panzyga®

Immune Globulin Intravenous (Human)
Octapharma's new Intravenous
Immunoglobulin (IVIG)

Panzyga® Administration Guide

An educational service tool provided by Octapharma Canada Medical Information Service.
It is not intended to provide medical advice on dosing or IVIG infusion speed.

Panzyga® is indicated for:

- The treatment of patients with primary immune deficiency (PID) and secondary immune deficiency (SID).
- The treatment of patients with immune thrombocytopenic purpura (ITP).

Please refer inside for important Safety Information for Panzyga® and refer to the accompanying Product Monograph for complete prescribing details.

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Indications and Dosing Recommendations[1]

Panzyga® is a liquid intravenous immunoglobulin (IVIG) preparation of highly purified immunoglobulin G (IgG)

Table 1: Panzyga® Indications and Dosing

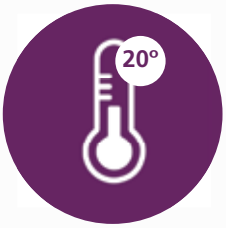
Indication	Dose
Primary immunodeficiency (PID)	Between 200 to 800 mg/kg body weight administered every 3 to 4 weeks. The dosage may be adjusted over time to achieve the desired trough levels of IgG (at least 5 g/L) and clinical responses.
Secondary immunodeficiency (SID)	Between 200 to 800 mg/kg body weight administered every 3 to 4 weeks. The dosage may be adjusted over time to achieve the desired trough levels of IgG (at least 5 g/L) and clinical responses.
Immune thrombocytopenic purpura (ITP)	Total dose of 2 g/kg, divided into 2 doses of 1 g/kg given on 2 consecutive days. Treatment can be repeated if a relapse occurs.

Panzyga® Administration Guide

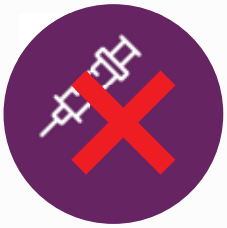
Administration Recommendations for Patients

Following the initial infusion rate of 0.01 mL/kg/min, the infusion rate may be gradually increased* every 15-30 minutes to a maximum of 0.14 mL/kg/min in PID/SID and to 0.08 mL/kg/min in chronic ITP, as tolerated

Use separate IV line for infusion



Bring to room temperature



Panzyga® should not be mixed with:
- Other IV fluids or medications
- Other IVIG products

1. Panzyga® Product Monograph, June 24, 2016

* The recommended ramp-up for an infusion is 1, 2, 4, and 8 mg/kg/min in naive PID/SID and ITP patients, and 1, 4, 8, and 12 or 14 mg/kg/min in experienced PID/SID patients

Panzyga® Administration Guide[1]

New patients starting Panzyga®

Assess each situation individually and use caution to transition patients carefully

- When transitioning a patient from another IVIG brand or if a patient is naïve to IVIG, always start at the minimum rate of infusion, especially in patients with risk factors.
- Patients should be switched after the last infusion of the previous IVIG brand, commencing at the same dose and infusion frequency.
- Patients should be adequately hydrated.

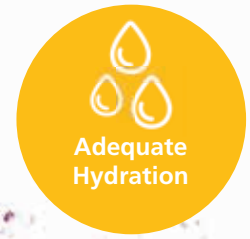
Important notes when administrating Panzyga®[1]:

- Initial infusion should be started slowly at a rate of 0.01 mL/kg/min for 30 minutes.
- Monitor the patient throughout the infusion and for the first hour after the infusion.
- Increase infusion rate as tolerated by patient
- It is recommended to repeat vital signs at regular intervals (e.g. when increasing rate).[2]
- Following the initial infusion rate of 0.01 mL/kg/min, the infusion rate may be gradually increased every 15-30 minutes to a maximum of 0.14 mL/kg/min in PID/SID and to 0.08 mL/kg/min in chronic ITP, as tolerated.

Specific nursing advice and management of adverse events depends on the nature and severity of any potential adverse reaction:

- Standard hospital policies for all IVIG infusion procedures should be adopted and followed.
- Certain adverse drug reactions may be related to the rate of infusion. Slowing or stopping the infusion usually allows the symptoms to disappear promptly. Once the symptoms subside, the infusion may then be resumed at a lower rate.[1]

Considerations prior to infusion:



1. Panzyga® Product Monograph, June 24, 2016
2. IVIG infusion Guide for Ontario, Version 2.0 October 31, 2015

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Immune Globulin Intravenous (Human)

Panzyga® Infusion Recommendations[1]

Panzyga® Infusion Rate[1]

	Primary and Secondary immune deficiency Naïve patients*	Primary and Secondary immune deficiency Experienced patients**	Immune thrombocytopenic purpura patients
Maximum Infusion Rate	0.08 mL/kg/min	0.12 or 0.14 mL/kg/min	0.08 mL/kg/min
Infusion rate (mg)			
Infusion Rate (As Tolerated): mg/kg/min	*Initial Infusion Rate:* 1 mg/kg/min (30 Min) *If well tolerated:* 2 mg/kg/min (15-30 Min) 4 mg/kg/min (15-30 Min) 8 mg/kg/min (by end of infusion)	*Initial Infusion Rate:* 1 mg/kg/min (30 Min) *If well tolerated:* 4 mg/kg/min (15-30 Min) 8 mg/kg/min (15-30 Min) 12 mg/kg/min (15-30 Min) 14 mg/kg/min (by end of infusion)	*Initial Infusion Rate:* 1 mg/kg/min (30 Min) *If well tolerated:* 2 mg/kg/min (15-30 Min) 4 mg/kg/min (15-30 Min) 8 mg/kg/min (by end of infusion)
Infusion Rate (As Tolerated): mg/kg/hour	*Initial Infusion Rate:* 60 mg/kg/hr (30 Min) *If well tolerated:* 120 mg/kg/hr (15-30 Min) 240 mg/kg/hr (15-30 Min) 480 mg/kg/hr (by end of infusion)	*Initial Infusion Rate:* 60 mg/kg/hr (30 Min) *If well tolerated:* 240 mg/kg/hr (15-30 Min) 480 mg/kg/hr (15-30 Min) 720 mg/kg/hr(15-30 Min) 840 mg/kg/hr (by end of infusion)	*Initial Infusion Rate:* 60 mg/kg/hr (30 Min) *If well tolerated:* 120 mg/kg/hr (15-30 Min) 240 mg/kg/hr (15-30 Min) 480 mg/kg/hr (by end of infusion)
Infusion rate (mL)			
Infusion Rate (As Tolerated): mL/kg/min	*Initial Infusion Rate:* 0.01 mL/kg/min (30 Min) *If well tolerated:* 0.02 mL/kg/min (15-30 Min) 0.04 mL/kg/min (15-30 Min) 0.08 mL/kg/min (by end of infusion)	*Initial Infusion Rate:* 0.01 mL/kg/min (30 Min) *If well tolerated:* 0.04 mL/kg/min (15-30 Min) 0.08 mL/kg/min (15-30 Min) 0.12 mL/kg/min (15-30 Min) 0.14 mL/kg/min (by end of infusion)	*Initial Infusion Rate:* 0.01 mL/kg/min (30 Min) *If well tolerated:* 0.02 mL/kg/min (15-30 Min) 0.04 mL/kg/min (15-30 Min) 0.08 mL/kg/min (by end of infusion)
Infusion Rate (As Tolerated): mL/kg/hour	*Initial Infusion Rate:* 0.6 mL/kg/hr (30 Min) *If well tolerated:* 1.2 mL/kg/hr (15-30 Min) 2.4 mL/kg/hr (15-30 Min) 4.8 mL/kg/hr (by end of infusion)	*Initial Infusion Rate:* 0.6 mL/kg/hr (30 Min) *If well tolerated:* 2.4 mL/kg/hr (15-30 Min) 4.8 mL/kg/hr (15-30 Min) 7.2 mL/kg/hr (15-30 Min) 8.4 mL/kg/hr (by end of infusion)	*Initial Infusion Rate:* 0.6 mL/kg/hr (30 Min) *If well tolerated:* 1.2 mL/kg/hr (15-30 Min) 2.4 mL/kg/hr (15-30 Min) 4.8 mL/kg/hr (by end of infusion)

In subjects receiving Panzyga® for the[1]:
*first time (since more than 8 weeks),
**for more than 3 (0.12 mL/kg/min) to 6 (0.14 mL/kg/min) times when infused every 3-4 weeks.

Adapted from Panzyga® Product Monograph. Please see Product Monograph for complete dosing and administration

1. Panzyga® Product Monograph, June 24, 2016

Dosing Calculator[1]

IV infusion rate calculations in mL (cc) per minute and per hour

Patient's Weight	Kg:	10	20	30	40	50	60	70	80	90	100	110	120
	Lb:	22	44	66	88	110	132	154	176	198	220	242	264

Infusion Rate:														
mL/kg/min	mL/kg/hr													
		mL/kg/min	0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9	1	1.1	1.2
0.01	0.6	mL/kg/hr	6	12	18	24	30	36	42	48	54	60	66	72
		mL/kg/min	0.2	0.4	0.6	0.8	1	1.2	1.4	1.6	1.8	2	2.2	2.4
0.02	1.2	mL/kg/hr	12	24	36	48	60	72	84	96	108	120	132	144
		mL/kg/min	0.3	0.6	0.9	1.2	1.5	1.8	2.1	2.4	2.7	3	3.3	3.6
0.03	1.8	mL/kg/hr	18	36	54	72	90	108	126	144	162	180	198	216
		mL/kg/min	0.4	0.8	1.2	1.6	2	2.4	2.8	3.2	3.6	4	4.4	4.8
0.04	2.4	mL/kg/hr	24	48	72	96	120	144	168	192	216	240	264	288
		mL/kg/min	0.5	1	1.5	2	2.5	3	3.5	4	4.5	5	5.5	6
0.05	3	mL/kg/hr	30	60	90	120	150	180	210	240	270	300	330	360
		mL/kg/min	0.6	1.2	1.8	2.4	3	3.6	4.2	4.8	5.4	6	6.6	7.2
0.06	3.6	mL/kg/hr	36	72	108	144	180	216	252	288	324	360	396	432
		mL/kg/min	0.7	1.4	2.1	2.8	3.5	4.2	4.9	5.6	6.3	7	7.7	8.4
0.07	4.2	mL/kg/hr	42	84	126	168	210	252	294	336	378	420	462	504
		mL/kg/min	0.8	1.6	2.4	3.2	4	4.8	5.6	6.4	7.2	8	8.8	9.6
0.08	4.8	mL/kg/hr	48	96	144	192	240	288	336	384	432	480	528	576
		mL/kg/min	0.9	1.8	2.7	3.6	4.5	5.4	6.3	7.2	8.1	9	9.9	10.8
0.09	5.4	mL/kg/hr	54	108	162	216	270	324	378	432	486	540	594	648
		mL/kg/min	1	2	3	4	5	6	7	8	9	10	11	12
0.1	6	mL/kg/hr	60	120	180	240	300	360	420	480	540	600	660	720
		mL/kg/min	1.2	2.4	3.6	4.8	6	7.2	8.4	9.6	10.8	12	13.2	14.4
0.12	7.2	mL/kg/hr	72	144	216	288	360	432	504	576	648	720	792	864
		mL/kg/min	1.4	2.8	4.2	5.6	7	8.4	9.8	11.2	12.6	14	15.4	16.8
0.14	8.4	mL/kg/hr	84	168	252	336	420	504	588	672	756	840	924	1008

Commence infusion at 0.01/mL/kg/min for 30 minutes. If well tolerated, the rate of administration may gradually be increased (in 15-30 minute intervals) to a maximum of 0.08mL/kg/min.

In PID/SID patients who tolerate an infusion rate of 0.08mL/kg/min, the rate may be further increased to a maximum of 0.14mL/kg/min.

Titration should be based on patient tolerability.[1]

1. Panzyga® Product Monograph, June 24, 2016

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Immune Globulin Intravenous (Human)

Presentation and Storage[1]

Manufactured in 6 different pack sizes

The following vial sizes will be available in Canada

Pack size (100 mg/mL)						
Fill size (mL)	10*	25	50	100	200	300
Fill size (g)	1*	2.5	5	10	20	30

*available upon request

Ease of storage

- 6 months at room temperature above +8°C and below +25°C
- 2 years at +2°C to +8°C

1. Panzyga® Product Monograph, June 24, 2016

Safety Information[1]

Contraindications:

Panzyga® is contraindicated in patients who have had an anaphylactic or severe systemic reaction to the administration of a human immunoglobulin preparation.

Panzyga® is contraindicated in individuals with selective IgA deficiency with known anti-IgA antibodies.

Most serious warnings and precautions:

There is clinical evidence of an association between the administration of immunoglobulins and thromboembolic events such as myocardial infarction, stroke, pulmonary embolism and deep vein thromboses. Therefore, caution should be exercised when prescribing and administering immunoglobulins.

In general the risk factors for thromboembolic events include: obesity, advance age, hypertension, diabetes mellitus, history of vascular disease or thrombotic episodes, acquired or inherited thrombophilic disorders, prolonged periods of immobilisations, severely hypovolemic patients, diseases which increase blood viscosity, hypercoagulable conditions, use of estrogens, indwelling central vascular catheters, and cardiovascular risk factors.

Thrombosis may occur even in the absence of known risk factors.

Other relevant warnings and precautions:

- Products made from human plasma may contain infectious agents, such as viruses and theoretically, the variant Creutzfeldt-Jakob disease (vCJD) agent that can cause disease. The risk that such products will transmit an infectious agent has been reduced by screening plasma donors for prior exposure to certain viruses, by testing for the presence of certain current virus infections, and by inactivating and/or removing certain viruses.
- IVIG products can contain blood group antibodies which may act as hemolysins and induce in vivo coating of red blood cells (RBCs) with immunoglobulin, causing a positive direct antiglobulin reaction and, rarely, hemolysis. Hemolytic anaemia can also develop subsequent to Panzyga® therapy due to enhanced RBC sequestration. IVIG recipients should be monitored for clinical signs and symptoms of hemolysis.
- Aseptic meningitis syndrome (AMS) has been reported to occur infrequently in association with IVIG treatment. AMS usually begins within several hours to two days following treatment. The signs include severe headache (migraine-like), neck stiffness, drowsiness, fever, inability to stand bright light, painful eye movements, and nausea and vomiting. The condition usually reverses without ill effects when treatment is stopped. AMS may occur more frequently in association with high dose (2 g/kg) IVIG treatment. Patients with a history of migraine appear to be more susceptible. Preventive measures to avoid the occurrence of aseptic meningitis include careful risk/benefit evaluation in patients with history of migraine, premedication with analgesics with or without caffeine, proper hydration and maintenance of good fluid intake throughout treatment, and slow infusion rates.

Safety Information[1]

- Cases of acute renal failure have been reported in patients receiving IVIG therapy especially with preparations containing sucrose: Panzyga does not contain sucrose.
  In most cases, risk factors have been identified, such as pre-existing renal insufficiency, diabetes mellitus, hypovolemia, overweight, concomitant nephrotoxic medications, or over the age of 65.
- Transfusion-related acute lung injury (TRALI) has been rarely reported after treatment with IVIG products.
- True hypersensitivity reactions are rare. They can occur in patients with anti-IgA antibodies. IVIG is not indicated in patients with selective IgA deficiency where the IgA deficiency is the only abnormality of concern.
- Pregnant Women: The safety of Panzyga® for use in human pregnancy and during lactation has not been established in controlled clinical trials and therefore should only be given with caution to pregnant woman and breast-feeding mothers.
- Nursing Women: Immunoglobulins are excreted into the milk and may contribute to the transfer of protective antibodies to the neonate.
- Pediatrics (2-15 years of age): The listed warnings and precautions apply both to adults and children.
- Geriatrics (> 65 years of age): Panzyga® should be used with caution in patients over 65 years of age who are judged to be at increased risk of developing renal failure. In most cases, additional risk factors have been identified, such as pre-existing renal insufficiency, diabetes mellitus, dehydration, overweight, or concomitant nephrotoxic medications. The number of elderly patients studied in clinical trials is limited.
- IgG administration may impair the efficacy of live attenuated virus vaccines such as measles, mumps, rubella and varicella for at least six weeks, and possibly up to three months. In some cases, where large doses are given this period may be as long as one year.

Adverse Drug Reaction Overview:

Replacement Therapy:

The most common adverse reactions observed at a rate of >5% in subjects in clinical trials were: headache, abdominal pain, fever, nausea, and fatigue.

Immune Thrombocytopenic Purpura in adults:

The most common adverse reactions observed at a rate of >5% in subjects in clinical trials were: headache, fever, nausea, vomiting, dizziness, and anemia.

For more information:

Please consult the product monograph at
http://www.octapharma.ca/en/healthcare-professionals/products-therapies/products-in-canada.html
for important information relating to adverse reactions, drug interactions, and dosing information which have not been discussed in this brochure. The product monograph is also available by calling us at 1-888-438-0488 or by contacting us via email: medinfo@octapharma.ca

Notes

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For healthcare professionals only.

Additional resources and information about Panzyga® is available from www.octapharma.ca

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octapharma®
For the safe and optimal use of human proteins

PAAB

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