

Immune Globulin (Ig) GamaSTAN® S/D

Supplier: Grifols Canada Ltd.

INDICATIONS:

- Post-exposure prophylaxis of hepatitis A contacts for whom hepatitis A vaccine is contraindicated:
 - household, close non-household, drug-sharing, and sexual contacts, as well as co-workers if the case is a food handler, and patrons of involved food-handling establishment at risk of hepatitis A, provided it is within 14 days after the last exposure.
 - for exposures in day care centres, institutions for the developmentally challenged and correctional facilities see [Communicable Disease Control Manual, Chapter 1: Hepatitis A](#).
- Post-exposure prophylaxis of measles contacts:
 - susceptible infants under 6 months of age
 - susceptible pregnant women
 - susceptible immunocompetent contacts 6 months of age and older who have never been immunized and who present more than 72 hours, but less than 7 days, after exposure (i.e., too late for vaccine)
 - susceptible immunocompromised contacts
 - those for whom MMR is contraindicated.
- Pre-exposure prophylaxis against hepatitis A (not provided free):
 - Ig may be indicated for infants under 6 months of age and for persons in whom hepatitis A vaccine is contraindicated when traveling to areas with intermediate or high endemic rates of HAV.

DOSES AND SCHEDULE:

Post-exposure prophylaxis of hepatitis A contacts: given as 0.02 mL/kg **IM**.

Post-exposure prophylaxis of measles contacts:

- Susceptible infants under 6 months of age, susceptible pregnant women, susceptible immunocompetent contacts who have never been immunized and who present too late for vaccine after exposure: given as 0.25 mL/kg **IM** (max. 15 mL).
- Susceptible immunocompromised contacts and those for whom MMR is contraindicated: given as 0.5 mL/kg **IM** (max. 15 mL).

Pre-exposure prophylaxis against hepatitis A:

Required duration of protection:

- Less than 3 months: given as 0.02 mL/kg **IM**.
- 3 months or more: given as 0.06 mL/kg **IM** prior to exposure and then every 4-6 months if exposure continues.

ADMINISTRATION:

- See [Immune Globulin Preparations \(HBIg, Ig, TIg, VarIg, RabIg\)](#) for administration information and maximum volume to be administered per site according to age.
- Ig contains no preservatives. Vials are single dose use. Once entered, discard any unused contents.

BOOSTER DOSES:

None.

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SEROLOGICAL TESTING:

Serological testing is not required before or after immunization; however, it may be done on a case-by-case basis prior to measles post-exposure prophylaxis. See [Communicable Disease Control Manual, Chapter 1: Measles](#).

CONTRAINDICATIONS:

1. History of anaphylactic reaction to a previous dose of any immune globulin product or any component of GamaSTAN® S/D.

PRODUCT COMPONENTS:

Potential allergens: none.

Other components: glycine.

PRECAUTIONS:

- Human Ig products are among the safest blood-derived products available. The method of preparation includes one or more steps that exclude or inactivate hepatitis B, C and HIV; therefore the risk of transmission is extremely low. However, it is possible that unknown infectious agents may be present in such products.
- Special measures should be considered when administering IM injections to people with bleeding disorders. A smaller gauge needle (23 gauge or smaller) should be used and steady, firm pressure should be applied to the injection site for 5 minutes. If there is concern that the injection may stimulate bleeding, the client should connect with their medical specialist.
- Persons with IgA deficiency have the potential for developing antibodies to IgA and could have an anaphylactic reaction to subsequent administration of blood products that contain IgA. Therefore, Ig should only be given to such persons if the expected benefits outweigh the risks, and should be administered in an emergency room setting.

SPECIAL CONSIDERATIONS:

- Document receipt of Ig in the client's electronic record (e.g., Panorama, PARIS) and/or chart. The following information must be recorded: trade name of product, date, lot number, dosage, route and site(s).
- Provide a written record to individuals who receive any immune globulin product.
- Ig should be given as soon as possible after a known exposure and no later than 6 days for measles post-exposure prophylaxis (PEP) and 2 weeks for hepatitis A PEP.
- When clinical measles does not develop in a person given Ig, a measles-containing vaccine should be given 5 months later, provided the person is 1 year of age and older and there are no contraindications to the vaccine. If the person is immunocompromised, give a measles-containing vaccine 6 months later with physician referral.
- Regarding Ig and the administration of live vaccines, see [Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus](#).

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ADVERSE EVENTS:

Local: pain, tenderness.

Systemic: allergic reactions (urticaria and angioedema).

A potential increased risk of thrombosis (blood clots) has been observed within 24 hours of receipt of immune globulin products, especially when given in large doses (i.e., more than 10 mL). Additional risk factors include: age 45 years and older, history of thrombosis or those with risk factors for thrombosis (e.g., obesity, high blood pressure, diabetes, prolonged periods of immobilization, use of estrogens, a history of heart disease, blood clotting disorders, indwelling central vascular catheters, or diseases that thicken the blood). ^{A, B}

^A Daniel WG, Menis M, Sridhar G, et al. Immune globulins and thrombotic events as recorded in a large administrative database in 2008 through 2010. *Transfusion*. 2012; 52:2113-2121.

^B Menis M, Sridhar G, Selvam N, et al. Hyperimmune globulins and same-day thrombotic adverse events as recorded in a large healthcare database during 2008-2011. *Am. J. Hematol*. 2013; 88:1035-1040.