

Intramuscular Immune Globulin (GamaSTAN® S/D)



When requesting GamaSTAN® S/D, the individual requiring treatment must be diagnosed with an FDA-approved indication or an approved off-label compendial use and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved Indications

GamaSTAN® S/D is a human immune globulin indicated:

- For prophylaxis following exposure to hepatitis A. The prophylactic value of GamaSTAN is greatest when given before or soon after exposure to hepatitis A. GamaSTAN is not indicated in persons with clinical manifestations of hepatitis A or in those exposed more than 2 weeks previously.
- To prevent or modify measles in a susceptible person exposed fewer than 6 days previously. A susceptible person is one who has not been vaccinated and has not had measles previously.
- To modify varicella when Varicella Zoster Immune Globulin is not available
- To modify rubella in exposed women who will not consider a therapeutic abortion

Approved Off-label Compendial Use

- Pre-exposure prophylaxis of Hepatitis A virus infection

Coverage Guidelines

For all approved indications, the individual must meet **ALL** of the following criteria for approval:

- For an individual with immunoglobulin A (IgA) deficiency, does not have antibodies to IgA AND a history of hypersensitivity
- Does not have severe thrombocytopenia
- Does not have any coagulation disorders

For pre-exposure prophylaxis of Hepatitis A virus infection

- Hepatitis A vaccine is not available **OR**
- Has contraindication to Hepatitis A vaccine **OR**
- Planning to travel in areas where hepatitis A is common

For post-exposure prophylaxis of Hepatitis A virus infection

- Does not have clinical manifestations of hepatitis A **AND**
- Has been exposed to hepatitis A less than 2 weeks previously

For post-exposure prophylaxis of measles:

- Has been exposed to measles less than 6 days previously **AND**
- Does not have laboratory evidence of measles immunity or confirmation of prior measles infection **AND**
- At increased risk for severe measles and complications

For post-exposure prophylaxis of varicella (*Note: Per Centers for Disease Control and Prevention [CDC], Intravenous immune globulin (IVIG) is recommended when Varicella-Zoster Immune Globulin is not available. Please provide clinical reason for GamaSTAN® S/D request*)

- Varicella-Zoster immune Globulin (VZIG) is not available

For post-exposure prophylaxis of rubella

- GamaSTAN® S/D will be used in a susceptible pregnant woman who is exposed to confirmed case of rubella

Approval duration: one dose (30 days)

Dosing Recommendations

For intramuscular use only. Do not administer intravenously.

For pre-exposure prophylaxis of Hepatitis A (for an individual who plan to travel in areas where hepatitis A is common):

The recommended dose varies according to planned duration of travel area as follows:

- Up to 1 month: 0.1 mL/kg
- Up to 2 months: 0.2 mL/kg
- 2 months or longer: repeat dose of 0.2 mL/kg every 2 months

For post-exposure prophylaxis of Hepatitis A:

The recommended dose is 0.1 mL/kg administered within 2 weeks of prior exposure to hepatitis A

For post-exposure prophylaxis of measles:

The recommended dose is 0.25 mL/kg administered within 6 days of exposure. 0.5 mL/kg should be administered immediately to an immunocompromised child.

For post-exposure prophylaxis of varicella:

The recommended dose is 0.6 mL/kg to 1.2 mL/kg administered promptly if Varicella-Zoster Immune Globulin is unavailable

For post-exposure prophylaxis of rubella:

The recommended dose is 0.55 mL/kg

References

1. GamaSTAN S/D prescribing information. Research Triangle Park, NC. Grifols Therapeutics Inc. June 2017.
2. Klasco RK (Ed): DRUGDEX® System. Thomson Micromedex, Greenwood Village, CO. Accessed June 13, 2018.
3. AHFS Drug Information. Immune globulin.
http://online.lexi.com/lco/action/doc/retrieve/docid/complete_ashp/413799. Accessed June 18, 2018.
4. Centers for Disease Control and Prevention. Varicella (Chickenpox). Available at:
<https://wwwnc.cdc.gov/travel/yellowbook/2018/infectious-diseases-related-to-travel/varicella-chickenpox>. Accessed July 13, 2018.
5. Centers for Disease Control and Prevention. Hepatitis A Questions and Answers for Health Professionals. Available at: <https://www.cdc.gov/hepatitis/hav/havfaq.htm>. Accessed July 13, 2018.