OREGON HEALTH AUTHORITY
IMMUNIZATION PROGRAM

IMMUNE GLOBULIN (GamaSTAN®)¹, ³
for the prevention of HEPATITIS A or MEASLES

09-19-2017:

- Increase in dosage amounts for Hepatitis A prophylaxis
- Changes to dosages for travelers based on new lengths of stay

I. OREGON MODEL IMMUNIZATION STANDING ORDER:

1. Check the ALERT Immunization Information System (IIS) for vaccine history.
2. Screen clients 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, Section II.
6. GamaSTAN®: **Aspirate to check for blood return.**³

A. Pre-exposure and Post-exposure Prophylaxis for Hepatitis A: for susceptible travelers to HepA−endemic countries:
   - **Length of stay:** See table III. A. for dosage and schedule.
   - **Post-exposure contacts:** See table III. A for dosage and schedule.
   - IG and hepatitis A vaccine may be given at the same time.

B. Post-exposure Prophylaxis for Measles: for contacts to a case:
   See Table III. B. for dosage and schedule.
   - **Note:** Measles vaccine is the biologic of choice if given within 72 hours of exposure. For persons in whom vaccine is contraindicated or more than 72 hours passed, and they are still within 6 days of exposure, immune globulin should be used.⁴
   - IG and measles vaccine should **not** be given at the same time

7. Observe client for 15 minutes after vaccination to decrease the risk for injury should they faint.
This order expires July 31, 2018
II. WARNING: THROMBOSIS

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.

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].

<table>
<thead>
<tr>
<th>Recommended intervals between administration of immune globulin preparations and measles- or varicella-containing vaccine: ¹</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Immune globulin</strong></td>
</tr>
<tr>
<td>Hepatitis A Contact Prophylaxis¹</td>
</tr>
<tr>
<td>Hepatitis A International Travel¹</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Measles Prophylaxis Immunocompetent Contact²</td>
</tr>
<tr>
<td>Measles Prophylaxis Immunocompromised Contact²</td>
</tr>
</tbody>
</table>

For complete table, see MMR or Varicella standing orders.

Revised 09-2017
### III. Recommendations for Use:

#### A. Hepatitis A Prophylaxis

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Vaccine Components</th>
<th>Duration of Travel(^1)</th>
<th>Dose *</th>
</tr>
</thead>
<tbody>
<tr>
<td>GamaSTAN® S/D</td>
<td>Human Plasma</td>
<td>Up to 1 month</td>
<td>0.1 mL/kg (0.05 mL/lb) IM</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Up to 2 months</td>
<td>0.2 mL/kg (0.1 mL/lb) IM</td>
</tr>
<tr>
<td></td>
<td></td>
<td>≥2 months</td>
<td>Repeat 0.2 mL/kg every 2 months IM</td>
</tr>
<tr>
<td>Exposure of Contacts(^1)</td>
<td></td>
<td></td>
<td>0.1 mL/kg (0.05 mL/lb) IM</td>
</tr>
</tbody>
</table>

*This dosage change is based on lower concentrations of anti-hepatitis A virus (HAV) due to the decreasing prevalence of previous HAV infection among plasma donors.\(^1\)
III. B. Measles Prophylaxis – Immunocompetent contacts*

<table>
<thead>
<tr>
<th>&lt;6 months of age§</th>
<th><strong>Product</strong></th>
<th><strong>Components</strong></th>
<th><strong>Dose</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>GamaSTAN® S/D◊</td>
<td>Human Plasma</td>
<td>0.5 mL/kg IM (max dose=15 mL)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>≥6 months of age§</th>
<th><strong>&lt; 72 hrs after exposure</strong></th>
<th><strong>≥ 72 hrs after exposure</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MMR Vaccine</td>
<td>GamaSTAN® S/D◊</td>
</tr>
<tr>
<td></td>
<td>Measles, mumps, rubella</td>
<td>Human Plasma</td>
</tr>
<tr>
<td></td>
<td>See MMR order</td>
<td>0.5 mL/kg IM (max dose=15 mL)</td>
</tr>
</tbody>
</table>

*Severely immunocompromised patients should be referred to the hospital for IV IG administration. Severely immunocompromised patients include patients with 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 Anti-Retroviral Therapy; some experts would include HIV-infected persons who lack recent confirmation of immunologic status or measles immunity.5

◊ IG should be administered at room temperature and within 6 days of exposure.

§IG can be given to anyone who lacks evidence of measles immunity, but priority should be given to persons exposed in settings with intense, prolonged, close contact (e.g. household, child care, classroom, etc.)

‡The maximum dose is 15 mL intramuscularly for all persons.3, 5 B, 6

III. C. Recommendations for Use

Give immune globulin (IG) intramuscularly (IM) to children and adults with a 5/8 to 2 inch needle, depending on recipient’s weight and condition.

Select a large muscle mass that can support the administration of a large volume of IG.

**DOSE CALCULATION – EXAMPLE ONLY** (Adult traveler for 2 months):

Revised 09-2017
(weight of person in pounds) ÷ 2.2046 = weight in kilograms (kg).

(weight of person in kilograms) X 0.06 = dose of 0.06mL/kg (extended traveler dose)

(150 pounds ÷ 2.2046) = 68.039 X 0.06mL = 4.2mL or 4mL 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. ⑧

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Deltoid:
- Average 0.5mL
- Range 0.5–2mL

Vastus Lateralis:
- Average 1–4mL
- Range 1–5mL

Infants and toddlers would fall at the lower end of the range, whereas adolescents and adults would generally fall on the higher end of the range.

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**III. A. HEPATITIS A PRE-EXPOSURE PROPHYLAXIS FOR ALL SUSCEPTIBLE PERSONS TRAVELING TO OR WORKING IN COUNTRIES WITH HIGH OR INTERMEDIATE HEPATITIS A ENDEMICITY**

1. Hepatitis A vaccination 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 (0.1 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. ④
   - If vaccination is contraindicated or refused, a single dose of IG (0.2 ml/kg) will confer short-term (<2 months) protection.
   - A single dose of IG (0.2 ml/kg) will confer ≥2 months of protection. This dosage may be
repeated every 2 months. 

1. In people >40 years of age, IG is preferred, however, vaccine can be used if IG cannot be obtained. 

2. 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.

3. 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 licensed in the U.S., or a product meeting the same standards.

III. B. HEPATITIS A POST-EXPOSURE PROPHYLAXIS OF CONTACT

Confirmation of HAV infection in the index patient by IgM anti-HAV testing is recommended prior to providing post-exposure prophylaxis to contacts. Screening for immunity to hepatitis A is not recommended before giving hepatitis A vaccine or IG.

In healthy people aged ≥12 months, single-antigen hepatitis A vaccine is preferred to IG for long-term protection and ease of administration.

In people >40 years of age IG is recommended.

IG should be used in children <12 months of age, immunocompromised persons, persons with chronic liver disease, and persons for whom vaccine is contraindicated.

Hepatitis A prophylaxis of 0.1mL/kg should be administered as soon as possible, preferably within 2 weeks of exposure for those cannot have vaccine or who refuse vaccine.

When indicated, IG and hepatitis A vaccine can be simultaneously administered.

Contacts for whom post-exposure prophylaxis is recommended:
- Household contacts
- Persons with chronic liver disease, including those with hepatitis B or C virus infection
- Sexual contacts
- Drug sharing contacts
- Persons with a significant opportunity for fecal-oral exposure (repeatedly ate food
prepared by case)4

- 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.

IV. CONTRAINDICATIONS3

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 WARNINGS3

**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 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.  
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.
3. **Nursing Mothers**: All classes of immunoglobulins can be detected in breast milk. Immunoglobulins from the mother help to support the infant’s health.
4. **Product Interactions**: Passive transfer of antibodies may transiently impair the immune responses to live attenuated virus vaccines such as MMR®, MMRV® and Varicella3 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.6, 9
5. **Food handlers and hepatitis A**: Food handlers are not at any greater risk of hepatitis A infection than the general public. Vaccination is not recommended for food handlers without other risk factors. Food handlers with other risk factors should be immunized for their own protection. Per Acute and Communicable Disease Program 02-22-2016.
6. **Food handlers with hepatitis A infection**: When a food handler contracts hepatitis A, he or she may be at increased risk of transmitting the infection to others because of their occupation. See ACDP Investigative Guidelines.
7. In settings where repeated exposures to HAV may have occurred (e.g., institutional cafeterias), stronger consideration of vaccine may be warranted.
IX. Storage and Handling

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).

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Temp</th>
<th>Storage Issues</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>GamaSTAN® ³</td>
<td>Store at 2°–8°C (36°F–46°F)</td>
<td>Do not use if frozen. Report to health educator. Do not use after expiration date</td>
<td>No natural rubber latex</td>
</tr>
</tbody>
</table>

X. ADVERSE EVENTS REPORTING

Public providers are to complete the Vaccine Adverse Events Reporting System (VAERS) report online at https://vaers.hhs.gov/reportevent.html

1. Save a copy of the report number for your records
2. Send copies of the report and VAERS ID number to the Oregon Immunization Program Vaccine Safety Coordinator via confidential email at ORVAERS.Reports@state.or.us or fax (971-673-0278).

Private providers are to report events directly to VAERS and can read about options on how to do so at https://vaers.hhs.gov/reportevent.html.

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: http://1.usa.gov/OregonStandingOrders
References


SUGGESTED INTERVALS BETWEEN ADMINISTRATION OF IMMUNE GLOBULIN PREPARATIONS AND MEASLES- OR VARICELLA-CONTAINING VACCINE

<table>
<thead>
<tr>
<th>Product/Indication</th>
<th>Dose (mg IgG/kg) and route</th>
<th>Recommended interval before measles- or varicella-containing vaccine administration (months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood transfusion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RBCs, washed</td>
<td>10 mL/kg, negligible IgG/kg IV</td>
<td>None</td>
</tr>
<tr>
<td>RBCs adenine-saline added</td>
<td>10 mL/kg (10mg IgG/kg) IV</td>
<td>3</td>
</tr>
<tr>
<td>Packed RBCs (hematocrit 65%)</td>
<td>10 mL/kg (60mg IgG/kg) IV</td>
<td>6</td>
</tr>
<tr>
<td>Whole blood (hematocrit 35%–50%)</td>
<td>10 mL/kg (80-100 mg IgG/kg) IV</td>
<td>6</td>
</tr>
<tr>
<td>Plasma/platelet products</td>
<td>10 mL/kg (160mgIgG/kg) IV</td>
<td>7</td>
</tr>
<tr>
<td>Botulinum Immune Globulin IV (Human)</td>
<td>1.5 mL.kg (75mg IgG/kg) IV</td>
<td>6</td>
</tr>
<tr>
<td>Cytomegalovirus IGIV</td>
<td>150 mg/kg maximum IV</td>
<td>6</td>
</tr>
<tr>
<td>Hepatitis A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contact prophylaxis</td>
<td>0.02 mL/kg (3.3 mg IgG/kg) IM</td>
<td>3</td>
</tr>
<tr>
<td>International travel &lt;3 months</td>
<td>0.02 mL/kg (3.3 mg IgG/kg) IM</td>
<td>3</td>
</tr>
<tr>
<td>International travel &gt;3 months</td>
<td>0.06 mL/kg (10mg IgG/kg) IM</td>
<td>3</td>
</tr>
<tr>
<td>Hepatitis B IG</td>
<td>0.06 mL/kg (10mg IgG/kg) IM</td>
<td>3</td>
</tr>
<tr>
<td>IG IV</td>
<td></td>
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</tr>
<tr>
<td>Replacement therapy for immune deficiencies</td>
<td>300-400 mg/kg IVd</td>
<td>8</td>
</tr>
<tr>
<td>Immune thrombocytopenic purpura treatment</td>
<td>400 mg/kg IV</td>
<td>8</td>
</tr>
<tr>
<td>Postexposure varicella prophylaxis</td>
<td>400 mg/kg IV</td>
<td>8</td>
</tr>
<tr>
<td>Postexposure measles prophylaxis for immunocompromised contacts</td>
<td>400 mg/kg IV</td>
<td>8</td>
</tr>
<tr>
<td>Condition</td>
<td>Dose Description</td>
<td>Footnote(s)</td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>---------------------------------------</td>
<td>-------------</td>
</tr>
<tr>
<td>Immune thrombocytopenic purpura treatment</td>
<td>1000 mg/kg IV</td>
<td>10</td>
</tr>
<tr>
<td>Kawasaki disease</td>
<td>2 g/kg IV</td>
<td>11</td>
</tr>
<tr>
<td>Measles prophylaxis IG</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Standard (i.e., nonimmunocompromised) contact</strong></td>
<td>0.50 mL/kg (80 mg IgG/kg) IM</td>
<td>6</td>
</tr>
<tr>
<td><strong>Monoclonal antibody to respiratory syncytial virus F protein (e.g., Synagis [MedImmune])</strong></td>
<td>15 mg/kg IM</td>
<td>None</td>
</tr>
<tr>
<td>Rabies IG</td>
<td>20 IU/kg (22 mg IgG/kg) IM</td>
<td>4</td>
</tr>
<tr>
<td>Tetanus IG</td>
<td>250 units (10 mg IgG/kg) IM</td>
<td>3</td>
</tr>
<tr>
<td>Varicella IG</td>
<td>125 units/10 kg (60-200 mg IgG/kg) IM</td>
<td>5</td>
</tr>
</tbody>
</table>

Footnotes:

Table 3-5, page 37-39:

Abbreviations: HIV = human immunodeficiency virus; IG = immune globulin; IgG = immune globulin G; IGIV = intravenous immune globulin; mg IgG/kg = milligrams of immune globulin G per kilogram of body weight; IM = intramuscular; IV = intravenous; RBCs = red blood cells.

(a) This table is not intended for determining the correct indications and dosages for using antibody-containing products. Unvaccinated persons might not be protected fully 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.

(b) Does not include zoster vaccine. Zoster vaccine may be given with antibody-containing blood products.
(c) Assumes a serum IgG concentration of 16 mg/mL.
(d) Measles vaccination is recommended for children with mild or moderate immunosuppression from HIV infection, and varicella vaccination may be considered for children with mild or moderate immunosuppression, but both are contraindicated for persons with severe immunosuppression from HIV or any other immunosuppressive disorder.
(e) Licensed VariZIG, similar to licensed varicella-zoster IG (VZIG), is a purified human IG preparation made from plasma containing high levels of antivaricella antibodies (IgG).
(f) Contains antibody only to respiratory syncytial virus.