intragam® P

Human Normal Immunoglobulin **6%** (6g/100ml) – Intravenous

Before prescribing, please review Data Sheet available at www.cslbehring.com.au/products/products-list
The approved Data Sheet is also available to download from the New Zealand Blood Service website: www.nzblood.co.nz.

Minimum Product Information: Intragam® P (Human Normal Immunoglobulin [Ig] 6% (6g/100mL)). **Indications:** In adults and children; for IgG replacement in primary immunodeficiency diseases and symptomatic hypogammaglobulinaemia secondary to underlying disease or treatment. Immunomodulatory therapy in idiopathic thrombocytopenic purpura (ITP) in patients at high risk of bleeding or prior to surgery to correct platelet count, Kawasaki disease and Guillain-Barré Syndrome (GBS). **Contraindications:** Patients who have had a true anaphylactic reaction to a human Ig preparation. **Precautions:** Intravenous (IV) administration only. Monitor patients throughout infusion period. Risk of reactions to IVIg increased during first hour of infusion, with high infusion rate, when receiving Ig for the first time, with long interval since previous infusion, or when Ig product is switched. Contains trace amounts of IgA which may provoke anaphylaxis in patients with anti-IgA antibodies. Aseptic meningitis syndrome, renal dysfunction, acute renal failure, thrombotic events, positive direct antiglobulin tests and haemolysis have been reported in association with IVIg. Consider additional acid load that Intragam® P may present. Use in pregnancy, lactation, paediatrics or elderly has not been established. Made from human plasma, may contain infectious agents – risk of infectious agent transmission reduced by donor screening and dedicated manufacturing procedures. Consider vaccination where appropriate. **Interactions:** May interfere with some blood glucose measurements and may affect the response to live, attenuated vaccines. **Adverse Effects:** Reported adverse reactions include headache, migraine, vertigo, fatigue, somnolence, haemolysis, anaemia, neutropenia, thrombocytopenia, leucopenia, lymphopenia, reticulocytosis, positive direct Coombs test, abdominal pain, vomiting, nausea, rigors, fever, myalgia, hypertension, flushing, hot flushes, allergic reactions, injection site inflammation. For post-marketing reports, refer to Data Sheet. **Dosage & Administration:** Administer intravenously. Replacement therapy: 0.2-0.6 g/kg body weight (bw) per month to achieve IgG serum levels of ≥ 5 g/L. ITP: total cumulative dose ≤ 2 g/kg bw over 2-5 days. Kawasaki disease: 1.6-2.0 g/kg bw in divided dose over 2-5 days or 2.0 g/kg bw as a single dose, concomitant treatment with acetylsalicylic acid required. GBS: 0.4 g/kg bw/day for 3-7 days. Commence infusion at rate of 1 mL/min. After 15 minutes the rate may be gradually increased to 3-4 mL/min over a further 15 minutes. **Medicine Classification:** Prescription Medicine. Based on Intragam® P Approved Data Sheet, date of revision: 29 June 2018. (V14).

References: 1. INTRAGAM P approved Data Sheet.

CSL Behring is committed to the development and provision of high quality product education and support materials to assist the appropriate use of the plasma-derived therapies we manufacture for the New Zealand Blood Service. CSL Behring willingly complies with the ASA Code of Practice (www.asa.co.nz) which defines New Zealand's standards for the content of therapeutic product education and support materials.

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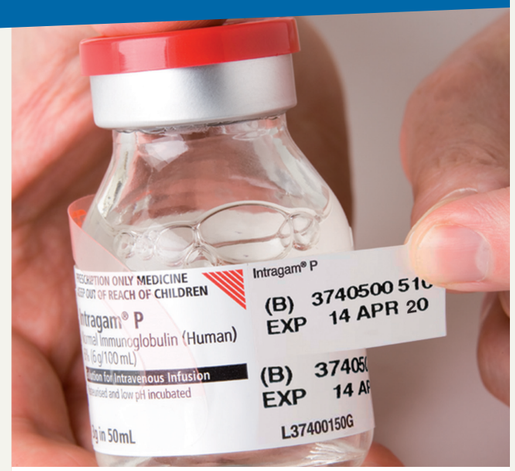
This resource contains general recommendations for the administration of INTRAGAM® P. You may find the recommendations useful if your institution does not have an existing protocol for administering IVIg, or wishes to update its current protocol. This information is for guidance only, please refer to approved Data Sheet for indications, dosage and infusion rates. For guidance on paediatric infusions, please refer to your hospital protocol.

Always refer to the approved Data sheet prior to use. If you have any queries, please contact the New Zealand Blood Service or CSL Behring.

INFUSION RATES AND PUMP SETTINGS[1]

INFUSION RATES		PUMP SETTINGS	
		mL/hr	Volume Infused over 15 min
First 15 minutes	1.0mL/min	60	15mL
Next 15 minutes	Gradually increase by 1.0mL/min to maximum 3-4mL/min	120 180 240	30mL 45mL 60mL
Remainder of infusion	Maximum 3-4mL/min	180-240	45-60mL

Reactions to IVIg tend to be related to the infusion rate and are most likely to occur during the first hour of the infusion. Considerations should be given to reducing the rate of infusion in patients who are naive to INTRAGAM P, paediatric, elderly, or patients with pre-existing renal disease.



Detachable label with batch number and expiry date for inclusion in patient's notes.

General Recommendations for Administration of INTRAGAM P

1) Prior to booking patient infusions, first calculate the expected administration time using the approved Data Sheet for INTRAGAM P.
2) Avoid starting the infusion overnight in non-urgent situations (confirm with treating doctor).
3) Use of a volumetric infusion pump is recommended.
4) INTRAGAM P should be brought to room temperature prior to administration.
5) Before commencing the infusion ensure that:
   - the patient is adequately hydrated
   - adrenaline, oxygen and resuscitation equipment are available and in working order
   - premedications, if required, are administered.
6) Do not use INTRAGAM P if it is turbid or cloudy, or contains any sediment or particles. Contact the New Zealand Blood Service to request a replacement vial. Return the suspect vial to the New Zealand Blood Service.
7) If an adverse event occurs, stop the infusion immediately and consult the treating doctor. In the case of minor reactions the infusion can often be restarted cautiously at a slower rate after the patient shows clinical improvement.
8) Please report adverse events to the New Zealand Blood Service Tranfusion Medicine Specialist at the nearest hospital Blood Bank or telephone the New Zealand Blood Service on: 09 523 5744. The New Zealand Blood Service will notify CSL Behring.
9) Unused bottles of INTRAGAM P should be returned to the New Zealand Blood Service.
10) Any transfusion report or stickers with batch details must be permanently filed in the patient's case notes.

Monitoring of vital signs

The patient's vital signs and general status should be monitored regularly throughout the infusion, in line with your hospital's protocol. As a general guide, CSL Behring recommends that the patient's blood pressure, pulse, respiratory rate and temperature are monitored every 15 minutes for the first hour, twice in the next hour, and hourly for the duration of the infusion. However, the clinical status of individual patients, and their responses, should be considered when determining observation frequency and rate of infusion.

NZBLOOD Te Ratonga Toto O Aotearoa

CSL Behring

Administration of INTRAGAM P

STEP 1

Remove the plastic cover from the rubber stopper.

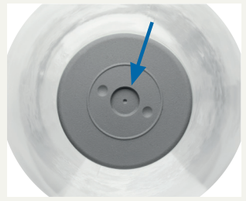
STEP 2

Wipe the top of the rubber stopper with appropriate antiseptic and allow to dry.

STEP 3

Clamp the tubing of a vented giving set. If a vented giving set is not available, use an alternative IV giving set in conjunction with an airway needle.

STEP 4



Insert the giving set spike into the large indentation. This will prevent the spike pushing the rubber stopper into the INTRAGAM P bottle.

If using an airway needle it should be inserted aseptically into one of the smaller indentations on the rubber stopper, after insertion of the giving set into the larger indentation.

STEP 5

Peel down the hanger which is attached to the label on the INTRAGAM P bottle.

STEP 6

Invert the INTRAGAM P bottle and hook the hanger to an IV support located higher than the patient.

STEP 7

Fill the drip chamber with sufficient fluid by squeezing the chamber. Open the clamp on the tubing and prime the giving set. (giving sets can be pre-primed / flushed with Saline 0.9% or Glucose 5%) Re-clamp the tubing. Connect the giving set to the venous access device (peripheral of central). Insert giving set into pump and set infusion rate.

INTRAGAM P is now ready for infusion.

STEP 8

When the INTRAGAM P bottle is empty, the giving set can be transferred into a new bottle of INTRAGAM P and the infusion recommenced. Replace the giving set periodically as per your hospital protocol.

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