

**OREGON HEALTH AUTHORITY
IMMUNIZATION PROGRAM**

**IMMUNE GLOBULIN (IG)
FOR THE PROPHYLAXIS OF HEPATITIS A**

Date Formatting and Adverse Events Reporting link change.

I. ORDER:

1. Check the ALERT Immunization Information System to determine whether the patient needs this vaccine and any other vaccines.
2. Screen for contraindications.
3. Provide product information, answering questions.
4. Obtain a signed Vaccine Administration Record (VAR).
5. Post-exposure Prophylaxis of Contacts to a case:
 - a. Administer 0.02ml/kg (0.01 ml/lb) of IG intramuscularly into the vastus lateralis (outer thigh) muscle or the deltoid muscle with a 1–2 inch needle, depending on recipient’s weight and volume of material to be injected.
6. Pre-exposure Prophylaxis:for susceptible travelers to HepA–endemic countries:
 - a. Length of stay <3 months: Administer 0.02ml/kg (0.01 ml/lb) of IG intramuscularly into the vastus lateralis (outer thigh) muscle or the deltoid muscle with a 1–2 inch needle, depending on recipient’s weight and volume of material to be injected.
 - b. Length of stay ≥3 months: Administer 0.06 ml/kg of IG intramuscularly into the vastus lateralis (outer thigh) muscle or the deltoid muscle with a 1–2 inch needle, depending on recipient’s weight and volume of material to be injected.
6. Do not administer more than 3ml of IG per injection site in children or more than 5ml of IG per injection site in adults.
7. IG may be administered simultaneously with, or at any interval before or after any inactivated vaccine, including hepatitis A vaccine.

Signature

Health Officer or Medical Provider

Date

II. LICENSED IMMUNE GLOBULIN (HUMAN) FOR HEPATITIS A PROPHY

Product Name	How Supplied	Preservative
GamaSTAN [®] S/D	2ml and 10ml vials	NONE

III. 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:

- A. General Recommendations: 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.
- B. 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)

III. RECOMMENDED POST-EXPOSURE PROPHYLAXIS, Continued

- C. Child-care centers staff and attendees: if
- a) One or more cases of hepatitis A are recognized in children or employees or
 - b) 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.
 - c) 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.
- D. 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.
- 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.
- E. Common-source exposure: 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. RECOMMENDED PRE-EXPOSURE PROPHYLAXIS FOR ALL SUSCEPTIBLE PERSONS TRAVELING TO OR WORKING IN COUNTRIES WITH HIGH OR INTERMEDIATE HEPATITIS A ENDEMICITY

- A. Primary immunization should be initiated at least 4 weeks prior to expected exposure to HAV.
- Persons can be assumed to be protected 4 weeks after receiving the first dose of vaccine, although the second dose 6–12 months later is needed for long-term protection.
 - If immunization begins ≤ 2 weeks before expected exposure, IG (0.02 ml/kg) should also be given at a separate injection site for persons >40 years of age, immunocompromised persons, and person with chronic liver disease or other chronic medical conditions.
 - If vaccination is contraindicated or refused, a single dose of IG (0.02 ml/kg) will confer short-term (<3 months) protection.
 - A larger single dose of IG (0.06 ml/kg) will confer ≥ 3 months of protection. This dosage may be repeated every 4–6 months. (package insert)
- B. IG is recommended for susceptible children <12 months of age who are traveling to high risk areas. Current HAV vaccines are not licensed for children less than one year of age.
- C. IG produced by developing nations may not meet U.S. purity standards for plasma-derived products. Should persons need repeat doses of IG abroad, use IG produced by the U.S., or a product meeting the same standards.

V. IMMUNE GLOBULIN (IG) SCHEDULE FOR HEPATITIS A MANAGEMENT

Exposure	Dose	Duration of Coverage
Pre-exposure prophylaxis ^{1,2} AND Post-exposure prophylaxis ^{1,3}	0.02ml/kg	<3 months
Pre-exposure prophylaxis ⁴	0.06ml/kg ⁴	3–6 months

¹ 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, or who plan travel to high-risk areas.

² If the person is traveling for longer than 6 months in areas where hepatitis A is common, a repeat dose is recommended 4 to 6 months after the first IG dose if the patient has not received hepatitis A vaccine or is >40 years of age.

³ Must be administered within 2 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.

⁴ This dosage will offer longer protection for travelers who plan to reside in a Hepatitis A endemic area for longer than 3months.

<p>VI. CONTRAINDICATIONS</p> <p>A. IG should not be given to people with immunoglobulin A (IgA) deficiency. Persons with IgA deficiencies have the potential for developing antibodies to IgA and therefore could experience an anaphylactic reaction when IG is administered</p> <p>B. IG should not be administered to persons with severe thrombocytopenia or any coagulating disorder that would contraindicate intramuscular injections.</p> <p>C. 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.</p>	<p>VII. PRECAUTIONS</p> <p>A. Pregnancy: It is unknown whether IG can cause fetal harm when administered to a pregnant woman or if it could affect reproduction.</p> <p>B. Careful administration in persons reporting a history of systemic allergic reaction following the administration of IG.</p>
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VIII. SIDE EFFECTS AND ADVERSE REACTIONS	
<u>Event</u>	<u>Frequency</u>
Soreness, tenderness, or pain at the injection site.	Occasionally

IX. OTHER CONSIDERATIONS

A. PRE-VACCINATION SEROLOGIC TESTING:

1. Children - Prevaccination testing of children is not indicated because of expected low prevalence of infection.
2. Adults - The decision about whether to test should be based on cost of vaccination compared with the cost of the testing and whether testing is likely to interfere with initiating vaccination. In adults more than 40 years of age and in certain populations (e.g. American Indians, Alaskan Natives, and Hispanics) the prevalence may be high enough to warrant prevaccination testing.

B. Since 2ml and 10ml IG vials of GamaSTAN™ do not contain preservatives, discard opened vial after a single use regardless of whether entire amount of IG was given. Do not re-refrigerate.

C. Hepatitis A IG may interfere with the response to live, attenuated vaccines (e.g. MMR, VARIVAX). Delay administration of these live, attenuated vaccines for 3 months after the administration of IG. (Reference: Appendix A-19, 12th Edition "Pink Book," May 2011).

D. Ideally, IG should not be administered for at least 2 weeks following the administration of MMR or for 3 weeks following varicella vaccine. Should this occur, the individual should be revaccinated, but no sooner than 5 months after IG administration.

E. When administering IG following exposure, and infection already has occurred, IG may modify the expression of the disease.

X. REFERENCES

1. CDC. Advisory Committee on Immunization Practices (ACIP). Update: Prevention of hepatitis A after exposure to hepatitis A virus and in international travelers. Updated recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2007;56:1080-4. Available at: www.cdc.gov/mmwr/preview/mmwrhtml/mm5641a3.htm
2. Hepatitis A. In: *Epidemiology and Prevention of Vaccine Preventable Disease*, ("Pink Book"). Atkinson W, Hamborsky J, Wolfe S, eds. 12th ed. Washington, DC: Public Health Foundation, 2012: 101–13. Available at: www.cdc.gov/vaccines/pubs/pinkbook/hepa.html
3. Oregon Health Authority Public Health Division Hepatitis A Investigative Guideline, January 2012. Available at: <http://1.usa.gov/OregonDiseaseInvestigativeGuidelines>
4. CDC. Prevention of Hepatitis A through active or passive Immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 1999;48(RR-12):1–37.
5. Greenway K. Using the ventrogluteal site for intramuscular injection. *Nurs Stand* 2004;18: 39–42.
6. Nicholl LH & Hesby A. Intramuscular injection: an integrative research review and guideline for evidence-based practice. *Appl Nurs Res* 2002;15:149–62.
7. GamaSTAN[®] Sept 2013 package insert. Available at: www.talecris-pi.info/inserts/gamastans-d.pdf

For more information or to clarify any part of the above order, consult with your health officer or contact the Oregon State Public Health Immunization Program at (971) 673-0300.

**Visit our website at: <http://1.usa.gov/OregonStandingOrders>
To request this material in an alternate format (e.g., braille),
please call (971) 673-0300.**