

Immunization Protocol

Immune globulin (GamaSTAN®) for the prevention of Hepatitis A or Measles

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1. What's new

Hepatitis A vaccine is preferred to immune globulin (IG) for hepatitis A post-exposure prophylaxis in all recipients ≥ 12 months of age.

2. Oregon immunization protocol

- A. Check the ALERT Immunization Information System (IIS) to determine whether the patient needs this vaccine and any other vaccines.
- B. Screen clients for contraindications.
- C. Provide product information and answer any questions.
- D. Record all required data elements in the client's permanent health record.
- E. Read thrombosis warning in section 7.
- F. Verify needle length for IM injection.
- G. To avoid injury related to vaccine administration, make sure staff who administer vaccines recognize the anatomic landmarks for identifying the vastus lateralis or deltoid muscle and use proper IM administration technique.
- H. Aspirate to check for blood return.¹
- I. Administer dosage appropriate for indication and patient weight. Doses over 10 mL should be divided and injected into several muscle sites.¹

Health Officer Signature

Date

Health Officer Signature

Date

3. Schedule for Immune Globulin

Route: IM	
Indication	Dose ^{2,3}
Prophylaxis for contact of hepatitis A case	0.1 mL/kg (0.05 mL/lb) IM
Prophylaxis for international travel	Up to 1 month: 0.1 mL/kg (0.05 mL/lb) IM
	Up to 2 months: 0.2 mL/kg (0.1 mL/lb) IM
	≥2 months: Repeat 0.2 mL/kg every 2 months
Measles prophylaxis – immunocompetent contact	0.5 mL/kg IM, maximum dose 15 mL
Measles prophylaxis – immunocompromised or non-immune pregnant contact ³	Refer to hospital for IV administration

4. Licensed Immune Globulin¹

Product Name	Vaccine Components	Presentation	Thimerosal
GamaSTAN S/D®	Human plasma	2 mL and 10 mL vials	None

5. Recommendations for use²

A. Pre-exposure prophylaxis for hepatitis A.

- Hepatitis A vaccine administered with the appropriate dose and schedule is preferred to IG for travelers ≥6 months of age. Doses given before 12 months of age do not count towards the 2-dose series.
- For adults ≥40 years of age, immunocompromised persons and persons with chronic liver disease who will be traveling internationally within 2 weeks, IG can be given at the same time as hepatitis A vaccine. Use separate anatomic sites for administration.
- IG can be used for short-term protection or infants <6 months or if vaccine is contraindicated or refused.

Product Name	Vaccine Components	Duration of Travel	Dose
GamaSTAN S/D®	Human plasma	Up to 1 month	0.1 mL/kg (0.05 mL/lb) IM
		Up to 2 months	0.2 mL/kg (0.1 mL/lb) IM
		≥2 months	Repeat 0.2 mL/kg every 2 months IM

B. Post-exposure prophylaxis (PEP) for hepatitis A.²

- Hepatitis A vaccine is preferred over IG for PEP.
- IG may be administered concurrently with hepatitis A vaccine for immunocompromised patients and adults ≥ 40 years of age, depending on provider risk assessment.
- IG alone should be used in infants < 12 months of age.
- PEP should be administered within 2 weeks¹ to all unvaccinated persons who have been exposed or are at risk for exposure through close personal contact with a person who has serologically confirmed HAV infection. See [Oregon Disease Investigative Guidelines](#) for more information.

Product Name	Vaccine Components	Indication	Dose
GamaSTAN S/D®	Human plasma	Exposure of Contacts	0.1mL/kg (0.05 mL/lb) IM

C. Post-exposure prophylaxis (PEP) for measles.³

- For vaccine-eligible people ≥ 12 months of age, MMR vaccine administered within 72 hours of initial exposure is preferred for PEP.
- Infants 6-11 months of age who can be vaccinated within 72 hours of exposure should receive MMR vaccine. The dose does not count as one of the two recommended doses.
- Administer within 6 days of exposure to nonimmune persons.¹

Immunocompetent patients			
Age	Product	Components	Dose
<6 months of age	GamaSTAN S/D®	Human plasma	0.5 mL/kg IM, max dose 15mL
72 hours or more after exposure			
≥6 months of age	GamaSTAN S/D®	Human plasma	0.5 mL/kg IM, max dose 15mL

Immunocompromised* or non-immune pregnant patients
Refer to the hospital for IV IG administration.

*Severe primary immunodeficiency; patients who have received a bone marrow or stem cell transplant until at least 12 months after finishing all immunosuppressive treatment, or longer where the patient has developed graft-versus-host disease; patients on treatment for Acute Lymphocytic Leukemia until at least six months after completion of immunosuppressive chemotherapy; and patients with a diagnosis of AIDS or HIV-infected persons with CD4 percent <15% (all ages) or CD4<200 lymphocytes /mm³ (age>5 years) and those who have not received MMR vaccine since receiving effective antiretroviral therapy.

6. Contraindications¹

- A. GamaSTAN S/D and measles vaccine should not be given at the same time.
- B. Do not give GamaSTAN® to person with isolated immunoglobulin A (IgA) deficiency. Such persons have the potential for developing antibodies to IgA and could have anaphylactic reactions to subsequent administration of blood products that contain IgA.
- C. IG should not be administered to persons with severe thrombocytopenia or any coagulating disorder that would contraindicate intramuscular injections.
- D. IG should not be given to persons with a history of anaphylactic reaction (hives, swelling of the mouth or throat, difficulty breathing, hypotension or shock) to a previous dose of IG.

7. Warnings and precautions¹

- A. Thrombosis may occur with immune globulin products, including GamaSTAN®. Risk factors may include:
 - advanced age;
 - prolonged immobilization;
 - hypercoagulable conditions;
 - history of venous or arterial thrombosis;
 - use of estrogens;
 - indwelling central vascular catheters;
 - hyperviscosity;
 - cardiovascular risk factors.
- B. Thrombosis may occur in the absence of known risk factors.
- C. For patient at risk of thrombosis, do not exceed the recommended dose of GamaSTAN®.
- D. Ensure adequate hydration in patients before administration.
- E. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.
- F. GamaSTAN S/D is made from human plasma. Because GamaSTAN S/D is made from human blood, it may carry a risk of transmitting infectious agents, e.g., viruses, and theoretically, the Creutzfeldt – Jakob disease (CJD) agent. No cases of transmission of viral diseases or CJD have ever been identified for

GamaSTAN S/D. ALL infections suspected by a physician possibly to have been transmitted by this product should be reported by the physician or other healthcare provider to Grifols Therapeutics Inc. [1-800-520-2807].

- G. Do not administer SQ or IV because of the potential for serious adverse events.¹
- H. Not indicated for anyone who has received at least one dose of measles vaccine at 12 months of age or older unless immunocompromised.³

8. Other considerations^{2,3}

- A. Patients who receive IG may not be able to respond to MMR, varicella, or MMRV vaccines for several months after administration. IG does not interfere with yellow fever, oral typhoid, or live-attenuated influenza vaccines.

Indication	Interval between IG and live vaccine ⁴
Hepatitis A prophylaxis	6 months
Measles prophylaxis, healthy patient	6 months
Measles prophylaxis, immunocompromised patient	8 months

- B. A 5/8" to 2" needle should be used for IM administration, depending on recipient's age, weight, and condition.
- C. Select a large muscle mass that can support the administration of a large volume of IG.
- D. Calculate total dose volume by determining recipient's weight in kilograms. Multiply weight by the appropriate dose for indication. Maximum IG dose for measles prophylaxis is 15 mL. There is no maximum volume for hepatitis A prophylaxis.
- E. The deltoid muscle can accept a range of 0.5 mL- 2mL, with infants and toddlers on the low end of the range; and adolescents and adults on the high end of the range.⁵
- F. The vastus lateralis muscle (anterolateral thigh) can accept a range of 1 mL- 5mL, with infants and toddlers on the low end of the range; and adolescents and adults on the high end of the range.⁵
- G. Doses over 10mL should be divided and injected into several muscle sites to reduce local pain and discomfort.¹

9. Side effects and adverse reactions¹

Local pain and tenderness at the injection site, urticaria, and angioedema may occur. Anaphylactic reactions, although rare, have been reported following the injection of human immune globulin preparations.

10. Storage and handling¹

All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

Vaccine	Temp	Storage Issues
GamaSTAN S/D®	2°-8° C	Do not freeze. Do not use after expiration date.

11. Adverse events reporting

Report suspected adverse events to the Vaccine Adverse Events Reporting System (VAERS) online at <https://vaers.hhs.gov/reportevent.html>. VAERS Reporting Table: <https://vaers.hhs.gov/resources/infoproviders.html>

12. References

1. GamaSTAN S/D® package insert. Revised 2013. Available at: <https://www.fda.gov/media/86789/download>. Accessed 13 September 2021.
2. Nelson NP, Weng MK, Hofmeister MG, et al. Prevention of Hepatitis A Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices, 2020. MMWR 2020;69(5). Available at: <https://www.cdc.gov/mmwr/volumes/69/rr/pdfs/rr6905a1-H.pdf>. Accessed 13 September 2021.
3. McLean HQ, Fiebelkorn AP, Temte JL, et al. Prevention of Measles, Rubella, Congenital Rubella Syndrome, and Mumps, 2013 Summary Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2013;62(4). Available at: <https://www.cdc.gov/mmwr/pdf/rr/rr6204.pdf>. Accessed 13 September 2021.
4. Kroger AT, Duchin J, Vázquez M. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP). Available at: <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html>. Accessed

on 13 September 2021.

5. Immunization Action Coalition. Ask the Experts, Administering Vaccines. Available at: <http://immunize.org/askexperts/administering-vaccines.asp>. Accessed 13 September 2021.

To request this material in an alternative format (e.g., Braille) or to clarify any part of the above order, contact the Oregon Health Authority Immunization Program at 971.673.0300 and 711 for TTY. For other questions, consult with the vaccine recipient's primary health care provider or a consulting physician.

Electronic copy of this standing order is available at: [standing orders](#)

Electronic copy of this pharmacy protocol is available at: [protocols](#)