

OREGON HEALTH AUTHORITY
IMMUNIZATION PROTOCOL FOR PHARMACISTS
HEPATITIS A IMMUNE GLOBULIN (GamaSTAN®)¹

I. OREGON IMMUNIZATION PHARMACY PROTOCOL:

1. Check the ALERT Immunization Information System (IIS) for vaccine history.
2. Screen clients ≥ 7 years of age for contraindications.
3. Provide product information, and answer any questions.
4. Record all required data elements in the client's permanent health record.
5. Read warning on page 2
6. GamaSTAN®
 - A. Post-exposure Prophylaxis of Contacts to a case:²**
 1. Administer 0.02ml/kg (0.01 ml/lb) of IG intramuscularly into the deltoid muscle with a 1–2 inch needle, depending on recipient's weight and volume of material to be injected.
 2. For healthy persons aged 12 months–40 years, single-antigen hepatitis A vaccine at the age appropriate dose is preferred to IG because of the vaccine's advantages, including long-term protection and ease of administration.
 3. For persons >40 years of age, IG is preferred because of the absence of information regarding vaccine performance and the more severe manifestations of hepatitis A in this age group. Vaccine can be used if IG cannot be obtained.
 4. IG should be used for immunocompromised persons, persons with chronic liver disease, and persons for whom vaccine is contraindicated.
 5. Persons administered IG for whom Hepatitis A vaccine also is recommended for other reasons should receive a dose of vaccine simultaneously with IG.
7. Observe client for 15 minutes after vaccination to decrease the risk for injury should they faint.

Immunization Pharmacist Signature

Date

WARNING: THROMBOSIS¹

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, and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors.

For patient at risk of thrombosis, do not exceed the recommended dose of GamaSTAN[®]. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.

Recommended intervals between administration of hepatitis A immune globulin preparations and measles- or varicella-containing vaccine: ^{4*}

Immune globulin: Hepatitis A IG	Dose	Months
Contact Prophylaxis	0.02mL/kg (3.3mg IgG/kg) IM	3

*See pages 9 and 10 for complete table.

II. Licensed Immune Globulin¹

CALCULATION FOR ADULT:

(weight of person in pounds) ÷ 2.2046 = weight in kilograms (kg).

(weight of person in kilograms) X 0.02 = dose of 0.02mL/kg

(150 pounds ÷ 2.2046) = 68.039 X 0.02mL = 1.36mL per dose.

ACCEPTABLE VOLUME for a single dose of immune globulin (IG) to inject into either the deltoid or vastus lateralis muscle of a normal-weight adult.⁵

Deltoid:

- Average 0.5mL
- Range 0.5–2mL

Vastus Lateralis:

- Average 1–4mL
- Range 1–5mL

III. A. **RECOMMENDED POST-EXPOSURE PROPHYLAXIS OF CONTACTS**

The confirmation of HAV infection in the index patient by IgM anti-HAV testing is recommended prior to providing post-exposure prophylaxis to contacts. It is not recommended that contacts be serologically screened for immunity before giving hepatitis A vaccine or IG. These contacts should be considered for prophylaxis:³

1. **General Recommendations:**³ Persons who recently have been exposed to HAV and who previously have not received hepatitis A vaccine should be administered a dose of hepatitis A vaccine, a single IM dose of IG (0.02 ml/kg), or both depending upon their age or medical situation as soon as possible, preferably within 2 weeks of last exposure.
 - For healthy persons aged 12 months–40 years, single-antigen hepatitis A vaccine at the age appropriate dose is preferred to IG because of the vaccine’s advantages, including long-term protection and ease of administration.
 - For persons >40 years of age, IG is preferred because of the absence of information regarding vaccine performance and the more severe manifestations of hepatitis A in this age group. Vaccine can be used if IG cannot be obtained.
 - IG should be used for children <12 months of age, immunocompromised persons, persons with chronic liver disease, and persons for whom vaccine is contraindicated.
 - Persons administered IG for whom Hepatitis A vaccine also is recommended for other reasons should receive a dose of vaccine simultaneously with IG.

2. Close contacts to Hepatitis A case

- Household contacts
- Sexual contacts
- Drug sharing contacts
- Persons with a significant opportunity for fecal-oral exposure (repeatedly ate food prepared by case)³

3. Child-care centers staff and attendees: if

- One or more cases of hepatitis A are recognized in children or employees or
- Cases are recognized in two or more households of center attendees. In centers that do not provide care to children who wear diapers, vaccine or IG needs to be given only to classroom contacts of an index case-patient.
- When an outbreak occurs in a center, (i.e., HAV cases in 3 or more families), vaccine or IG should also be considered for household contacts of children in diapers who attend the center.

4. Food handlers and hepatitis A: In general, persons working as food handlers in Oregon are not at increased risk of hepatitis A infection when compared to the general public. Therefore, it is not currently recommended that food handlers without other risk factors be immunized. Some food handlers, however, do have risks for hepatitis A and should be immunized for their own protection. Per ACDP 02-22-2016.

- In the event that a food handler contracts hepatitis A, he or she may be at increased risk of transmitting the infection to others because of their occupation. Be alert to identify any co-workers who handle food, only then should the local health jurisdiction consider offering prophylaxis to other food handlers at the site.
- In settings where repeated exposures to HAV may have occurred (e.g., institutional cafeterias), stronger consideration of vaccine may be warranted.

5. Common-source exposure:³ Because common-source transmission to patrons at a food establishment is unlikely, prophylaxis of patrons usually is not recommended. However, it can be considered when:

- While infectious, the Hep A+ food handler handled uncooked food or foods after cooking; and
 - The food handler had diarrhea or poor hygienic practices; and
 - Patrons can be identified and treated within 2 weeks of exposure.

- Schools, hospitals, and work settings where epidemiologic investigation indicates transmission has occurred.

IV. IMMUNE GLOBULIN (IG) SCHEDULE FOR HEPATITIS A MANAGEMENT^{1, 3}

Exposure	Dose	Duration of Coverage
Post-exposure prophylaxis ^{*◇}	0.02mL/kg	<3 months

* IG should be administered as prophylaxis for Hepatitis A exposure in all susceptible (no history of disease, no history of immunization for HAV) children and adults who have been exposed within the past 14 days.

◇ Must be administered within two weeks of exposure to a known HAV–IgM positive case. When IG is administered within two weeks of exposure, it is >85% effective in preventing Hepatitis A infection. The efficacy of IG when administered >2 weeks after exposure has not been established.

V. CONTRAINDICATIONS¹

1. Do not give GamaSTAN[®] to person with isolated immunoglobulin A (IgA) deficiency. Such person have the potential for developing antibodies to IgA and could have anaphylactic reactions to subsequent administration of blood products that contain IgA.
2. IG should not be administered to persons with severe thrombocytopenia or any coagulating disorder that would contraindicate intramuscular injections.
3. 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.

VI. PRECAUTIONS AND WARNINGS¹

General: Do not administer subcutaneously or intravenously because of the potential for serious reaction (e.g., Renal Dysfunction/Failure/Hemolysis, Transfusion-Related Acute Lung Injury [TRALI]). Do not inject into a blood vessel.

Thrombosis: See black box warning on page 2. Symptoms may include: pain, swelling of the arm or leg with warmth over the affected area, discoloration of an arm or leg, unexplained shortness of breath, chest pain or discomfort that worsens on deep breathing, unexplained rapid pulse, numbness or weakness on one side of the body.

Hypersensitivity: Do not perform skin tests as misinterpretation of the results of such tests can lead the physician to withhold beneficial IG from a patient who is not actually allergic to this material. No preservatives. No latex.

VII. ADVERSE REACTIONS

1. Local pain and tenderness at the injection site.
2. Urticaria and angioedema may occur.
3. Anaphylactic reactions although rare, have been reported following the injection of human IG. Anaphylaxis is more likely to occur if GamaSTAN[®] is inadvertently given intravenously. Always give IM.

VIII. Other Considerations

1. **Adverse Events:** epinephrine hydrochloride solution (1:1,000) and other appropriate agents and equipment must be available for immediate use in case of anaphylactic or acute hypersensitivity reaction.⁷
2. **Pregnancy:** It is not known whether GamaSTAN[®] can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. GamaSTAN[®] should only be given to a pregnant woman only if clearly needed.¹
3. **Product Interactions:** Passive transfer of antibodies may transiently impair the immune responses to live attenuated virus vaccines such as MMR[®], MMRV[®] and Varicella¹ IG preparations do not interfere with the immune response to oral poliovirus vaccine, yellow fever vaccine, Ty21a typhoid vaccine, Zoster or live-attenuated influenza vaccine.^{4, 7}

IX. Storage and Handling¹

All clinics and pharmacies enrolled with the VFC program must **immediately** report any storage and handling deviations to their Oregon Immunization Program health educator. The health educator assignment map is located at: http://bit.ly/HE_Map

Vaccine	Temp	Storage Issues	Notes
GamaSTAN [®] 1	Store at 2°–8°C (36°F–46°F)	Do not use if product has been frozen. Report to Oregon Immunization Program at 971–673–0300. Do not use after expiration date.	No natural rubber latex

X. ADVERSE EVENT REPORTING

Adverse events following immunization must be reported to the Vaccine Adverse Events Reporting System (VAERS). The VAERS online report form is available at <https://vaers.hhs.gov/esub/step1>.

A pharmacist who administers any vaccine must report the following elements to the OHA ALERT Immunization Information System in a manner prescribed by OHA within 15 days of administration. This replaces the former requirement to notify the primary health care provider. A pharmacist is not required to notify the primary health care provider. Oregon Administrative Rule 855-019-0290-(2)(3).^{8, 9}

Electronic copy of this protocol available at: 1.usa.gov/PharmacyImmunizationProtocols

References

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3. CDC. Update: Prevention of hepatitis A after exposure to hepatitis A virus an in international travelers. Updated recommendations of the Advisory Committee on Immunization practices (ACIP). 2007;56:1080-83. Available at: www.cdc.gov/mmwr/pdf/wk/mm5641.pdf Accessed 4 November 2015. Accessed 18 December 2015.
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5. Immunization Action Coalition. *Question of the Week* IAC Express – Issue 1157. Available at: www.immunize.org/askexperts/whatsnew.asp Accessed 30 October 2015.
6. CDC. Sources for IG and HBIG. IG for hepatitis A prophylaxis. Available at: www.cdc.gov/hepatitis/iq-hbig_sources.htm Accessed 27, October 2015. GamaSTAN® is the only available hepatitis A IG product in the US as of June 5, 2013.
7. CDC. General Recommendations on Immunizations. Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2011; 60 (RR-2). Available at: www.cdc.gov/mmwr/pdf/rr/rr6002.pdf Accessed 18 December 2015.
8. *State of Oregon, Administration of Vaccines by Pharmacists: 855–019–270*. Available at: www.oregon.gov/pharmacy/Imports/Rules/December10/855-019_Perm.pdf. Accessed 11 August 2015.
9. *Oregon Administrative Rule. Board of Pharmacy. Division 19. Licensing of pharmacists: 855-019-0290 (2)*. Available at: http://www.oregon.gov/pharmacy/Imports/Rules/December10/855-019_Perm.pdf. Accessed 11 September 2015.

Recommended intervals between administration of immune globulin preparations and
measles– or varicella–containing vaccine

Product / Indication	Dose, including mg immunoglobulin G (IgG)/kg body weight	Recommended interval before measles or varicella-containing ¹ vaccine administration
Blood transfusion		
- Red blood cells (RBCs), washed	10 mL/kg (negligible IgG/kg) IV	None
- RBCs, adenine-saline added	10 mL/kg (10 mg IgG/kg) IV	3 months
- Packed RBCs (hematocrit 65%) ²	10 mL/kg (60 mg IgG/kg) IV	6 months
- Whole blood (hematocrit 35%-50%) ²	10 mL/kg (80-100 mg IgG/kg) IV	6 months
- Plasma/platelet products	10 mL/kg (160 mg IgG/kg) IV	7 months
Botulinum Immune Globulin Intravenous (Human)	1.5 mL/kg (75 mg IgG/kg) IV	6 months
Cytomegalovirus IGIV	150 mg/kg maximum	6 months
Hepatitis A IG		
- Contact prophylaxis	0.02 mL/kg (3.3 mg IgG/kg) IM	3 months
- International travel	0.06 mL/kg (10 mg IgG/kg) IM	3 months
Hepatitis B IG (HBIG)	0.06 mL/kg (10 mg IgG/kg) IM	3 months
IGIV		
- Replacement therapy for immune deficiencies ³	300-400 mg/kg IV	8 months
- Immune thrombocytopenic purpura treatment	400 mg/kg IV	8 months
- Measles IG, contact prophylaxis (immunocompromised contact)	400 mg/kg IV	8 months
- Postexposure varicella prophylaxis	400 mg/kg IV	8 months
- Immune thrombocytopenic purpura treatment	1,000 mg/kg IV	10 months
Measles IG, contact prophylaxis		
- Standard (i.e., nonimmunocompromised) contact	0.5 mL/kg (80 mg IgG/kg) IM	6 months
Monoclonal antibody to respiratory syncytial virus F protein (Synagis™) ⁴	15 mg/kg (IM)	None
Rabies IG (RIG)	20 IU/kg (22 mg IgG/kg) IM	4 months
Tetanus IG (TIG)	250 units (10 mg IgG/kg) IM	3 months
Varicella IG ⁵	125 units/10 kg (60-200 mg IgG/kg) IM, maximum 625 units	5 months

Kawasaki Disease

2gm/kg IV

11 months

This table is not intended for determining the correct indications and dosages for using antibody-containing products. Unvaccinated persons might not be fully protected against measles during the entire recommended interval, and additional doses of IG or measles vaccine might be indicated after measles exposure. Concentrations of measles antibody in an IG preparation can vary by manufacturer's lot. Rates of antibody clearance after receipt of an IG preparation also might vary. Recommended intervals are extrapolated from an estimated half-life of 30 days for passively acquired antibody and an observed interference with the immune response to measles vaccine for 5 months after a dose of 80 mg IgG/kg.

¹ Does not include zoster vaccine. Zoster vaccine may be given with antibody-containing blood products.

² Assumes a serum IgG concentration of 16 mg/mL.

³ Measles vaccination is recommended for children with mild or moderate immunosuppression from human immunodeficiency virus (HIV) infection, and varicella vaccination may be considered for children with mild or moderate immunosuppression from HIV, but both are contraindicated for persons with severe immunosuppression from HIV or any other immunosuppressive disorder.

⁴ Contains antibody only to respiratory syncytial virus.

⁵ Licensed VariZIG is a purified human IG preparation made from plasma containing high levels of anti-varicella antibodies (IgG).

Adapted from Table 5, ACIP General Recommendations on Immunization June 2014⁷

Centers for Disease Control and Prevention Epidemiology and Prevention of Vaccine-Preventable Diseases, 13th Edition
April, 2015⁴