



OCTAGAM® Immune Globulin 10%

Class: Manufactured product, derived from human plasma

OTHER NAMES: Intravenous Immune Globulin, IVIG
Company: OCTAPHARMA

ROUTES	INTRAVENOUS			OTHER		
	DIRECT IV	Intermittent Infusion	Continuous Infusion	SC	IM	OTHER
Acceptable Routes*	No	Yes	No	No	No	N/A

*** Professionals performing these restricted activities have received authorization from their regulatory college and have the knowledge and skill to perform the skill competently.**

DESCRIPTION OF PRODUCT:

- OCTAGAM® 10% is a sterile liquid preparation of purified IgG manufactured from large pools of human plasma by cold alcohol fractionation.
- Viral inactivation and/or removal processes include: solvent detergent method, and ph 4 treatment.
- Each mL contains 100 mg protein (≥ 96% of which is gamma globulin), and 90 mg maltose.
- Majority of gamma globulin is IgG, but contains trace amounts of IgA (≤ 0.4 mg/ml)
- Solution is colourless, free of particulate matter and non turbid.
- Dispensed in 20 g, 10 g, 5 g bottles (1 gram = 10 mL)
- Latex free

AVAILABILITY:

- Canadian Blood Services (CBS) provides 3 different IVIG products from 3 different manufacturers: Grifols **Gammunex®**, CSL Behring **Privigen®** and OCTAPHARMA **OCTAGAM®** at a predetermined percentage.
- Contact your local laboratory/transfusion service regarding stock availability on site.
- Please complete the IVIg request form found at <http://www.albertahealthservices.ca/frm-20549.pdf> where required (i.e. Edmonton zone) when IVIg is initially ordered for a patient.

Note: Baxter Gammagard S/D® (lyophilized) is also available. This preparation contains the least amount of IgA of all the IVIG products and is reserved only for patients that have IgA deficiency and documented anti-IgA.

INDICATIONS FOR USE:

- Idiopathic Thrombocytopenia Purpura (ITP)

CONTRAINDICATIONS:

- Known hypersensitivity to OCTAGAM®, its formulation or ingredients or components of the container.
- Known anaphylactic or severe systemic response to human immune globulins.
- Individuals with severe, selective IgA deficiencies who have known antibody against IgA (anti-IgA antibody).

WARNINGS:

- There is evidence of an association between IVIG administration and thromboembolic events in patients with pre-existing risk factors for thrombotic events including: obesity, advanced age, diabetes mellitus, history of vascular disease or thrombotic episodes, acquired or inherited thrombophilic disorders, patients with prolonged periods of immobilization, severe hypovolemia and patients with disease states that increase blood viscosity.

Caution: May impair the efficacy of live attenuated virus vaccines. Refer to the Canadian National Advisory Committee on Immunization for further recommendations.

DOSE:

Idiopathic Thrombocytopenia Purpura:

- Highest approved daily dose is 1 g/kg up to a total of 2 g/kg.

Adult Patients: All OCTAGAM® doses should be rounded up or down to nearest 5 gram increment at time of ordering. The transfusion service will provide OCTAGAM® to the nearest 5 gram increment if prescriber omits this step.

ADMINISTRATION:

Ensure patient consent has been obtained prior to requesting blood product from lab/transfusion service where possible.

Pre-Infusion: Ensure recent patient weight and height is on file, pertinent labs are available as required (i.e. trough IgG, IgA, CBC), and that any premedications ordered have been given (antihistamines, antipyretics prn). Perform the appropriate pre-transfusion checks per protocol. Report any new onset acute illness to MD/authorized prescriber prior to commencing infusion.

Access: OCTAGAM® can be given via CVC, PICC or peripheral venous line.

Compatible IV Solutions: Normal saline or D5W only.

Administration Set: OCTAGAM® should be given using a vented unfiltered set.

Priming & infusing IVIG bottles (to minimize air bubbles):

- Allow IVIG time to come to room temperature where possible.
- Spike a minibag of D5W with vented and unfiltered set, fill drip chamber to ~2/3 full and prime entire line.
- Invert the first IVIG bottle (smallest bottle first) and spike the bottle using aseptic technique.
- Using the plastic hanger affixed to the IVIG bottle, hang the first bottle from the IV pole.
- Load the line into the IV pump, program and infuse as per guidelines below.
- **Note: Subsequent bottles can be infused at the same maximum rate as tolerated by the patient on previous bottles (ie. new bottles do not have to be restarted at initial rate).**

Infusion Rate:

- For adult infusions, please refer to the following table:
<http://www.albertahealthservices.ca/assets/wf/lab/wf-lab-clin-tm-adult-rate-ivig.pdf>
- For pediatric infusions, please refer to following table:
<http://www.albertahealthservices.ca/assets/wf/lab/wf-lab-clin-tm-ped-rate-ivig.pdf>

POTENTIAL HAZARDS WITH PARENTERAL ADMINISTRATION:

- Most reactions to IVIG are due to serum osmolarity changes and are rate related reactions (vs. reactions to a single donor in a pool of IVIG).
- Slower infusion rates will diminish rate related symptoms such as headache, shivering, tachycardia and blood pressure alterations.
- Some patients may require pretreatment with antihistamines, anti-inflammatories and corticosteroids, particularly if they have a past history of reaction
- Serious but rare complications of IVIG include anaphylaxis, hemolytic anemia (delayed reaction up to 10 days later), thromboembolic events, aseptic meningitis and renal failure (with older sucrose containing IVIG preparations). These reactions are reportable to Health Canada via Transfusion Medicine/lab.

Minor IVIG Reactions	
If patient experiences any of the following after starting the infusion:	Then:
<ul style="list-style-type: none"> - Skin rash - Dizziness - Mild headache (not improved with rate decrease) - Flushing - Muscle pain and arthralgias - RR 30% increase over baseline (ie. RR of 18 increasing to 24) - HR 15% increase over baseline (ie. HR of 60 increasing to 70) - Diastolic BP 15% change from baseline - Temperature increase less than 1.0C 	<ol style="list-style-type: none"> 1. Decrease infusion rate to highest previously tolerated 2. Recheck vitals within 5 minutes 3. Continue new rate, if tolerated 4. Recheck vital signs after 10 minutes 5. Continue at new rate and progressively increase vital signs and rate increase schedule, restarting at q15 minutes x 2, for remainder of infusion. 6. Notify MD/authorized prescriber and Transfusion Medicine/lab after completion of infusion. 7. Document reaction & care provided in patient health record and by completing the appropriate notification of reaction for the Transfusion Service/Laboratory
Major IVIG Reactions	
If patient experiences any of the following after starting the infusion:	Then:
<ul style="list-style-type: none"> - RR 60% increase over baseline (ie. RR of 18 increasing to 28) - HR 30% increase over baseline (ie. HR of 60 increasing to 78) - SBP or DBP 30% change from baseline - Temperature increase more than 1.0 C - Chills, rigors, diaphoresis - SOB, wheezing - Severe headache + meningeal signs - Anaphylaxis - Chest or abdominal pain 	<ol style="list-style-type: none"> 1. Stop infusion 2. Assess vitals and ABCs (airway, breathing, circulation) 3. Notify MD/authorized prescriber and Transfusion Medicine/lab 4. Disconnect IV tubing at a point closest to patient. 5. Flush IV site with 0.9% normal saline rather than D5W 6. Infuse 0.9% normal saline at a rate equal to current IVIG rate 7. Administer emergency medications as ordered. 8. Closely monitor patient 9. Document reaction/ care provided in patient health record and by completing the appropriate notification of reaction for the Transfusion Service/Laboratory 10. Return unused product to Transfusion Medicine/lab.

NURSING IMPLICATIONS:

Patient Vital Signs and Monitoring:

	Pre-transfusion	At each rate increase (to assess tolerability)	Remainder of transfusion	Post transfusion
ADULTS and PEDIATRICS	Yes	Yes	q1h	20-30 min post, then PRN

Note: Vital signs/patient monitoring may be conducted more frequently as determined by clinical condition of patient.

Patients receiving blood product transfusions must be observed closely for signs of any unexpected or untoward reactions. These reactions may occur during or after the infusion of blood or blood products. For follow up instructions to a transfusion reaction, click <http://www.albertahealthservices.ca/4240.asp>

Documentation:

- Ensure documentation is completed as per the AHS *Transfusion of Blood Components and Products* procedure.
- Patient tolerability should also be documented in appropriate flow chart or clinical record (electronic or paper) as required.
- Document vital signs as required in the appropriate flow chart or clinical record (electronic or paper).

LABORATORY MONITORING:

- High doses of IVIG (ie. 2 g/kg) or consecutive days of IVIG therapy may cause temporary increases in serum and urine glucose.
- False positive results in serological tests may occur (e.g. CMV serology, Direct Antiglobulin Test, etc.).

STORAGE & STABILITY of PRODUCT:

- Stored at 2-8 °C for 23 months from date of manufacture. **Do not freeze.**
- May be stored for up to 3 months at 8-25 °C
- Protect from light.

COMMENTS:

Date Effective: 10 Mar 2017

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Approved By: TM Integration Network

If you have any questions regarding this document please email: transfusion.safetyteam@ahs.ca

REFERENCES

OCTAGAM® product monograph SCN 190893

LINK to WEBSITE for PRESCRIBING INFORMATION

<http://www.octapharma.ca>