Immune Globulin (Human)

Revision Date: October 16, 2017

Rationale for update: Updated to incorporate change in dose recommended in Hepatitis A post-exposure as per *Grifols Therapeutics Inc.* change in prescribing Information and MMWR.

Please consult the Product Monograph[1] for further information about this product.

	GamaSTAN® S/D
Manufacturer	Grifols Therapeutics Inc. – distributed by Grifols Canada Ltd.
Off-license use	None
Indications for use of provincially funded immune globulin	**Measles:** 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. **IG should be considered for the following susceptible contacts:** • Immunocompromised individuals for whom measles-containing vaccine is contraindicated. • Pregnant women • Infants 6 – 11 months of age inclusive **Note**: During an outbreak the MOH may recommend MMR vaccine for children 6 – 11 months of age inclusive. • Infants younger than six months of age (if mother contracts measles or is known to be non-immune)[2] **Note**: Infants younger than six months of age are usually considered immune from antibody transfer from the mother. Risk needs to be determined on a case-by-case assessment of the mother's immune status.[2] • HIV-infected children after a known exposure to confirmed measles even with documented previous MMR immunization.[2] **Note**: An Infectious Diseases Physician should be consulted if any HIV-infected individual is exposed to measles. • On a case-by-case basis, the MOH may in consultation with the Office of the Chief Medical Officer of Health (OCMOH) consider offering IG to other susceptible individuals. **Notes**: • IG should be administered within six days after exposure to modify or prevent measles.[2] • 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 Contraindications and Precautions to Immunization – Guidelines for Interval between Blood Products and Live Vaccines. See also, Canadian Immunization Guide – Blood products, human immune globulin and timing of immunization. For disease investigation, contact assessment and reporting requirements refer to *Public Health Notifiable Disease Management Guidelines – Measles*.[3]

	Hepatitis A: 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)[2] should receive both IG and hepatitis A vaccine (two-dose series). See Biological Products – Hepatitis A Vaccine. • Contacts younger than one year of age and individuals in whom hepatitis A vaccine is contraindicated should receive immune globulin only.[2] • All other contacts should receive hepatitis A vaccine only.[2] See Biological Products - Hepatitis A Vaccine. For disease investigation, contact assessment and reporting information refer to *Public Health Notifiable Disease Management Guidelines – Hepatitis A*.[4]
Dose	**Measles post-exposure:** • 0.25 mL/kg of body weight (maximum 15 mL) OR • 0.5 mL/kg of body weight (maximum 15 mL) for individuals who are immune compromised or have underlying malignant disease. **Hepatitis A post-exposure:** • 0.1 mL/kg of body weight[5,6]
Route	Intramuscular injection **Note**: Doses may need to be divided and injected into several muscle sites to reduce local pain and discomfort.
Schedule	**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.[2] **Notes:** • The recommended interval between IG (administered intramuscularly) and subsequent immunization with MMR or varicella vaccines varies from three to six months, depending on the dosage of IG administered.[2] • When it is necessary for IG to be administered intramuscularly less than 14 days after receiving MMR or varicella vaccine, the immunization with MMR or varicella should be repeated as per the intervals outlined in the *Guidelines for Interval between Blood Products and Live Vaccines* unless serologic testing indicates that antibodies were produced. If IG is administered more than 14 days post MMR or varicella immunization, the dose does not need to be repeated.[2] Refer to Contraindications and Precautions to Immunization - Guidelines for Interval between Blood Products and Live Vaccines. See also Canadian Immunization Guide[2] – Blood products, human immune globulin and timing of immunization.

	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.[2]
Contraindications	• Known severe hypersensitivity to any component of GamaSTAN® S/D or its container.[1] • Should not be given to individuals with isolated IgA deficiency.[1,7] Such persons have the potential for developing antibodies to IgA and could develop anaphylactic reactions to subsequent administration of blood products that contain IgA.[1]
Precautions	• Individuals with thrombocytopenia or coagulation disorders that contraindicate IM injections should not be given IM immune globulin unless the expected benefits outweigh the risks.[2, 7] • Use with caution for individuals with a history of prior systemic allergic reactions following administration of human immunoglobulin preparations.[7] • Do not administer intravenously because of the potential for serious reactions.[1] • Human IG preparations are among the safest blood-derived products available.[2] • GamaSTAN® is made from human plasma. Products made from human plasma may contain infectious agents, such as viruses, 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.[1]
Possible reactions following IG administration	**Local reactions**: • Local pain and tenderness at the injection site[1] **Systemic reactions:** • Urticaria and angioedema may occur[1]. • Anaphylactic reactions, although rare, have been reported[1]. • There is clinical evidence of an association between the administration of all immunoglobulins and thromboembolic events such as myocardial infarction, stroke, pulmonary embolism and deep vein thrombosis.[1] Refer to *Adverse Events Following Immunization (AEFI), Policy for Alberta Immunization Providers*.[8]
Pregnancy	Should be administered if indicated.[2,7] Intact IgG crosses the placenta from the maternal circulation increasingly after 30 weeks gestation.[7]
Lactation	Should be administered if indicated. It is not known if IG antibodies are excreted in breast milk.[7]

References

[1] Grifols Therapeutics Inc. (2014, July 21). GamaSTAN® S/D: Immune globulin (human). *Product Monograph.*

[2] National Advisory Committee on Immunization. (2016). *Canadian Immunization Guide* (Evergreen ed.). Ottawa, ON: Public Health Agency of Canada. www.canada.ca/en/public-health/services/canadian-immunization-guide.html

[3] Alberta Health. Measles. In *Public Health Notifiable Disease Management Guidelines*. www.health.alberta.ca/professionals/notifiable-diseases-guide.html

[4] Alberta Health. Hepatitis A. In *Public Health Notifiable Disease Management Guidelines*. www.health.alberta.ca/professionals/notifiable-diseases-guide.html

[5] Grifols Therapeutics Inc. (2017, July 7). *Important Change in prescribing Information – Immune Globulin (Human): GamaSTAN®S/D*. Retrieved October 16, 2017 from: https://www.hypermunes.com/documents/31474919/31475115/Healthcare+Provider+Letter+GamaSTAN+SD+Revised+Dosage+July+7+2017_with+LIT+CODE.pdf/b831e517-9d0b-472c-b5b5-719f5bb5e47c

[6] Centers for Disease Control and Prevention. (2017) Morbidity and Mortality Weekly Report (MMWR). Updated Dosing Instructions for Immune Globulin (Human) GanaSTAN S/D for Hepatitis A Virus Prophylaxis. https://www.cdc.gov/mmwr/volumes/66/wr/mm6636a5.htm

[7] Grabenstein, J. D. (2012). *ImmunoFacts: Vaccines and Immunologic Drugs - 2013*. St. Louis, MO: Wolters Kluwer Health.

[8] Alberta Health. (2016, December). *Adverse Events Following Immunization (AEFI), Policy for Alberta Immunization Providers.* https://open.alberta.ca/dataset/d86b52a9-45f4-4948-8a06-53b2c045135e/resource/7598f59a-3dfc-4c70-9065-c3bf5b4ee363/download/AIP-AEFI-Policy.pdf

