Intravenous immunoglobulin

Blood Matters and the Victorian Transfusion Nurses (Australian Red Cross Lifeblood)

March 2023

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Blood Matters

Acknowledgement of Country

We acknowledge and pay our respects to the past, present and future Traditional Custodians and Elders of this land and the continuation of cultural, spiritual and educational practices of Aboriginal and Torres Strait Islander peoples.

Disclaimer

This presentation is intended to assist with education of clinical staff who provide treatment and care for patients receiving intravenous immunoglobulin therapy.

Information in this presentation is accurate at time of publication.

Background

Immunoglobulin products provide critical therapy, and can be a life-saving treatment, for people with immunodeficiencies and some autoimmune disorders.

The NBA actively manages the national supply and allocation of immunoglobulin in conjunction with the Australian Red Cross Lifeblood (Lifeblood).

Increase in demand for IVIg has declined since IVIg governance program was initiated but remains at 7.3% PA.
(https://www.blood.gov.au/Ig-program-updates)

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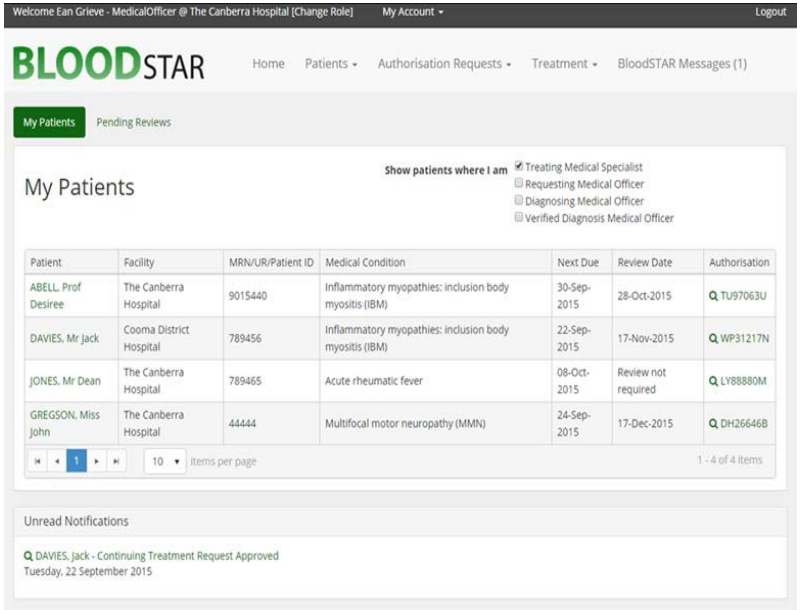
Current supply arrangements

Domestic IVIg product	**Privigen® AU 10%** (to replace Intragam® 10) available April 2023	**CSL Behring**
Imported IVIg products	Flebogamma® 5% & 10%	Grifols Australia
	Gamunex® 10%	Grifols Australia
	Privigen® 10%	CSL Behring
	Octagam® 10%	Octapharma
	Kiovig 10% from May 2023	Takeda
Domestic SCIg product	Evogam®	CSL Behring
Imported SCIg products	Hizentra® 20%	CSL Behring
	Cuvitru® 20%	Takeda

BloodSTAR

Who uses BloodSTAR?

- **Prescribers** – request authorisation for access to government funded Ig for patient treatment
- **Authorisers** – specified staff of the Australian Red Cross Lifeblood; authorise initial and continuing access
- **Nurses** – coordinate patient treatments
- **Dispensers** – manage inventory, order products and dispense the correct products to authorised patients



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BloodSTAR – view authorisation

View authorisation provides a central point for checking a patients authorised dose and status.

In BloodSTAR:

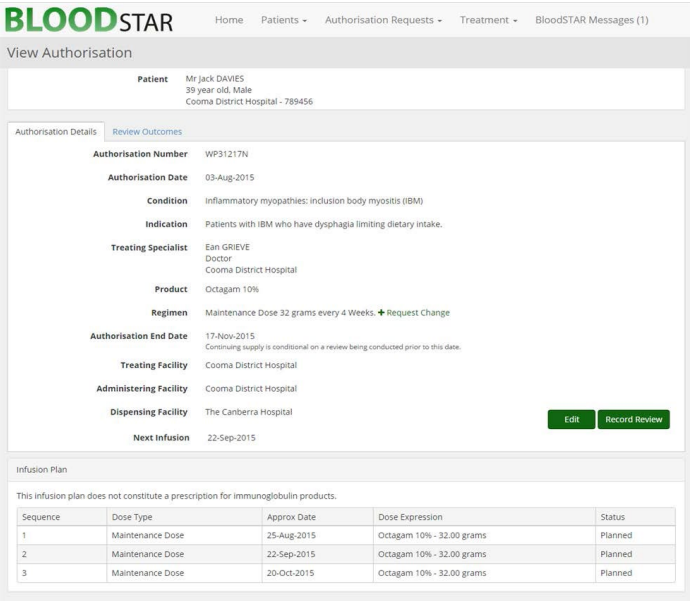
- Prescribers and nurses can view this for all patients at their facility.
- Medical Officers can also record review outcomes for the patients from this screen.

In BloodNET:

- Dispensers can view the same level of detail using the *Check Authorisation* function

[BloodSTAR-Tip-Sheet-Viewing-authorisation-details-in-BloodSTAR.pdf]

The prescriber should be contacted for questions about dose or product



The Criteria for Immunoglobulin Use in Australia

The Criteria for Immunoglobulin Use in Australia (the Criteria) Version 3, released in October 2018

Why did the Criteria change?

- To align with new evidence
- To ensure Ig therapy is available for appropriate patient use
- To manage the growth in demand for this precious, human-derived product

For more information on the Criteria and the Immunoglobulin Governance program visit https://www.blood.gov.au/Ig-governance

For the latest Immunoglobulin Governance updates visit https://www.blood.gov.au/Ig-program-updates

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BloodSTAR – further information

- Further information on BloodSTAR and its' use you can find at the National Blood Authority website:L https://www.blood.gov.au/bloodstar-support-materials

Call: 13 000 BLOOD

Jurisdictional direct orders (JDOs)

- Doctors may want to prescribe IVIg for medical conditions not funded under the Criteria
- In this case, the doctor can seek funding for IVIg through local arrangements (e.g. local health service therapeutics committee (usually via pharmacy)
- Only imported IVIg is available for purchase under the JDO arrangements for indications that are not listed in the criteria
- Imported IVIg can be accessed directly from the supplier at the same price negotiated by the NBA and must be paid for in full by the Approved Recipient (health service or individual patient)

Intragam® 10 and Privigen® AU comparison

Characteristics	Intragam® 10 (Discontinued)	Privigen® AU
Source plasma	Australian voluntary non-remunerated donors	Australian voluntary non-remunerated donors
Concentration	10% normal immunoglobulin (human)	10% normal immunoglobulin (human)
Presentation	25mL (2.5g), 100mL (10g), 200mL (20g)	50mL (5g), 100mL (10g), 200mL (20g)
Excipient	Glycine	L-proline
Shelf life	2 years	3 years
Storage conditions	Store at 2°C-8°C. Once removed from refrigeration store below 25°C and use within 3 months.	Store below 25°C. Do not shake

- Registered indications and dosing – The indication and dosing for PRIVIGEN® AU and INTRGAM® 10 are different. Please refer to the approved product information for more information
- Do not freeze. Protect from light
- See infusion rate tables for comparison of infusion rates
- Comparison information is based on the CSL Behring Privigen AU Compendium (refer to: Access to new Materials and information: https://hcp.cslbehring.com.au/)

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Description - Privigen® AU

Description	Privigen® AU
Presentation	5g (50mL); 10g (100mL); 20g (200mL)
Concentration	10%
Source plasma	Australia
Stabiliser	L-proline
Storage conditions	Store below 25°C (Do not freeze) Protect from light
Infusion rate	Start at 0.3mL/kg/hr If well tolerated, the rate can gradually increased at 30 minute intervals to maximum rate Max infusion rate of 4.8mL/kg/hr

Description - Privigen® (imported)

Description	Privigen® AU
Presentation	5g (50mL); 10g (100mL); 20g (200mL)
Concentration	10%
Source plasma	European and USA remunerated and non-remunerated donors
Stabiliser	L-proline
Storage conditions	Store below 25°C (Do not freeze) Protect from light
Infusion rate	Start at 0.3mL/kg/hr If well tolerated, the rate can gradually be increased at 30 minute intervals to maximum rate Max infusion rate of 4.8mL/kg/hr

Infusion rate guide

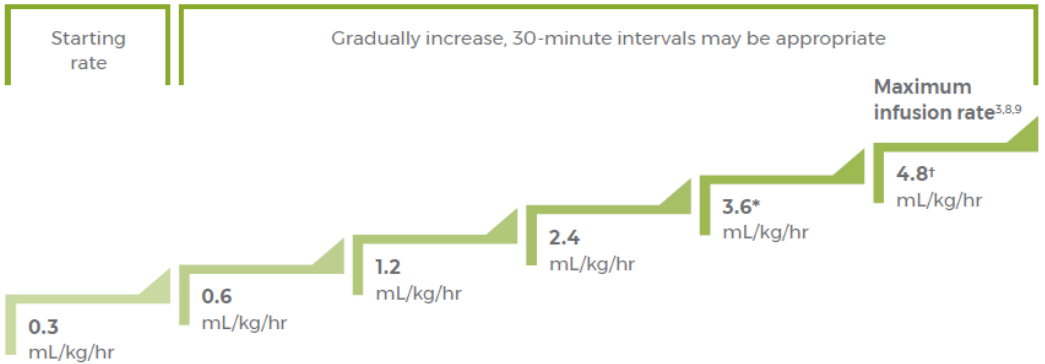
Privigen® AU infusion rate guide (adults)

Suggested PRIVIGEN® AU infusion rate

The infusion rate table below is provided as a guide only. Infusion rate needs to be individualised to patient's risk factors, comorbidities and tolerability.

- The **initial infusion rate** for PRIVIGEN® AU is **0.3 mL/kg/hr**[3]
- If the first infusion is well tolerated the rate **can be gradually increased as long as it continues to be tolerable**[3]
- A similar **step-wise approach** can then be used for **subsequent infusions**

Example of PRIVIGEN® AU infusion rate step-up:[8–11]



*Step rate rises used between 2.4 mL/kg/hr and 4.8 mL/kg/hr are at the discretion of the healthcare professional and as tolerated by the patient.
†In the pivotal PID study maximum rate for the first three infusions was capped at 2.4 mL/kg/hr. From the fourth infusion onwards the maximum rate was 4.8 mL/kg/hr.[9] In the extension trial to the pivotal PID study a stepwise approach was used up to a maximum rate of 4.8 mL/kg/hr in 45% of infusions and 7.2 mL/kg/hr in 36% of infusions.[10] In the pivotal ITP study the maximum rate was 2.4 mL/kg/hr (only 2 infusions given).[11]

All patients should be regularly monitored throughout the infusion and for a period after.[3]

Ref: CSL Behring
Privigen AU Compendium

Privigen® AU (10%) and Privigen® (10%) infusion rate guide

Infusion rate mL/kg/ hr	Pump rate	10 kg	15 kg	20 kg	25 kg	30 kg	35 kg	40 kg	45 kg	50 kg	55 kg	60 kg	65 kg	70 kg	75 kg	80 kg	85 kg	90 kg	95 kg	100 kg
0.3	mL/hr	3	4.5	6	7.5	9	10.5	12	13.5	15	16.5	18	19.5	21	22.5	24	25.5	27	27	30
0.6	mL/hr	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	54	60
1.2	mL/hr	12	18	24	30	36	42	48	54	60	66	72	78	84	90	96	102	108	108	120
2.4*	mL/hr	24	36	48	60	72	84	96	108	120	132	144	156	168	180	192	204	216	246	240
3.6*	mL/hr	36	54	72	90	108	126	144	162	180	198	216	234	252	270	288	306	324	324	360
4.8*	mL/hr	48	72	96	120	144	168	192	216	240	264	288	312	336	360	384	408	432	432	480

*Step-up rate rises used between 2.4mL/kg/hr are at the discretion of the health care professional and as tolerated by the patient.
See the product information for more detail regarding infusion rate studies for specific patient groups.

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Prescribing and ordering

Clinicians must take care to prescribe and order through BloodSTAR the product they need for their patient.

Privigen ≠ Privigen AU

Flebogamma® 5% DIF

Description	Flebogamma® 5% DIF
Presentation	2.5g (50mL), 5g (100mL), 10g (200mL), 20g (400mL) vials
Concentration	5% **Pay careful attention that you have the correct product strength**
Source plasma	USA and European remunerated and non-remunerated donors
Stabiliser	Sorbitol
Storage conditions	• Store below 30°C for up to 2 years • Protect from light. • Do not freeze
Infusion rate	• First 30 minutes: 0.01 – 0.02 mL/kg/minute • If well tolerated gradually increase rate to a maximum of 0.1 mL/kg/minute • Maximum rate 0.1 mL/kg/min (6mL/kg/hour)

Note: B. Flebogamma 5% and 10% is contraindicated in babies and young children as hereditary fructose intolerance may not yet be diagnosed and may lead to a fatal reaction associated with the sorbitol stabiliser.

Image: http://www.igliving.com/magazine/ads/IGL_2010-10_AD_Grifols_Flebogamma-5-percent-DIF.pdf

Flebogamma® 5% DIF infusion rate guide

Infusion rate mL/kg/min	Infusion rate mL/kg/hr	Pump rate	10 kg	20 kg	30 kg	40 kg	50 kg	60 kg	70 kg	80 kg	90 kg	100 kg	110 kg	120 kg
0.01	0.6	mL/hr	6	12	18	24	30	36	42	48	54	60	66	72
0.02	1.2	mL/hr	12	24	36	48	60	72	84	96	108	120	132	144
0.03	1.8	mL/hr	18	36	54	72	90	108	126	144	162	180	196	216
0.04	2.4	mL/hr	24	48	72	96	120	144	168	192	216	240	264	288
0.05	3.0	mL/hr	30	60	90	120	150	180	210	240	270	300	330	360
0.06	3.6	mL/hr	36	72	108	144	180	216	252	288	324	360	396	432
0.07	4.2	mL/hr	42	84	126	168	210	252	294	336	378	420	462	504
0.08	4.8	mL/hr	48	96	144	192	240	288	336	384	432	480	528	576
0.09	5.4	mL/hr	54	108	162	216	270	312	378	432	486	540	594	648
0.10	6.0	mL/hr	60	120	180	240	300	348	420	480	540	600	660	720

Increase the rate by 0.01 mL/kg/min (0.6 mL/kg/hr) 30 minutely to the maximum rate or as tolerated by the patient.

This table is based on the FLEBOGAMMA® 5% DIF product information, always refer to the product information and your local Clinical Practice Guidelines for more information.

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Flebogamma® 10% DIF

Description	Flebogamma® 10% DIF
Presentation	5g (100mL), 10g (200mL), 20g (400mL) vials
Concentration	10% **Pay careful attention that you have the correct product strength**
Source plasma	USA and European remunerated and non-remunerated donors
Stabiliser	Sorbitol
Storage conditions	• Store below 30°C for up to 2 years • Protect from light. • Do not freeze
Infusion rate	• First 30 minutes: 0.01 mL/kg/minute • Second 30 minutes: 0.02 mL/kg/minute • If tolerated increase by a further 0.02 mL/kg/minute each 30 minutes to maximum 0.08 mL/kg/minute • Maximum rate 0.08mL/kg/minute (4.8mL/kg/hour)

Note: B. Flebogamma 5% and 10% is contraindicated in babies and young children as hereditary fructose intolerance may not yet be diagnosed and may lead to a fatal reaction associated with the sorbitol stabiliser.

Image: https://www.grifols.com/en/product/-/product/spain/flebogamma_10_dif

Flebogamma® 10% DIF infusion rate guide

Infusion rate mL/kg/min	Infusion rate mL/kg/hr	Pump rate	10 kg	20 kg	30 kg	40 kg	50 kg	60 kg	70 kg	80 kg	90 kg	100 kg	110 kg	120 kg
0.01	0.6	mL/hr	6	12	18	24	30	36	42	48	54	60	66	72
0.02	1.2	mL/hr	12	24	36	48	60	72	84	96	108	120	132	144
0.03	1.8	mL/hr	18	36	54	72	90	108	126	144	162	180	196	216
0.04	2.4	mL/hr	24	48	72	96	120	144	168	192	216	240	264	288
0.05	3.0	mL/hr	30	60	90	120	150	180	210	240	270	300	330	360
0.06	3.6	mL/hr	36	72	108	144	180	216	252	288	324	360	396	432
0.07	4.2	mL/hr	42	84	126	168	210	252	294	336	378	420	462	504
0.08	4.8	mL/hr	48	96	144	192	240	288	336	384	432	480	528	576

Increase rate by 0.01 mL/kg/min (0.6 mL/kg/hr) 30 minutely to the maximum rate or as tolerated by the patient.
This table is based on the FLEBOGAMMA® 10% DIF product information, always refer to the product information and your local Clinical Practice Guidelines for more information.

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Gamunex® 10%

Description	Gamunex® 10%
Presentation	5g (50mL), 10g (100mL), 20g (200mL) vials
Concentration	10%
Source plasma	USA and European remunerated and non-remunerated donors
Stabiliser	Glycine
Storage Condition	• Store at 2˚C - 8˚C for up to 36 months, may be stored at temperatures not exceeding 25˚C for up to 6 months anytime during the 36 month shelf life, after which the product must be used immediately or discarded. • Do not freeze.
Infusion rate	• First 30 minutes: 0.01 mL/kg/minute • If well tolerated gradually increase rate to a maximum of 0.08 mL/kg/minute • Maximum rate: 0.08 mL/kg/minute (4.8mL/kg/hour)

Picture published by Grifols Australia

Gamunex® 10% infusion rate guide

Infusion rate mL/kg/min	Infusion rate mL/kg/hr	Pump rate	10 kg	20 kg	30 kg	40 kg	50 kg	60 kg	70 kg	80 kg	90 kg	100 kg	110 kg	120 kg
0.01	0.6	mL/hr	6	12	18	24	30	36	42	48	54	60	66	72
0.02	1.2	mL/hr	12	24	36	48	60	72	84	96	108	120	132	144
0.03	1.8	mL/hr	18	36	54	72	90	108	126	144	162	180	196	216
0.04	2.4	mL/hr	24	48	72	96	120	144	168	192	216	240	264	288
0.05	3.0	mL/hr	30	60	90	120	150	180	210	240	270	300	330	360
0.06	3.6	mL/hr	36	72	108	144	180	216	252	288	324	360	396	432
0.07	4.2	mL/hr	42	84	126	168	210	252	294	336	378	420	462	504
0.08	4.8	mL/hr	48	96	144	192	240	288	336	384	432	480	528	576

Increase rate by 0.01 mL/kg/min (0.6 mL/kg/hr) 30 minutely to the maximum rate or as tolerated by the patient. This table is based on the Gammunex® 10% product information, always refer to the product information and your local Clinical Practice Guidelines for more information.

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Octagam® 10%

Description	Octagam® 10%
Presentation	5g in 50mL, 10g in 100mL, 20g in 200mL
Concentration	10%
Source plasma	European and USA remunerated and non-remunerated donors
Stabiliser	Maltose
Storage conditions	Store at 2-8˚C for up to 2 years. Once removed from refrigeration, store below 25°C and use within 9 months. Do not freeze Protect from light
Infusion rate	• Initial infusion rate: 0.6-1.2mL/kg/hour for 30 minutes • If well tolerated, the rate of administration may gradually be • increased to a maximum of 7.2 mL/kg/hour. • Suggested rate of increase is 0.6mL/kg/hour each 30 minutes • Maximum infusion rate is 7.2mL/kg/hour

Octagam® 10% infusion rate

Infusion rate mL/kg/hr	Pump rate	10 kg	20 kg	30 kg	40 kg	50 kg	60 kg	70 kg	80 kg	90 kg	100 kg	110 kg	120 kg
0.6	mL/hr	6	12	18	24	30	36	42	48	54	60	66	72
1.2	mL/hr	12	24	36	48	60	72	84	96	108	120	132	144
1.8	mL/hr	18	36	54	72	90	108	126	144	162	180	196	216
2.4	mL/hr	24	48	72	96	120	144	168	192	216	240	264	288
3.0	mL/hr	30	60	90	120	150	180	210	240	270	300	330	360
3.6	mL/hr	36	72	108	144	180	216	252	288	324	360	396	432
4.2	mL/hr	42	84	126	168	210	252	294	336	378	420	462	504
4.8	mL/hr	48	96	144	192	240	288	336	384	432	480	528	576
5.4	mL/hr	54	108	162	216	270	324	378	432	486	540	596	648
6.0	mL/hr	60	120	180	240	300	360	420	480	540	600	660	720
6.6	mL/hr	66	132	198	264	330	396	462	528	594	660	726	792
7.2	mL/hr	72	144	216	288	360	432	504	576	648	720	794	864

Increase rate by 0.6 mL/kg/hr 30 minutely to the maximum rate or as tolerated by the patient.

This table was developed using the Octagam® 10% product information, always refer to the product information and your local Clinical Practice Guideline for more information

Kiovig® 10%

Description	Kiovig 10%
Presentation	1g in 10 mL, 2.5g in 25 mL, 5g in 50 mL, 10g in 100 mL, 20g in 200 mL, 30g in 300mL
Concentration	10%
Source plasma	European and USA remunerated and non-remunerated donors
Stabiliser	Glycine
Storage conditions	Store at 2°C to 8°C for up to 36 months from date of manufacture. Refrigerate. Do not freeze.
Infusion rate	• Initial infusion rate: 0.5 mL/kg/hour • If well tolerated gradually increased, by 0.5mL/kg/hour, every 30 minutes to a rate of 5.0 mL/kg/hour • For subsequent infusions follow the same rate increase to the maximum rate tolerated in the initial treatment

Reference: Kiovig product information

Kiovig® 10% infusion rate

Infusion rate mL/kg/hr	Pump rate	10 kg	20 kg	30 kg	40 kg	50 kg	60 kg	70 kg	80 kg	90 kg	100 kg	110 kg	120 kg
0.5	mL/hr	5	10	15	20	25	30	35	40	45	50	55	60
1.0	mL/hr	10	20	30	40	50	60	70	80	90	100	110	120
1.5	mL/hr	15	30	45	60	75	90	105	120	135	150	165	180
2.0	mL/hr	20	40	60	80	100	120	140	160	180	200	220	240
2.5	mL/hr	25	50	75	100	125	150	175	200	225	250	275	300
3.0	mL/hr	30	60	90	120	150	180	210	240	270	300	330	360
3.5	mL/hr	35	70	105	140	175	210	245	280	315	350	385	420
4.0	mL/hr	40	80	120	160	200	240	280	320	360	400	440	480
4.5	mL/hr	45	90	135	180	225	270	315	360	405	450	495	540
5.0	mL/hr	50	100	150	200	250	300	350	400	450	500	550	600

Increase rate by 0.5 mL/kg/hr 30 minutely to the maximum rate or as tolerated by the patient.

This table was developed using the Kiovig® 10% product information, always refer to the product information and your local Clinical Practice Guideline for more information.

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Pre-administration

- Document baseline observations
- Assess the patient for signs or symptoms that may be confused with a transfusion reaction
- Hydration – ensure patient is well hydrated as this will help to reduce the risk of some reactions
- Perform pre-administration patient and product identification checks (check local policy)
- Check the integrity of the product
    - All products should be clear or slightly opalescent liquids ranging from colourless to pale yellow
    - Do not use solutions that are cloudy or have deposits

Administration

1. Allow IVIg to come to room temperature before use
2. Remove the plastic cover from the seal
3. Apply a suitable antiseptic (alcohol swab) to the exposed part of the rubber stopper and allow to dry (as per local policy)

NOTE: Administration from glass bottles requires a vented system. A vented system can be in the form of a vented spike adaptor, a side vent in an IV line or an airway needle.

The product does not contain any preservative or antimicrobial protection, each vial should be completed within 4 hours of piercing the rubber stopper.

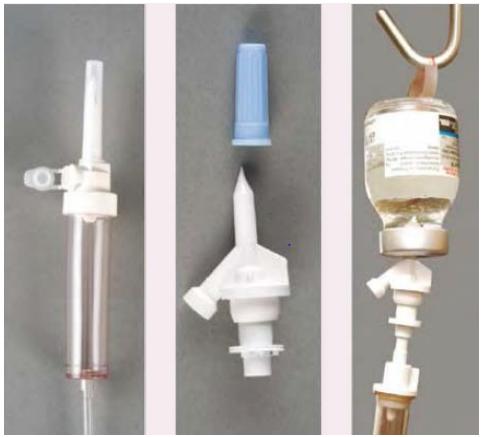

Image: Flippin Blood 2nd edition, 2012

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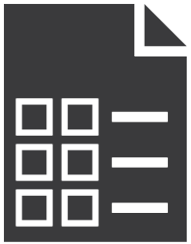
Infusion rates – paediatric/neonatal

- Consideration should be given to running IVIg at slower rates for paediatric/neonatal patients.
- Suggest discussing rate of infusion with a Consultant Paediatrician to determine the best rate for each child/infant/neonate.
- Contact Royal Children's Hospital for the latest paediatric and neonatal IVIg infusion guideline

Infusion rates

- Each product has it's own individual infusion protocol, **make sure you are using the correct one**
- Infusion via pump is recommended for accuracy
- Start with the smallest vials first, when the infusion rate is slowest as this helps to prevent waste if a reaction occurs



Precautions for all IVIg products

- Consider using a slower maximum rate of infusion for:
  - the elderly
  - those at risk of thrombosis
  - those with renal insufficiency
  - paediatric and neonatal patients
    - (check product information and previous slide)

- Patients should be well hydrated and observed closely during infusion to reduce the risk of adverse events

Patient observation

- Document observations as per hospital policy
- Patients with signs of reaction, or who have reacted previously, should be observed closely and more frequently and a slower infusion rate used
- Recommended - out patients remain in the infusion centre for 20 minutes (minimum) following infusion

Adverse events

Some of the more common signs and symptoms for adverse reactions to IVIg

chills headache fever arthralgia	nausea/vomiting rash/allergy	low blood pressure moderate low back pain

Adverse event response

Severe reactions
- Stop infusion
- MET call if needed
- Notify medical staff

Mild reactions
- Stop infusion – until clinical improvement
- Notify medical staff
- Treat symptoms

If the patient improves
- On advice of medical staff
- Cautiously restart infusion at a slower rate

Report and respond to reactions as per local policy
- Report serious adverse reactions to the manufacturer

Traceability

To maintain a link between the product and the recipient always record the product name and batch number in the medical record

Product not used for the intended patient must be returned to the blood bank, pathology provider, pharmacy. It should never be kept in the clinical area for infusion to another patient.

Image courtesy Royal Melbourne Hospital 2023

Subcutaneous immunoglobulin (SCIg)

For patients with suitable conditions, consideration should be given to moving the patient to SCIg

Further information is available on the Blood Matters webpage

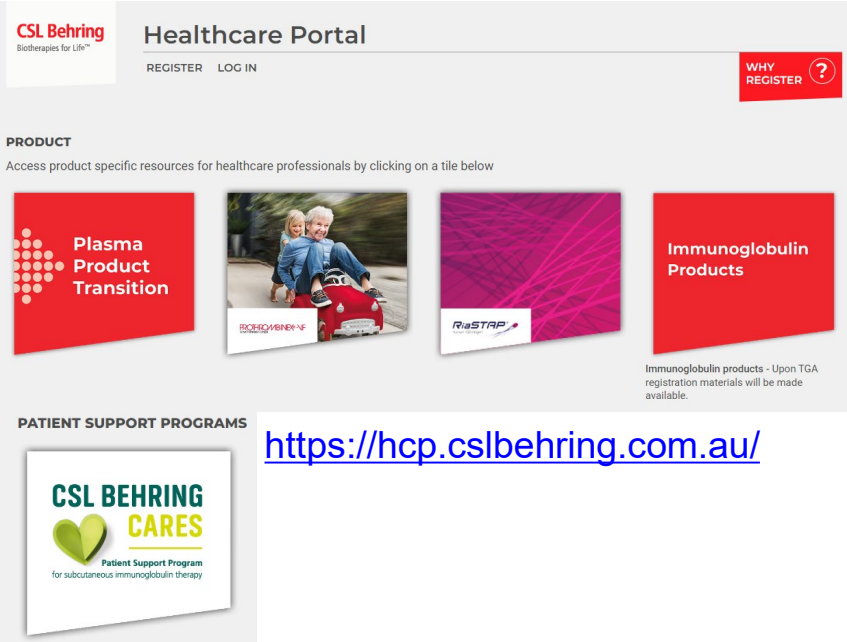
Why use SCIg?

SCIg can be administered in the home, either self administered or by a carer

SCIg provides stable immunoglobulin levels, leading to:

- Fewer or less frequent infections
- Reduced hospital admissions
- Improved compliance with treatment as the patient has greater control of their own care
- Do not need IV access
- Systemic side effects are rare

CSL Behring resources



https://hcp.cslbehring.com.au/

Privigen WebApp - online Infusion Calculator

Can help with calculating individual patient infusion rates and schedules: https://www.privigen.com.au/privigen-webapp

Useful links

- Victorian Australian Red Cross Lifeblood Transfusion Nurses contact: vtatn@redcrossblood.org.au
- Patient information: https://www.blood.gov.au/patient-factsheets-and- resources

SWITCHING IMMUNOGLOBULIN PRODUCTS – WHAT SHOULD I KNOW? WHAT CAN I DO?

The National Blood Authority website also has information for patients changing products

- CSL Behring: http://www.csl.com.au/products/product-finder.htm
- Grifols: http://www.grifols.com
- Octaphama: https://www.octapharma.com/australia/
- Takeda Pharmaceuticals Australia Pty Ltd. https://www.takeda.com/en-au/what-we-do/our-products/

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Acknowledgement/s

Australian governments fund the Australian Red Cross Lifeblood for the provision of blood, blood products and services to the Australian community.

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Australian Red Cross Lifeblood Blood Matters

Accessibility statement and publisher information

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