Alberta Health Services	Immune Globulin Biological Page		
Section 7:	**Biological Product Information**		**Standard #: 07.250**
Created by:	Province-wide Immunization Program Standards and Quality		
Approved by:	Province-wide Immunization Program, Standards and Quality		
Approval Date:	March 1, 2013	**Revised:**	August 1, 2019

<table>
<tr><th></th><th>IMIG
GamaSTAN® S/D</th><th>IVIG
Canada has a number of IVIG preparations available</th></tr>
<tr><td>Manufacturer</td><td>Grifols Therapeutics Inc.</td><td>• Gamunex® Grifols Therapeutics Inc.
• Gammagard® Shire Pharma Canada ULC
• IGIVnex® Grifols Therapeutics Inc.
• Privigen® CSL Behring Canada Inc.
• Panzyga® Octapharma</td></tr>
<tr><td>Biological Classification</td><td>Passive: Immune Globulin</td><td>Passive: Immune Globulin</td></tr>
<tr><td>Indications for Use of IG in Measles Post Exposure</td><td colspan="2">Measles:
Post-exposure:
• Post-exposure for measles-susceptible contacts as soon as possible, preferably within 72 hours but can be administered up to six days after exposure. Susceptible contacts should receive either measles-containing vaccine or Immune Globulin (IG) depending upon the time from exposure, age and health status. Immune globulin (IG) is offered to eligible contacts as outlined in the AH Public Health Notifiable Disease Management Guidelines. Refer to provincial guidelines as well as zone processes for follow-up of notifiable diseases.

Susceptible contacts: contacts without evidence of immunity.
Evidence of immunity includes:
• Two doses of measles-containing vaccine; or
• Laboratory evidence of immunity (i.e. positive IgG antibody); or
• Laboratory confirmation of disease</td></tr>
<tr><td></td><td>IMIG should be considered for the following susceptible contacts:
• Immunocompromised individuals less than 30 kg for whom measles-containing vaccine is contraindicated.
• HIV-infected individuals less than 30 kg after a known exposure to confirmed measles even with documented previous MMR immunization. Infectious Diseases Physician should be consulted if any HIV-infected individual is exposed to measles.</td><td>IVIG should be considered for the following susceptible contacts:
• Immunocompromised individuals 30 kg or more for whom measles-containing vaccine is contraindicated.
• HIV-infected individuals 30 kg or more after a known exposure to confirmed measles even with documented previous MMR immunization. Infectious Diseases Physician should be consulted if any HIV-infected individual is exposed to measles.</td></tr>
</table>

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	• Infants younger than six months of age.
	  o Infants younger than six months of age are generally considered to have the same susceptibility/protection as their mother due to antibody transfer.
	  o Infants are considered susceptible IF their mother does not have evidence of immunity.
	  o Infants born to mothers **with** evidence of immunity are not considered susceptible, however, IG is recommended as a precaution due to waning maternal antibodies. (*This may be particularly relevant for infants whose mothers who have vaccine induced immunity, infants who are preterm, and infants greater than 3 months of age.)*
	• Infants 6 -11 months of age who cannot receive MMR vaccine within 72 hours of exposure.
		• Pregnant women
		• Infants younger than six months of age when IMIG injection volume is a concern.
		  o Infants younger than six months of age are generally considered to have the same susceptibility/protection as their mother due to antibody transfer.
		  o Infants are considered susceptible IF their mother does not have evidence of immunity.
		  o Infants born to mothers **with** evidence of immunity are not considered susceptible, however, IG is recommended as a precaution due to waning maternal antibodies.
		• Infants 6 -11 months of age who cannot receive MMR vaccine within 72 hours of exposure but IMIG injection volume is a concern.
		
		IVIG necessitates administration in a setting where there is active patient monitoring over several hours of infusion, performed by appropriately trained staff.

	Notes: • Individuals already receiving replacement IVIG at 400 mg/kg of body weight or higher are considered protected against measles and do not require IG if the last dose of IVIG was received within three weeks prior to measles exposure. • If receiving IVIG is not operationally feasible for those susceptible individuals who are pregnant or immunocompromised IMIG can be provided understanding that those weighing 30 kg or more will not receive the measles antibody concentrations that are considered to be fully protective. • Individuals who receive IG should receive age-appropriate measles-containing vaccine at specified intervals after receipt of IG depending upon the dosage of IG administered unless the vaccine is contraindicated. Refer to 03.110 Standard for Recommended Immunization Schedules, Section 7 Guidelines for Intervals Between Immune Globulin and other Blood Products and Live Vaccines. **Additional Note:** • Susceptible-individuals excluding infants, pregnant or immunocompromised are no longer routinely recommended to receive IG following measles exposure.	

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<tr><td></td><td colspan="2">
<table>
<tr><th colspan="3">Summary of updated measles post-exposure prophylaxis recommendations for contacts</th></tr>
<tr><th rowspan="2">Population</th><th colspan="2">Time since exposure to measles</th></tr>
<tr><th>≤ 72 hours</th><th>73 hours to 6 days</th></tr>
<tr><td>Infants 0-6 months of age</td><td colspan="2">IMIG</td></tr>
<tr><td>Susceptible immunocompetent infants 6-12 months of age</td><td>MMR vaccine</td><td>IMIG</td></tr>
<tr><td>Susceptible immunocompetent infants 12 months of age and older</td><td>MMR vaccine</td><td>N/A</td></tr>
<tr><td>Susceptible pregnant individuals</td><td colspan="2">IVIG or
IMIG (limited protection if 30 kg or more)</td></tr>
<tr><td>Immunocompromised individuals 6 months of age and older</td><td colspan="2">IVIG (30 kg or more) or
IMIG (less than 30 kg)</td></tr>
</table>
Adapted from: Updated NACI recommendations for measles post-exposure prophylaxis (2018).
For disease investigation, contact assessment and reporting requirements refer to Public Health Notifiable Disease Management Guidelines – Measles.
</td></tr>
<tr><td>Indications for Use of IG in Hepatitis A Post Exposure</td><td>Hepatitis A:
IMIG
Post-exposure prophylaxis for hepatitis A susceptible contacts should be administered as soon as possible within 14 days of the last exposure to the case (when the exposure occurred while the case was in the infectious period) and may include hepatitis A vaccine, immune globulin or both. See specific recommendations below.
• Contacts at risk of developing severe complications (i.e., those with chronic liver disease; hepatitis B carriers; hepatitis C infection (anti-HCV positive); candidates and recipients of liver transplant) and individuals who are immunocompromised (congenital and acquired immunodeficiency; immunosuppressive therapy and HIV infection) should receive both IMIG and hepatitis A vaccine (two-dose series). See Hepatitis A Biological Page.
• Contacts younger than 6 months of age and individuals in whom hepatitis A vaccine is contraindicated should receive</td><td>Hepatitis A:
IVIG
N/A - IVIG is not used for Hepatitis A Post Exposure Prophylaxis.</td></tr>
</table>

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<tr><th></th><th>IMIG
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Canada has a number of IVIG preparations available</th></tr>
<tr><td></td><td>IMIG only.
All other contacts should receive hepatitis A vaccine only. See Hepatitis A Biological Page.
For disease investigation, contact assessment and reporting information refer to Public Health Notifiable Disease Management Guidelines – Hepatitis A</td><td></td></tr>
<tr><td>Preferred Use</td><td>N/A</td><td>N/A</td></tr>
<tr><td rowspan="2">Dose</td><td colspan="2">Measles post-exposure:</td></tr>
<tr><td>IMIG
0.5 mL/kg of body weight (maximum 15 mL)
Note:
Doses administered IM may need to be divided and injected into several muscle sites to reduce local pain and discomfort.</td><td>IVIG
400 mg/kg</td></tr>
<tr><td colspan="2">Hepatitis A post-exposure:</td></tr>
<tr><td>IMIG
0.1 mL/kg of body weight
Note:
Doses administered IM may need to be divided and injected into several muscle sites to reduce local pain and discomfort.</td><td>IVIG
N/A for Hepatitis A post exposure</td></tr>
<tr><td>Route</td><td>IMIG - Intramuscular injection</td><td>IVIG - Intravenous infusion</td></tr>
<tr><td>Schedule</td><td colspan="2">Measles contacts:
IG should be administered as soon as possible but can be administered up to six days after exposure to prevent or modify measles.
Notes:
The recommended interval between IMIG and subsequent immunization with MMR, MMR-Var or Varicella vaccines is 6 months.
The recommended interval between IVIG and subsequent immunization with MMR, MMR-Var or Varicella vaccine is 8 months.
When it is necessary for IG to be administered less than 14 days after receiving MMR, MMR-Var or Varicella vaccine, the immunization should be repeated as per the intervals outlined in the 03.110 Standard for Recommended Immunization Schedules, Section 7 Guidelines for Intervals between Immune Globulin and other Blood Products and Live Vaccines. If IG is administered more than 14 days post MMR containing or varicella containing immunization, the dose of vaccine does not need to be repeated.
Hepatitis A contacts:
IG should be administered as soon as possible after a known exposure for individuals who are eligible. It should be administered within 14 days of the last exposure. Efficacy of IG is unknown if more than 14 days after exposure.</td></tr>
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<tr><td></td><td colspan="2">Notes:
The recommended interval between IMIG and subsequent immunization with MMR, MMR-Var or Varicella vaccines is 3 months.
When it is necessary for IG to be administered less than 14 days after receiving MMR, MMR-Var or Varicella vaccine, the immunization should be repeated 3 months after the administration of IG.
If IG is administered more than 14 days post MMR containing or varicella containing immunization, the dose of vaccine does not need to be repeated.</td></tr>
<tr><td rowspan="2">Contraindications/ Precautions</td><td>Contraindications:
IMIG
Known severe hypersensitivity to any component of GamaSTAN® S/D or its container.
Should not be given to individuals with isolated IgA deficiency. Such persons have the potential for developing antibodies to IgA and could develop anaphylactic reactions to subsequent administration of blood products that contain IgA.</td><td>Contraindications:
IVIG
Individuals with known anaphylactic or severe response to IG.
Refer to specific product monograph for contraindications.</td></tr>
<tr><td colspan="2">Precautions:
Use with caution in clients with a history of prior systemic allergic reactions following administration of human immunoglobulin preparations.
Human IG preparations are among the safest blood-derived products available.
IG is made from human plasma. Products made from human plasma may contain infectious agents, such as viruses, and theoretically, the Creutzfeldt-Jakob (CJD) agent that can cause disease. The risk that such products will transmit an infectious agent has been reduced by screening plasma donors for prior exposure to certain viruses, testing for the presence of certain current viral infections and inactivating and/or removing certain viruses. Despite these measures, such products can still potentially transmit disease.
A signed Consent for Treatment/Procedure is required before administering immune globulin products: http://www.albertahealthservices.ca/frm-09741.pdf</td></tr>
<tr><td>Possible Reactions</td><td>IMIG
Common:
Local pain, tenderness, and erythema at the injection site.
Stiffness of local muscles.
Mild fever and malaise.
Uncommon:
Flushing, headache, chills or nausea.
Rare:
Anaphylactic reactions.
Urticaria and angioedema.
There is clinical evidence of an association between the administration of all</td><td>IVIG
Refer to specific product monographs prior to administering IVIG products for information on possible reactions.</td></tr>
</table>

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	immunoglobulins and thromboembolic events such as myocardial infarction, stroke, pulmonary embolism and deep vein thrombosis. • As with any immunization, unexpected or unusual side effects can occur. Refer to the product monograph for more detailed information.	
Pregnancy	Should be administered if indicated. Intact IgG crosses the placenta from the maternal circulation increasingly after 30 weeks gestation.	
Lactation	Should be administered if indicated. It is not known if IG antibodies are excreted in breast milk.	
Composition	**IMIG** • **GamaSTAN® S/D** o 15%-18% immune globulin at pH of 6.4 to 7.2 o pH is adjusted with sodium carbonate o 0.21 to 0.32 M glycine, USP o Contains no preservative	**IVIG** • Gamunex® • Gammagard® • IGIVnex® • Privigen® • Panzyga® Refer to specific IVIG product monographs for details (See reference section for links).
Blood/Blood Products	Prepared by cold ethanol fractionation from human plasma.	Refer to specific IVIG product monographs for details (See reference section for links).
Bovine/Porcine Products	• One material used in the early manufacturing process is of bovine origin, but this material is not present in the final product. • Contains no porcine products.	Contact manufacturer for specific product information.
Latex	Does not contain latex.	Contact manufacturer for specific product information.
Interchangeability	N/A	Based on supply and product availability.
Administration with Other Products	See scheduling section and #03.110 Standard for Recommended Immunization Schedules for details.	
Appearance	Opalescent liquid ranging from colorless to pale yellow or pink, viscous.	Refer to specific IVIG product monographs for details (See reference section for links).
Storage	• Store between +2° and +8°C. • Do not freeze. • Do not use beyond the labeled expiry date. • Store in original packaging when possible to protect from light.	Refer to specific IVIG product monographs for details (See reference section for links).
Vaccine Code	IG	IG
Antigen Code	IG	IG

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Licensed for	**IMIG** Licensed for all ages.	**IVIG** Measles PEP for susceptible contacts who are pregnant or immunocompromised and weighing 30 kg or more. **Note:** Although IVIG preparations are not currently indicated for measles PEP in Canada, NACI determined that it is an important strategy to prevent post-exposure measles disease in susceptible contacts who are pregnant or immunocompromised, particularly individuals weighing more than 30 kg.
Notes:	**IMIG** • Use a blunt fill or large bore needle to withdraw immune globulin Withdrawal through a small-gauge needle can lead to aggregation • Inject slowly • IMIG is supplied in 2 mL, 5 mL and 10 mL single use vials	**IVIG** • IVIG necessitates administration in a setting where there is active patient monitoring over several hours of infusion, performed by appropriately trained staff

Related Documents:

- Immune Globulin Information Sheet

References:

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