CIDP

panzyga®
Immune Globulin Intravenous (Human) - ifas 10% Liquid Preparation

Infusion Rate Chart for Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

Use this Panzyga Infusion Rate Chart to calculate the appropriate infusion rate for your adult patients with CIDP.

LOADING DOSE: 2 g/kg (20 mL/kg), divided into 2 daily doses of 1 g/kg (10 mL/kg) given on 2 consecutive days[1]

MAINTENANCE DOSE: 1 g/kg or 2 g/kg (10 or 20 mL/kg) every 3 weeks, to be given over 2 consecutive days[1]

- The initial infusion rate should be maintained for 30 minutes. Following the initial infusion, and if tolerated, the infusion rate may be gradually increased every 15-30 minutes, as tolerated, to the maximum infusion rate shown in the table below.[1]
- In the CIDP clinical study, patients in the 0.5 g/kg and 1 g/kg arms had the option of rescue dosing treatment with 2 consecutive infusions of 2 g/kg Panzyga at 3-week intervals if criteria were met.[1]

INDICATION AND USAGE

Panzyga (Immune Globulin Intravenous [Human] - ifas) is indicated for the treatment of primary humoral immunodeficiency (PI) in patients 2 years of age and older; this includes, but is not limited to, congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies; chronic immune thrombocytopenia (cITP) in adults to raise platelet counts to control or prevent bleeding; and chronic inflammatory demyelinating polyneuropathy (CIDP) in adults to improve neuromuscular disability and impairment.

Patient Weight		mL/hr				
In kg	In lb	First 30 minutes (0.01 mL/kg/min)	Next 15-30 minutes *if previous rate tolerated* (0.02 mL/kg/min)	Next 15-30 minutes *if previous rate tolerated* (0.04 mL/kg/min)	Next 15-30 minutes *if previous rate tolerated* (0.08 mL/kg/min)	Maximum *if previous rate tolerated* (0.12 mL/kg/min)
40	88	24	48	96	192	288
45	99	27	54	108	216	324
50	110	30	60	120	240	360
55	121	33	66	132	264	396
60	132	36	72	144	288	432
65	143	39	78	156	312	468
70	154	42	84	168	336	504
75	165	45	90	180	360	540
80	176	48	96	192	384	576
85	187	51	102	204	408	612
90	198	54	108	216	432	648
95	209	57	114	228	456	684
100	220	60	120	240	480	720
105	231	63	126	252	504	756
110	242	66	132	264	528	792
115	253	69	138	276	552	828
120	264	72	144	288	576	864
125	276	75	150	300	600	900
130	287	78	156	312	624	936
135	298	81	162	324	648	972
140	309	84	168	336	672	1008

Please click here for Full Prescribing Information, including BOXED WARNING.

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CIDP

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Tel: 201-604-1137
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Fax: 201-604-1141
or contact the FDA at 1-800-FDA-1088
or www.fda.gov/medwatch

Reference: 1. Panzyga. Prescribing information. Octapharma USA Inc.; 2021.

Date of preparation: 01/2025. PANZ-0829

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IMPORTANT SAFETY INFORMATION (continued)

WARNING: THROMBOSIS, RENAL DYSFUNCTION, AND ACUTE RENAL FAILURE

- **Thrombosis may occur with immune globulin intravenous (IGIV) products, including Panzyga. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling central vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors.**
- **Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur in predisposed patients who receive IGIV products, including Panzyga. Patients predisposed to renal dysfunction include those with a degree of pre-existing renal insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs. Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. Panzyga does not contain sucrose.**
- **For patients at risk of thrombosis, renal dysfunction, or acute renal failure, administer Panzyga at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity. [see Full Prescribing Information, Warnings and Precautions (5.2, 5.4)]**

Contraindications

PANZYGA is contraindicated in patients who have a history of severe systemic hypersensitivity reactions, such as anaphylaxis, to human immunoglobulin and in IgA-deficient patients with antibodies against IgA and history of hypersensitivity.

Warnings and Precautions

Monitor renal function, including blood urea nitrogen and serum creatinine, and urine output in patients at risk of developing acute renal failure. Hyperproteinemia, increased serum osmolarity, and hyponatremia may occur in patients receiving PANZYGA. Aseptic meningitis syndrome may occur in patients receiving PANZYGA, especially with high doses or rapid infusion. Hemolysis that is either intravascular or due to enhanced red blood cell sequestration can develop subsequent to PANZYGA treatments. Risk factors for hemolysis include high doses and non-O-blood group. Closely monitor patients for hemolysis and hemolytic anemia. Monitor patients for pulmonary adverse reactions (transfusion-related acute lung injury [TRALI]). Monitor blood pressure prior to, during, and following PANZYGA infusion. Carefully consider the relative risks and benefits before prescribing the high dose regimen (for cITP) in patients at increased risk of volume overload. PANZYGA is made from human plasma and may contain infectious agents, e.g. viruses and theoretically, the Creutzfeldt-Jakob disease agent.

Adverse Reactions

PI – The most common adverse reactions (≥5% study subjects) were headache, nausea, fever, fatigue, and abdominal pain.

cITP in adults – The most common adverse reactions (≥5% study subjects) were headache, fever, nausea, vomiting, dizziness, and anemia.

CIDP in adults – The most common adverse reactions reported in greater than 5% of subjects were: headache, fever, dermatitis, and blood pressure increase. The risk information provided here is not comprehensive; see full Prescribing Information and Boxed Warning for PANZYGA.

Please click here for Full Prescribing Information, including BOXED WARNING.

cITP

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Immune Globulin
Intravenous (Human) - ifas
10% Liquid Preparation

Infusion Rate Chart for Chronic Immune Thrombocytopenia (cITP)

Use this Panzyga Infusion Rate Chart to calculate the appropriate infusion rate for your adult patients with cITP.

- 2 g/kg, divided into 2 daily doses of 1 g/kg (10 mL/kg) given on 2 consecutive days.[1]
- The initial infusion rate should be maintained for 30 minutes. Following the initial infusion, and if tolerated, the infusion rate may be gradually increased every 15-30 minutes, as tolerated, to the maximum infusion rate shown in the table below.[1]

Patient Weight		mL/hr		
In kg	In lb	First 30 minutes (0.01 mL/kg/min)	Next 15-30 minutes *if previous rate tolerated* (0.04 mL/kg/min)	Maximum *if previous rate tolerated* (0.08 mL/kg/min)
40	88	24	96	192
45	99	27	108	216
50	110	30	120	240
55	121	33	132	264
60	132	36	144	288
65	143	39	156	312
70	154	42	168	336
75	165	45	180	360
80	176	48	192	384
85	187	51	204	408
90	198	54	216	432
95	209	57	228	456
100	220	60	240	480
105	231	63	252	504
110	242	66	264	528
115	253	69	276	552
120	264	72	288	576
125	276	75	300	600
130	287	78	312	624
135	298	81	324	648
140	309	84	336	672

INDICATION AND USAGE

Panzyga (Immune Globulin Intravenous [Human] - ifas) is indicated for the treatment of primary humoral immunodeficiency (PI) in patients 2 years of age and older; this includes, but is not limited to, congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies; chronic immune thrombocytopenia (cITP) in adults to raise platelet counts to control or prevent bleeding; and chronic inflammatory demyelinating polyneuropathy (CIDP) in adults to improve neuromuscular disability and impairment.

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cITP

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or www.fda.gov/medwatch

Reference: 1. Panzyga. Prescribing information. Octapharma USA Inc.; 2021.

Date of preparation: 05/2025. PANZ-0855

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IMPORTANT SAFETY INFORMATION (continued)

WARNING: THROMBOSIS, RENAL DYSFUNCTION, AND ACUTE RENAL FAILURE

- **Thrombosis may occur with immune globulin intravenous (IGIV) products, including Panzyga. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling central vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors.**
- **Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur in predisposed patients who receive IGIV products, including Panzyga. Patients predisposed to renal dysfunction include those with a degree of pre-existing renal insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs. Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. Panzyga does not contain sucrose.**
- **For patients at risk of thrombosis, renal dysfunction, or acute renal failure, administer Panzyga at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity. [see Full Prescribing Information, Warnings and Precautions (5.2, 5.4)]**

Contraindications

PANZYGA is contraindicated in patients who have a history of severe systemic hypersensitivity reactions, such as anaphylaxis, to human immunoglobulin and in IgA-deficient patients with antibodies against IgA and history of hypersensitivity.

Warnings and Precautions

Monitor renal function, including blood urea nitrogen and serum creatinine, and urine output in patients at risk of developing acute renal failure. Hyperproteinemia, increased serum osmolarity, and hyponatremia may occur in patients receiving PANZYGA. Aseptic meningitis syndrome may occur in patients receiving PANZYGA, especially with high doses or rapid infusion. Hemolysis that is either intravascular or due to enhanced red blood cell sequestration can develop subsequent to PANZYGA treatments. Risk factors for hemolysis include high doses and non-O-blood group. Closely monitor patients for hemolysis and hemolytic anemia. Monitor patients for pulmonary adverse reactions (transfusion-related acute lung injury [TRALI]). Monitor blood pressure prior to, during, and following PANZYGA infusion. Carefully consider the relative risks and benefits before prescribing the high dose regimen (for cITP) in patients at increased risk of volume overload. PANZYGA is made from human plasma and may contain infectious agents, e.g. viruses and theoretically, the Creutzfeldt-Jakob disease agent.

Adverse Reactions

PI – The most common adverse reactions (≥5% study subjects) were headache, nausea, fever, fatigue, and abdominal pain.

cITP in adults – The most common adverse reactions (≥5% study subjects) were headache, fever, nausea, vomiting, dizziness, and anemia.

CIDP in adults – The most common adverse reactions reported in greater than 5% of subjects were: headache, fever, dermatitis, and blood pressure increase. The risk information provided here is not comprehensive; see full Prescribing Information and Boxed Warning for PANZYGA.

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PI

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Infusion Rate Chart for Primary Immunodeficiency (PI)

Use this Panzyga Infusion Rate Chart to calculate the appropriate infusion rate for your patients 2 years of age and older with PI.

- 300 mg/kg to 600 mg/kg body weight (3-6 mL/kg) administered every 3 to 4 weeks.[1]
- The initial infusion rate should be maintained for 30 minutes. Following the initial infusion, and if tolerated, the infusion rate may be gradually increased every 15-30 minutes, as tolerated, to the maximum infusion rate shown in the table below.[1]

INDICATION AND USAGE

Panzyga (Immune Globulin Intravenous [Human] - ifas) is indicated for the treatment of primary humoral immunodeficiency (PI) in patients 2 years of age and older; this includes, but is not limited to, congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies; chronic immune thrombocytopenia (cITP) in adults to raise platelet counts to control or prevent bleeding; and chronic inflammatory demyelinating polyneuropathy (CIDP) in adults to improve neuromuscular disability and impairment.

Patient Weight		mL/hr			
In kg	In lb	First 30 minutes (0.01 mL/kg/min)	Next 15-30 minutes *if previous rate tolerated* (0.04 mL/kg/min)	Next 15-30 minutes *if previous rate tolerated* (0.08 mL/kg/min)	Maximum *if previous rate tolerated* (0.14 mL/kg/min)
10	22	6	24	48	84
15	33	9	36	72	126
20	44	12	48	96	168
25	55	15	60	120	210
30	66	18	72	144	252
35	77	21	84	168	294
40	88	24	96	192	336
45	99	27	108	216	378
50	110	30	120	240	420
55	121	33	132	264	462
60	132	36	144	288	504
65	143	39	156	312	546
70	154	42	168	336	588
75	165	45	180	360	630
80	176	48	192	384	672
85	187	51	204	408	714
90	198	54	216	432	756
95	209	57	228	456	798
100	220	60	240	480	840
105	231	63	252	504	882
110	242	66	264	528	924
115	253	69	276	552	966
120	264	72	288	576	1008
125	276	75	300	600	1050
130	287	78	312	624	1092
135	298	81	324	648	1134
140	309	84	336	672	1176

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PI

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Date of preparation: 01/2025. PANZ-0830

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IMPORTANT SAFETY INFORMATION (continued)

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