6 weeks and up to 3 months (up to 1 year in case of measles) the efficacy of live attenuated virus vaccines such as measles, rubella, mumps and varicella.

Undesirable effects: Adverse reactions in decreasing frequency: chills, headache, dizziness, fever, vomiting, allergic reactions, nausea, arthralgia, low blood pressure and moderate low back pain. Rare to very rare are reversible haemolytic reactions and haemolytic anaemia requiring transfusion; a sudden fall in blood pressure, anaphylactic shock, transient cutaneous reactions (including cutaneous lupus erythematosus), thromboembolic reactions, reversible aseptic meningitis, increased serum creatinine level and/or occurrence of acute renal failure. For a full list of undesirable effects see section 4.8 of your local SmPC.

Special precautions for disposal and storage: The shelf life is 3 years at +2 to +8°C. Do not freeze. Protect from light. The product may be stored at temperatures above +8°C and below +25°C for up to 12 months, and must be discarded if not used after this. The product should be brought to room or body temperature before use.

LEGAL CATEGORY: POM.

Marketing Authorisation Number: refer to your local Country for relevant information

Marketing Authorisation Holder: refer to your local Country for relevant information

Date of First Authorisation: 15/02/2016.

Date of Preparation: September 2020. This information was prepared in the EU based on panzyga_full-smpc_v08.07.

Adverse events should be reported to safetyreporting@octapharma.com