IVIG Paediatric Dose & Administration

HOSPITAL SUNGAI BULOH

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Comparison between Human Normal Globulin (IVIG) products available in HSgB

Prepared by PRIC, Hospital Sungai Buloh

Brand		Intragam NexGen	Privigen	Intragam P	Flebogamma 5% DIF	I.V. Globulin SN
Strength		10%		6%	5%	5%
Pack Size		5g/50ml	2.5g/25ml	3g/50ml	2.5g/50ml	2.5g/50ml
Content	IgG1	69%		61%	66.6%	⩾95% of total protein 90 - 110% of labelled content
	IgG2	26%		36%	28.5%	
	IgG3	3%		3%	2.7%	
	IgG4	2%		1%	2.2%	
	IgA	⩽25mcg/ml		<25mcg/ml	<50mcg/ml	<100mcg/ml
	Excipient	L-proline		10g maltose	5g D-sorbitol	10g maltose
Source		Malaysian donor	US/EU donor	Malaysian donor	US donor	US donor
Storage Conditions		Room temperature		2 - 8°C	Room temperature	2 - 8°C
Stability		Use immediately once opened		Once removed from fridge, store below 25°C & use within 3 months	Use immediately once opened	Unopened: Stable up to 6 months at room temperature Once opened: Stable for 1 hr
Presentation						

Refer **Table A** for **pediatric rate of administration**

Refer **Table B** for **pediatric rate of administration**

References:
1. Intragam NexGen [Product Insert]. Australia: CSL Behring; 5 October 2023.
2. Privigen [Product Insert]. Switzerland: CSL Behring; March 2021.
3. Intragam P [Product Insert]. Australia: CSL Behring; November 2020.
4. Flebogamma 5% DIF [Product Insert]. Spain: Grifols; August 2011.
5. I.V.-Globulin SN [Product Insert]. Korea: Green Cross; 7 April 2017.

Stock availability may vary—please confirm with Inpatient Pharmacy before supply.

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Table A

IVIG 10% = 2.5g/25ml or 5g/50ml Pediatric Administration Guide

IVIG DOSE CALCULATION

Step 1: Patient's dose of IVIG (g) = Dose in g/kg X Patient weight (kg)

Step 2: No of vials = $\frac{\text{Patient's dose (g)}}{\text{Strength of IVIG (g)}}$ [Available strengths: 2.5g/25ml or 5g/50ml]

Step 3: Convert to mL = Number of vials x volume of IVIG (ml)

Note:
- Use Ideal Body Weight (IBW) in obese pediatrics patients.[1]
- Round up to the nearest vial strength to reduce wastage
  e.g. **2.5g/25mL** for 21g dose = 8.4 vials (round down to 20g = 8 vials)

ADMINISTRATION

IVIG is given **UNDILUTED.**

Step (1) Start with **0.3 mL/kg/hour**
= 0.3 mL X (patient's weight) kg/hour
= ***A*** mL/hour run over 30 minutes

Step (2) Start with **0.6 mL/kg/hour**
= 0.6 mL X (patient's weight) kg/hour
= ***B*** mL/hour run over 30 minutes

Step (3) Start with 1.**2 mL/kg/hour**
= 1.2 mL X (patient's weight) kg/hour
= ***C*** mL/hour run over 30 minutes

Step (4) Start with **2.4 mL/kg/hour**
= 2.4 mL X (patient's weight) kg/hour
= ***D*** mL/hour run until infusion complete

For IVIG 10% only!

2.5g/25ml or 5g/50ml

Remarks:
- Max rate for patients with **Immune Thrombocytopenic Purpura (ITP)** is **2.4ml/kg/hr**
- For other indications, if no adverse reaction, may increase administration rate to 3.6ml/kg/hr for 30mins, then subsequently 4.8ml/kg/hr until the dose is completed.

Note:
1. Ensure product is brought to room temperature or body temperature before use.
2. **Monitor vital signs** for any **allergic / adverse reactions.**
   a) In response to a **minor allergic reaction (flushes, nausea, back or abdominal pain, dizziness, headache)**, withhold IVIG infusion and treat symptomatically. Once patient is stable, consider IVIG administration at the previous tolerable infusion rate.[2]
   b) In response to **severe allergic reaction (anaphylaxis) with respiratory or cardiac compromise),** stop IVIG infusion immediately and implement emergency procedures for treatment of acute anaphylaxis.[2]
   c) Adverse reactions are usually dependent on the infusion rate and most commonly occur in the first hour of infusion.[2]

   All adverse reactions must be reported to Pharmacy Resource Information Centre.

References:
1. Woodland, Gail (2021). Retrieved from https://www.sps.nhs.uk/articles/how-should-medicines-be-dosed-in-children-who-are-obese/
2. PRIVIGEN Human Normal Immunoglobbulin 10% Liquid Product Information Leaflet (2021: CSL Behring)

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Table B

IVIG 6% = 3g/50ml or 5% = 2.5g/50ml Pediatric Administration Guide

IVIG DOSE CALCULATION

Step 1: Patient's dose of IVIG (g) = Dose in g/kg X Patient weight (kg)

Step 2: No of vials = $\frac{\text{Patient's dose (g)}}{\text{Strength of IVIG (g/50ml)}}$ [Available strengths: 2.5g or 3g]

Step 3: Convert to mL = Number of vials x 50mL

Note:
- Use Ideal Body Weight (IBW) in obese pediatrics patients.[1]
- Round up to the nearest vial strength to reduce wastage
  e.g. if using **3g/50mL** for 20g dose = 6.67 vials (round up to 7 vials)
  if using **2.5g/50mL** for 20g dose = 8 vials

ADMINISTRATION

IVIG is given **UNDILUTED.**
The rate of administration of IVIG has been standardised for **all brands**.

Step (1) Start with **0.5 mL/kg/hour**
= 0.5 mL X (patient's weight) kg/hour
= ***A*** mL/hour run over 15 minutes

Step (2) Start with **1 mL/kg/hour**
= 1 mL X (patient's weight) kg/hour
= ***B*** mL/hour run over 15 minutes

Step (3) Start with **2 mL/kg/hour**
= 2 mL X (patient's weight) kg/hour
= ***C*** mL/hour run over 15 minutes

Step (4) Start with **3 mL/kg/hour**
= 3 mL X (patient's weight) kg/hour
= ***D*** mL/hour run over 15 minutes

For IVIG 6% or 5% ONLY

3g/50ml or 2.5g/50ml

Step (5) If no adverse reaction, continue administration for *up to 11 hours* **without exceeding maximum rate:**

Balance dose (mL) = Total dose (mL) – [$\frac{A+B+C+D}{4}$ **] (mL)**

Calculate based on **MAXIMUM rate of infusion (Brand specific):**
- I.V.-Globulin SN 5% : 3.6mL/kg/hour[5]
- Intragam P 6% : 5mL/kg/hour[2,3]
- Flebogamma 5% : 6mL/kg/hour[4]

Note:
1. Ensure product is brought to room temperature or body temperature before use.
2. **Monitor vital signs** for any **allergic / adverse reactions.**
   a) In response to a **minor allergic reaction (flushes, nausea, back or abdominal pain, dizziness, headache)**, withhold IVIG infusion and treat symptomatically. Once patient is stable, consider IVIG administration at the previous tolerable infusion rate.[2]
   b) In response to **severe allergic reaction (anaphylaxis) with respiratory or cardiac compromise),** stop IVIG infusion immediately and implement emergency procedures for treatment of acute anaphylaxis.[2]
   c) Adverse reactions are usually dependent on the infusion rate and most commonly occur in the first hour of infusion.[2]

   All adverse reactions must be reported to Pharmacy Resource Information Centre.

References:
1. Woodland, Gail (2021). Retrieved from https://www.sps.nhs.uk/articles/how-should-medicines-be-dosed-in-children-who-are-obese/
2. Guidelines – Standardised infusion rates for intravenous immunoglobulin replacement therapy (updated June 2018). Retrieved from https://www.allergy.org.au/images/stories/pospapers/ASCIA_Guidelines_IVIG_Infusion_Rates_2018.pdf
3. How to administer Intragam®P (Intravenous Immunoglobulin)- Quick Guide (2014). Retrieved from https://www.clinicaldata.nzblood.co.nz/resourcefolder/intragamp.php?dhbid=9#calculato
4. Flebogamma 5% Product Information Leaflet (2011 : Grifols)
5. I.V.-Globulin SN 5%: Product Information Leaflet (2016 : Green Cross Corp)

IVIG DOSE BASED ON SPECIFIC INDICATIONS

INDICATION	DOSE	REMARKS
Immune Thrombocytopenic Purpura (ITP)	**General management of ITP:** 0.8g/kg as a **SINGLE** dose **Emergency Treatment of ITP:** 0.8 – 1g/kg as a SINGLE dose; in combination with IV Methylprednisolone in severe life-threatening ITP[4,6]	• One repeat dose at 24 to 48 hours may be given if response is inadequate and symptomatic thrombocytopenia recurs, provided a total dose of 2g/kg is not exceeded.[4]
Kawasaki Disease	2 g/kg over 10-12 hours as a **single infusion**[6] OR 1 g/kg over 10-12 hours for 2 days (if concerned about fluid overload)	• Consider repeat dose of IVIG in Kawasaki Disease not responding to primary treatment whereby patient has persistent fever ≥ 36hrs after completion of initial dose of IVIG.[6]
Guillain-Barré syndrome (GBS)	To be started within first 2 weeks of illness **:**[3,6] 2 g/kg total divided over 2 - 5 days[6] **(To consult Paediatric Neuromedical Specialist)**	• Second dose of IVIG can be given to those who may suffer a relapse of symptoms in the first weeks after improvement from IVIG.[6]
Autoimmune Encephalitis	2 gm/kg total divided over 2 - 5 days[6] **(To consult Paediatric Neuromedical Specialist)**	• In adjunct with IV Methylprednisolone 10mg/kg/dose 8 hourly (up to 1 g daily) for 5 days with IV/Oral Omeprazole[6]
Multisystem inflammatory syndrome in children (MIS-C) associated with COVID-19	2 g/kg over 8-12 hours as a **single infusion**[1,2] OR 1 g/kg over 8-12 hours for **2 days** (if concerned about fluid overload) **PATIENTS WITH SIGNIFICANT LV DYSFUNCTION**[1,2] (caution for fluid overload) 1 g/kg over 8-12 hours **(DAY 1)** 0.5 g/kg over 8-12 hours **(DAY 2-3)**	
**** Dosing Adjustment in obese paediatric patients : Use Ideal Body Weight (IBW)*** **** Use with caution in patients with renal impairment***		

References

1. Annex 2e: Clinical Management of Confirmed COVID-19 Case in Adult and Children (updated August 2021). Retrieved from https//covid-19.moh.gov.my/garis-panduan/garis-panduan-kkm
2. Children's Minnesota Clinical Guideline for MIS-C Rev-6/21. Retrieved from https://www.childrensmn.org/Departments/Infectioncontrol/pdf/mis-c-clinical-guideline.pdf
3. Gullain-Barre syndrome including variants (GBS). Criteria for Clinical Use of Immunoglobulin in Australia, 30 March 2020. Retrieved from: https://www.criteria.blood.gov.au/MedicalCondition/View/2614
4. Immune thrombocytopenia (ITP) in children 15 Years and Younger. Criteria for Clinical Use of Immunoglobulin in Australia, 20 October 2018. Retrieved from: https://www.criteria.blood.gov.au/MedicalCondition/View/2574
5. Intragam P 6% Information Leaflet. Retrieved from https://www.medsafe.govt.nz/profs/Datasheet/i/IntragamPinj.pdf
6. Paediatric Protocols for Malaysian Hospitals. MOH Malaysia. 4th Edition. 2018.