IntraVenous ImmunoGlobin

TRANSFUSION MEDICINE SERVICES

OTHER NAMES	CLASSIFICATION	ALERTS
IVIG; IGIVnex®, Gamunex®, Gammagard® SD, Gammagard® Liquid, Privigen®, Octagam®, Panzyga®	Intravenous Immune Globulins	

PREPARATION and ADMINISTRATION

Prepared from human blood (plasma)

IVIG comes as a ready-to-use 10% solution for IV administration. Use vented tubing to administer.

Exception:

Gammagard SD Diluent: sterile water for injection

Note: See pages 6-8 for reconstitution steps. Allow 20-40 minutes for complete dissolution of powder into dilute. After reconstitution, only clear or slightly opalescent and colourless or pale-yellow solutions are to be administered.

Use the filtered IV tubing provided with Gammagard SD

For a **5% Gammagard SD concentration**:	For a **10% Gammagard SD concentration**:
5 g vial – add all diluent provided (96 mL)	5g vial – add half the diluent provided (48 mL)
10 g vial – add all diluent provided (192 mL)	10 g vial – add half the diluent provided (96 mL)

Primary Infusion

IV Bottle (large volume pump)

Administer within **4 hours of spiking bottle**

When no prescribed rate of infusion or care plans exists, follow the standardized tables
Rates of administration for adults receiving 10% solutions (or page 4)
Rates of administration for pediatrics receiving 10% solutions (or page 5)
Rates of administration can be found here for 5% solution (or page 9)
Maximum rate will be determined by patient dosing body weight. (See IVIG order set or Dosing Body Calculator)

> High infusion rates should not be used for patients with renal impairment, cardiac impairment or those with impaired homeostasis, previous thrombotic events or dehydration as they are at increased risk of thrombus formation.
>
> The maximum rate should only be used if the patient has had previous exposures to IVIG infusion and demonstrated tolerability on more than one occasion. In these chronic infusion situations, some intervening rate increases may be eliminated if close monitoring for adverse events is available.

Increase rates beyond table recommendations in consultation with the Authorized Prescriber.

Requirements and Monitoring

Administration: Infusion device, regular IV tubing with vent.

Baseline vitals within 60 minutes before starting infusion. Reassess 15 minutes after starting infusion under direct observation. If transfusion is less than one hour, check vital signs 15 minutes after initiation, with each new vial from a different lot number and/or rate increase, and immediately following the transfusion

Inpatients should be observed for an adverse event for 24 hours post infusion. **Document all vitals taken**.

Blood pressure via cuff or arterial line

Temperature

Heart Rate

Respirations

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Lung sounds in non-verbal, non-oriented or pediatric patients

Keep unopened back up bag of NS and standard IV tubing nearby for prompt response if an adverse event (AE) occurs.

INDICATIONS

- Indications and Criteria as outlined in NSHA CL-BP-025, IWK-629 Use of Intravenous and Subcutaneous Immunoglobulins (IVIG/SCIG) with order sets covering 7 specialties (Hematology; Neurology; Immunology; Dermatology; Rheumatology; Infectious Disease and Solid Organ Transplant) and lists of associated medical conditions both indicated and possibly indicated for IVIG use based on existing medical evidence.
- See individual product monographs for further information on indications for use.

ADVERSE EFFECTS

New onset of any of the following:

Hypertension/Hypotension
Tachypnea/bradypnea/dyspnea
Fever/chills/rigors
Puritis/urticaria/rash
Bleeding/pain at IV site
Patient feels unwell
Significant change in cardiac rate/rhythm
Severe headache
Back/chest/flank pain
Anuria/hematuria/oliguria
Nausea/vomiting
Unexplained anxiety

A rate of administration that is too rapid may cause headaches, flushing and changes in pulse rate and blood pressure. Slowing or stopping the infusion usually allows the symptoms to disappear promptly. The infusion may then be resumed at a rate that does not result in recurrence of the symptoms.

If an AE is suspected: stop the transfusion, disconnect and cap the blood tubing, initiate the backup line of NS and consult the authorized prescriber (AP) for medical management. Notify the TM lab of a suspected reaction.

- Review the product lot number, TM tag and patient ID to rule out a verification (clerical) error and that the expiry date and time has not passed.
- Resume transfusion cautiously as directed by AP. Directly observe patient x5min then closely observe x10min.
- Ensure TM tag, along with a copy of the documented clinical data and interventions are sent to TM lab once transfusion is discontinued or completed.
- If the transfusion must be discontinued and a transfusion reaction workup is ordered, send the additional following items to TM lab:

i. Blood work (1 Red top and 1 EDTA (Pink or Lavender top)

   * possible exception for pediatric patient: lab testing to be performed at discretion of Hematopathologist

ii. Product and administration set (ensure set is safely capped)

Note: AP may also require additional testing such as: blood cultures, chest x-ray, EKG, or urine specimen

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DOSAGE

- Dosing will be based on indications and criteria as outlined in NSHA CL-BP-025, IWK-629 Use of Intravenous and Subcutaneous Immunoglobulins (IVIG/SCIG)
- Order Sets for IVIG may be found at http://healthforms.cdha.nshealth.ca/ (enter IVIG in the search box) or within the Electronic Form Repository.

COMPATIBILITY, STABILITY

- Transfuse within 4 hours from when bottle was spiked
- Compatible with D5W
- Incompatible with all other IV formulations
- Single use vials. Do not use past expire date
- Do not dilute in any IV solutions
- Protect vials from light; inspect visually for particulate matter and discoloration prior to administration.
- Do not store unused vials in refrigerator. Administer at room temperature

DOSAGE FORMS

- Supplied in multiple vials by Transfusion Services

MISCELLANEOUS

- Ensure patient is properly hydrated before starting infusion to limit adverse events.

LIBRARIES

- Searchable Drug Library Document

REFERENCES

- CL-BP-030, IWK-625 Blood Component and Blood Product Administration - Policy and Procedure
- CL-BP-025, IWK-629 Use of Intravenous and Subcutaneous Immunoglobulins (IVIG/SCIG)
- Specific product monographs. Contact TM lab or NSPBCP@nshealth.ca for further information

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Standard Adult 10% IVIG Infusion Rate Table

This table represents recommended maximum infusion rates. Slower infusions reduce rate related effects such as headache, shivering, HR and BP changes. Assess patient with each rate change. Increase rates beyond table recommendations in consultation with the Authorized Prescriber. For specific product information, refer to product insert.

Pt Weight (kg) See IVIG order for *dosing body weight*		**Start rate for 30 min** **0.5 mL/kg/h**	**Increase rate in 15 minute intervals as tolerated** **1.5 mL/kg/h**	**3 mL/kg/h**	MAX rate for initial treatment OR more than 8 weeks since last IVIG treatment; and high risk patients **5 mL/kg/h***	If less than 8 weeks since last IVIG treatment and 5 mL/kg/h tolerated x15 min **6 mL/kg/h**	MAX rate if less than 8 weeks since last IVIG treatment and 6 mL/kg/h tolerated x15 min **8 mL/kg/h****
45 kg	mL/h	22.5	67.5	135	225	270	360
	(mL)	(11.3)	(16.9)	(33.8)	(56.3)	(65.5)	(90)
50 kg	mL/h	25	75	150	250	300	400
	(mL)	(12.5)	(18.8)	(37.5)	(62.5)	(75)	(100)
55 kg	mL/h	27.5	82.5	165	275	330	440
	(mL)	(13.8)	(20.7)	(41.3)	(68.8)	(82.5)	(110)
60 kg	mL/h	30	90	180	300	360	480
	(mL)	(15)	(22.5)	(45)	(75)	(90)	(140)
65 kg	mL/h	32.5	97.5	195	325	390	520
	(mL)	(17)	(25)	(49)	(81.3)	(97.5)	(130)
70 kg	mL/h	35	105	210	350	420	560
	(mL)	(17.5)	(26.25)	(52.5)	(87.5)	(105)	(140)
75 kg	mL/h	37.5	112.5	225	375	450	600
	(mL)	(18.8)	(28.2)	(56.3)	(93.8)	(112.5)	(150)
80 kg	mL/h	40	120	240	400	480	640
	(mL)	(20)	(30)	(60)	(100)	(120)	(160)
85 kg	mL/h	42.5	127.5	255	425	510	680
	(mL)	(21.3)	(31.9)	(63.8)	(106.3)	(127.5)	(170)
90 kg	mL/h	45	135	270	450	540	720
	(mL)	(22.5)	(33.8)	(67.5)	(112.5)	(135)	(180)
95 kg	mL/h	47.5	142.5	285	475	570	760
	(mL)	(23.8)	(35.6)	(71.3)	(118.8)	(142.5)	(190)
100 kg	mL/h	50	150	300	500	600	800
	(mL)	(25)	(37.5)	(75)	(125)	(150)	(200)
110 kg	mL/h	55	165	330	550	660	880
	(mL)	(27.5)	(41.3)	(82.5)	(137.5)	(165)	(220)
120 kg	mL/h	60	180	360	600	720	960
	(mL)	(30)	(45)	(90)	(150)	(180)	(240)

Rate calculation: Pt Weight (kg) x Desired Rate (mL/kg/h) = mL/h (if patient weight not on this infusion table) [e.g. 180 kg x 0.5 mL/kg/h = 90mL/h]
VTBI calculation: For 30 min (mL) = Infusion rate (mL/h) x 0.5 h For 15 min (mL) = Infusion rate (mL/h) x 0.25 h

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Standard Pediatric 10% IVIG Infusion Rate Table

This table represents recommended maximum infusion rates. Slower infusions reduce rate related side effects such as headache, shivering, HR and BP changes. Assess patient with each rate change. Increase rates beyond table recommendations in consultation with the Authorized Prescriber. For specific product information, refer to product insert.

Pt Weight in kg		**Start rate for 30 min** **0.5 mL/kg/h**	**Increase rate in 15 minute intervals as tolerated** **1 mL/kg/h**	**1.5 mL/kg/h**	**3 mL/kg/h**	MAX rate for initial IVIG treatment OR more than 8 weeks since last IVIG treatment; and high risk patients **4.8 mL/kg/h***	MAX rate if less than 8 weeks since last IVIG treatment and 4.8 mL/kg/h tolerated for at least 15 min **8 mL/kg/h****
1 kg	mL/h	0.5	1	1.5	3	4.8	8
	(mL)	(0.25)	(0.25)	(0.38)	(0.75)	(1.2)	(2)
2.5 kg	mL/h	1.25	2.5	3.75	7.5	12	20
	(mL)	(0.63)	(0.63)	(0.94)	(1.88)	(3)	(5)
5 kg	mL/h	2.5	5	7.5	15	24	40
	(mL)	(1.25)	(1.25)	(1.88)	(3.75)	(6)	(10)
7.5 kg	mL/h	3.75	7.5	11.25	22.5	36	60
	(mL)	(1.88)	(1.88)	(2.81)	(5.63)	(9)	(15)
10 kg	mL/h	5	10	15	30	48	80
	(mL)	(2.5)	(2.5)	(3.75)	(7.5)	(12)	(20)
15 kg	mL/h	7.5	15	22.5	45	72	120
	(mL)	(3.75)	(3.75)	(5.63)	(11.25)	(18)	(30)
20 kg	mL/h	10	20	30	60	96	160
	(mL)	(5)	(5)	(7.5)	(15)	(24)	(40)
25 kg	mL/h	12.5	25	37.5	75	120	200
	(mL)	(6.25)	(6.25)	(9.38)	(18.75)	(30)	(50)
30 kg	mL/h	15	30	45	90	144	240
	(mL)	(7.5)	(7.5)	(11.25)	(22.5)	(36)	(60)
35 kg	mL/h	17.5	35	52.5	105	168	280
	(mL)	(8.75)	(8.75)	(13.13)	(26.25)	(42)	(70)
40 kg	mL/h	20	40	60	120	192	320
	(mL)	(10)	(10)	(15)	(30)	(48)	(80)
45 kg	mL/h	22.5	45	67.5	135	216	360
	(mL)	(11.25)	(11.25)	(16.88)	(33.75)	(54)	(90)
50 kg	mL/h	25	50	75	150	240	400
	(mL)	(12.5)	(12.5)	(18.75)	(37.5)	(60)	(100)
60 kg	mL/h	30	60	90	180	288	480
	(mL)	(15)	(15)	(22.5)	(45)	(72)	(120)

Rate calculation: Pt Weight (kg) x Desired Rate (mL/kg/h) = mL/h (if patient weight not on this infusion table) [e.g. 180 kg x 0.5 mL/kg/h = 90mL/h]
VTBI calculation: For 30 min (mL) = Infusion rate (mL/h) x 0.5 h For 15 min (mL) = Infusion rate (mL/h) x 0.25 h

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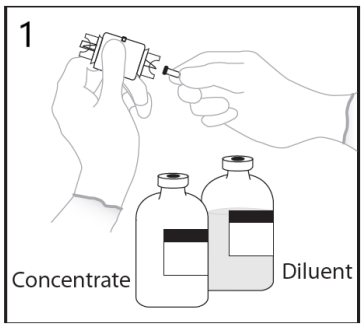
GAMMAGARD S/D RECONSTITUTION:

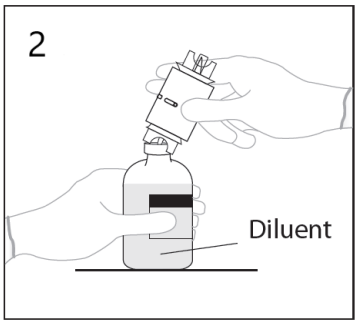
A. **5% Solution**

1. Note: Reconstitute immediately before use.
2. If refrigerated, warm the Sterile Water for Injection, USP (diluent) and GAMMAGARD S/D, Immunoglobulin Intravenous (Human) [IGIV], Solvent/Detergent - Treated (freeze-dried concentrate), to room temperature.
3. Remove caps from concentrate and diluent vials to expose central portion of rubber stoppers.
4. Cleanse stoppers with germicidal solution and allow to dry.

For 5 g & 10 g vials:

5. Remove spike cap from one end of transfer device. Do not touch spike (Fig 1).

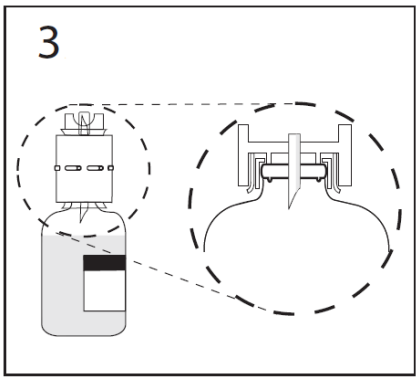




6. a. Place diluent vial on flat surface. Use exposed end of transfer device to spike diluent vial through center of the stopper (Fig 2).

   CAUTION: Failure to insert spike into center of the stopper may result in dislodging of the stopper

   b. Ensure the collar collapses fully into the device by pushing down on the transfer device firmly (Fig 3). While holding onto transfer device, remove remaining spike cover. Do not touch spike



7. Hold diluent vial with attached transfer device at an angle to the concentrate vial to prevent spilling the diluent (Fig 4).

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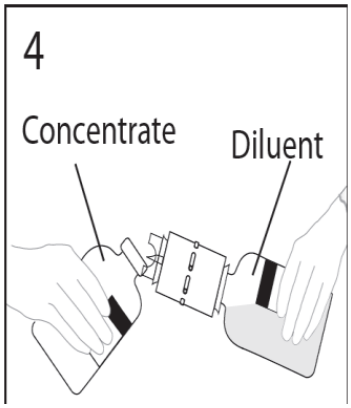
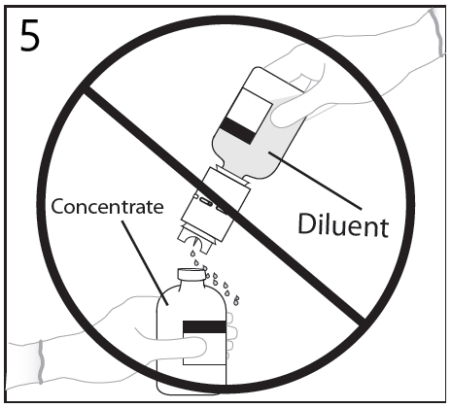


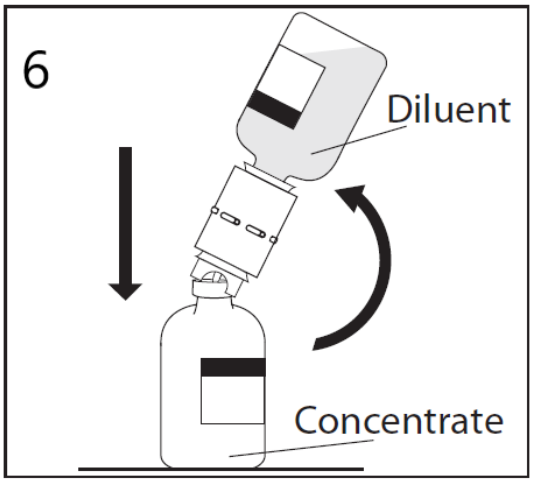


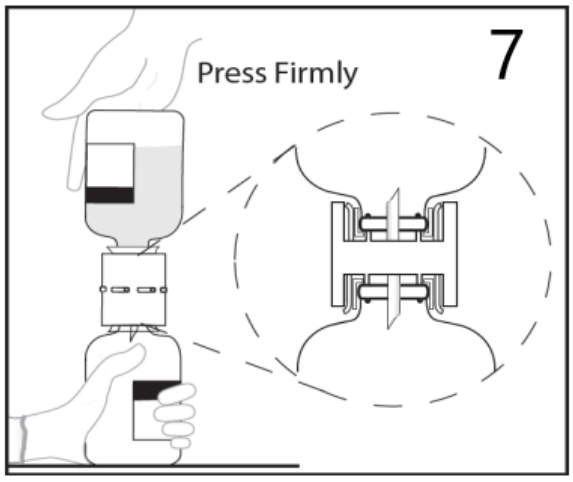
Note: Do not hold diluent vial upside down, for this can lead to diluent spillage (Fig 5)**.**

8. Spike concentrate vial through center of the stopper while quickly inverting the diluent vial to minimize spilling out diluent (Fig 6).

CAUTION: Failure to insert the spike into the center of the stopper may result in dislodging of the stopper and loss of vacuum.

9. Ensure that stopper collapses fully into the device by pushing down on the diluent vial firmly (Fig 7).





10. After transfer of diluent is complete, remove transfer device and empty diluent vial. Immediately swirl the concentrate vial gently to thoroughly mix contents (Fig 8). Discard transfer device after single use per local guidelines.

CAUTION: Do not shake. Avoid foaming. Typically takes 20–40 minutes to dissolve.

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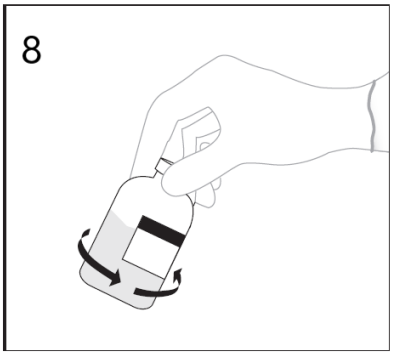

B. 10% Solution

Follow steps 1-4 as previously described in **A**.

For 5 g & 10 g vials:

5. To prepare a 10% solution, it is necessary to remove half of the volume of diluent. Table 1 indicates the volume of diluent that should be removed from the vial before attaching the transfer device to produce a 10% concentration. Using aseptic technique, withdraw the necessary volume of diluent using a sterile hypodermic needle and syringe. Discard the filled syringe into a suitable puncture proof container.
6. Remove the appropriate amount of diluent in the diluent vial and then follow steps 5 – 10 as previously described in **A**.

The volume of diluent PROVIDED with each IGIV, GAMMAGARD S/D package size is as follows:

Vial Size GAMMAGARD S/D	Vial Size-Sterile Water for Injection	For a 5% solution, no diluent is removed. For a 10% solution, remove one half (1/2) of the diluent.
5 g	96 mL	
10 g	192 mL	

Required Diluent Volume for 10% concentrations

Concentration	5 g/vial	10 g/vial
5%	Do not remove any diluent for reconstitution of 5% solution	
10%	48 mL	96 mL

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Gammagard® SD 5% Infusion Rate Table

For 10% concentrations, refer to standardized 10% rate table

Consult IVIG PPO for dosing body weight	**0.5 mL/kg/h**	**1.0 mL/kg/**h	**2.0 mL/kg/**h	***4.0 mL/kg/**h
	Start rate for 30 min	** Increase rate every 15 min as tolerated		Max. rate for 5% SD
	mL/h	**mL/h**	**mL/h**	**mL/h**
1kg	0.5	1.0	2.0	4.0
2.5 kg	1.25	2.5	5.0	10
5 kg	2.5	5.0	10	20
7.5 kg	3.75	7.5	15	30
10 kg	5	10	20	40
15 kg	7.5	15	30	60
20 kg	10	20	40	80
25 kg	12.5	25	50	100
30 kg	15	30	60	120
35 kg	17.5	35	70	140
40 kg	20	40	80	160
45 kg	22.5	45	90	180
50 kg	25	50	100	200
55 kg	27.5	55	110	220
60 kg	30	60	120	240
65 kg	32.5	65	130	260
70 kg	35	70	140	280
75 kg	37.5	75	150	300
80 kg	40	80	160	320
85 kg	42.5	85	170	340
90 kg	45	90	180	360
95 kg	47.5	95	190	380
100 kg	50	100	200	400
105 kg	52.5	105	210	420
110 kg	55	110	220	440
115 kg	57.5	115	230	460
120 kg	60	120	240	480

* Patients predisposed to renal dysfunction should be administered IVIG products at the minimum concentration and at the minimum rate of infusion practical (i.e at a rate less than 4 mL/kg/hr for a 5% solution or at a rate less than 2 mL/kg/hr for a 10% solution.

**Rapid infusion rates should not be used on patients at risk for renal dysfunction or thromboembolic events. Patients at high risk for thromboembolic events include the elderly, overweight, or immobilized as well as patients with a history of hypertension, cardiovascular disease, thrombotic disorders, or dehydration.

Patients who tolerate the 5% concentration at 4 mL/kg/hr can be infused with the 10% concentration starting at 0.5 mL/kg/hr. If no adverse effects occur, the rate can be increased gradually up to a maximum of 8 mL/kg/hr.