OREGON HEALTH AUTHORITY
IMMUNIZATION PROTOCOL FOR PHARMACISTS
INACTIVATED JAPANESE ENCEPHALITIS VIRUS VACCINE

Revision as 12-24-2013:
ACIP recommendation for certain travelers 11-15-2013:
  • Primary series is recommended for children aged 2 months through 16 years.
  • A booster dose may be administered to persons ≥17 years if the primary series was administered >1 year previously and if ongoing exposure or re-exposure to JEV is expected.

I. Order:
1. Check the ALERT Immunization Information System to determine whether the client needs this vaccine and any other vaccines.
2. Screen clients ≥11 years for contraindications.
3. Provide an Adolescent Well Visit Flyer to those 11–18 years of age.
4. Provide a current Vaccine Information Sheet (VIS) answering any questions.
5. See section IV. Pg. 4 for administration of IXIARO:
   a. Shake syringe thoroughly prior to administration; solution will be cloudy.
   b. Give IXIARO intramuscularly (IM) as a 2-dose series of 0.5mL to clients ≥11 years of age on days 0 and 28.
II. LICENSED VACCINE:

<table>
<thead>
<tr>
<th>Product name</th>
<th>Vaccine component(s)</th>
<th>Acceptable age range</th>
<th>Dose volume</th>
<th>Thimersol</th>
</tr>
</thead>
<tbody>
<tr>
<td>IXIARO®</td>
<td>6mcg purified, inactivated JEV proteins and 250 mcg of aluminum hydroxide per 0.5mL dose</td>
<td>2 months–2 years of age</td>
<td>0.25mL</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>≥3 years</td>
<td>0.5mL</td>
<td>No</td>
</tr>
</tbody>
</table>

III. A. RECOMMENDATIONS FOR USE:

A. Persons for whom Japanese Encephalitis vaccination is recommended

- JE Vaccine is recommended for travelers who plan to spend a month or longer in endemic areas\(^1\) during the Japanese encephalitis virus (JEV) transmission season. This includes longer-term travelers, recurrent travelers, or expatriates who will be based in urban areas but are likely to visit endemic rural or agricultural areas during a high-risk period of JEV transmission.

- Short-term travelers (<1 month) to endemic areas during the JEV transmission season if they plan to travel outside of an urban area and have an increased risk of JEV exposure:
  - Spending substantial time outdoors in rural or agricultural areas, especially during the evening or night.
  - Participating in extensive outdoor activities (e.g., camping, hiking, trekking, biking, fishing, hunting, or farming).
  - Staying in accommodations without air conditioning, screens, or bed nets.

- Travelers to an area with an ongoing JE outbreak.
- Travelers to endemic areas who are uncertain of specific destinations, activities, or duration of travel.
III. B. RECOMMENDATIONS FOR USE

B. Laboratory Workers

- JE vaccine is recommended for laboratory personnel who work with live, wild-type JEV strains. Vaccinated, at-risk laboratory personnel should receive appropriate booster doses of JE vaccine or be evaluated regularly for JEV-specific neutralizing antibodies to assure adequate titers.

- Those individuals who received JE-MB (JE-VAX) who need a booster must take the 2-dose primary IXIARO® vaccine.

- If the primary series of JE-VC (IXIARO®) was administered >1 year previously, a booster dose may be given before potential JE virus exposure.

C. Persons for whom Japanese Encephalitis vaccination is NOT recommended

- JE vaccine is not recommended for short-term travelers whose visit will be restricted to urban areas or times outside of a well-defined JEV transmission season.¹

¹ Information on expected JEV transmission by country can be obtained from CDC at: http://wwwnc.cdc.gov/travel/yellowbook/2014/chapter-3-infectious-diseases-related-to-travel/japanese-encephalitis

These data should be interpreted cautiously since JEV transmission activity varies within countries from year to year. MMWR 3-12-2010 available at http://www.cdc.gov/mmwr/pdf/rr/rr5901.pdf
# IV. VACCINE SCHEDULE:

## A. IXIARO®

<table>
<thead>
<tr>
<th>AGE</th>
<th>Doses in Series</th>
<th>Acceptable age range</th>
<th>Dose volume</th>
<th>BOOSTER</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥2 months–2 years</td>
<td>2</td>
<td>≥2 months of age</td>
<td>0.25mL</td>
<td></td>
</tr>
<tr>
<td>≥3 –16 years</td>
<td>2</td>
<td></td>
<td>0.5mL</td>
<td></td>
</tr>
<tr>
<td>≥17 years</td>
<td>2</td>
<td></td>
<td>0.5mL</td>
<td>Yes&lt;sup&gt;1,2,3,4&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

<sup>1</sup> The safety and immunogenicity of a booster dose has not been evaluated in infants, children and adolescents 2 months to ≤17 years of age.(pkg insert 2013)<br>

<sup>2</sup>If primary series of IXIARO® was administered to individuals ≥17 years of age and >1 year previously, a booster dose may be given before potential JE virus exposure.<br>

<sup>3</sup>There are no data on the use of IXIARO® as a booster for JE-VAX®. If a previously vaccinated person needs a booster dose, administer a full series (2 doses separated by at least 28 days of IXIARO®.<br>

<sup>4</sup>Data on the response to a booster dose administered >2 years after the primary series are not available.
### V. IXIARO® CONTRAINDICATIONS

| A. | Severe allergic reaction (e.g., anaphylaxis) after a previous dose. |

### VI. IXIARO® PRECAUTIONS

| A. | Hypersensitivity to protamine sulfate. |
| B. | Immunocompetence: There is no safety or efficacy data regarding the use of IXIARO® in immunocompromised individuals. Immunocompromised individuals may have a diminished immune response to IXIARO®. |
| C. | There are no data regarding the use of IXIARO® concomitantly with immunosuppressive therapies, e.g., irradiation, antimetabolites, alkylating agents, cytotoxic drugs, or corticosteroids used in greater than physiologic doses. |
| D. | Drug Interactions: There is no evidence for interference with the immune response when used concomitantly with Havrix®. Data are not available on concomitant administration of IXIARO® with other US-licensed vaccines. |
| E. | Pregnancy and Lactation: Use only if clearly needed. |
| F. | Pediatric / Geriatric: Not tested in individuals ≤2 months of age or ≥65 years of age. |
| G. | For someone with a history of fainting with injections, a 15-minute observation period is recommended after vaccination. |
### VII. IXIARO® SIDE EFFECTS AND ADVERSE REACTIONS

<table>
<thead>
<tr>
<th>Age</th>
<th>Reaction</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 months –≤2 years</td>
<td>Irritability</td>
<td>&gt;20%</td>
</tr>
<tr>
<td></td>
<td>Redness,</td>
<td>&gt;15%</td>
</tr>
<tr>
<td></td>
<td>Fever</td>
<td>&gt;15%</td>
</tr>
<tr>
<td></td>
<td>Diarrhea</td>
<td>&gt;10%</td>
</tr>
<tr>
<td>1 –&lt;3 years</td>
<td>Fever</td>
<td>&gt;20%</td>
</tr>
<tr>
<td>3–12 years</td>
<td>Fever</td>
<td>&gt;10%</td>
</tr>
<tr>
<td>12–&lt;18 years</td>
<td>Site pain,</td>
<td>15%</td>
</tr>
<tr>
<td></td>
<td>Site tenderness</td>
<td>10%</td>
</tr>
<tr>
<td>≥18 years</td>
<td>Site pain</td>
<td>&gt;25%</td>
</tr>
<tr>
<td></td>
<td>Site tenderness</td>
<td>&gt;25%</td>
</tr>
<tr>
<td></td>
<td>Headache</td>
<td>&gt;20%</td>
</tr>
<tr>
<td></td>
<td>Myalgia</td>
<td>&gt;10%</td>
</tr>
</tbody>
</table>
VIII. OTHER CONSIDERATIONS

Although ≤1% of JEV infections results in clinical disease, JE is a devastating illness that has a case-fatality rate of 20–30% and neurologic or psychiatric sequelae in 30–50% of survivors. No specific treatment exists.1

1. In all instances, travelers are advised to take personal precautions to reduce exposure to mosquito bites.3

2. The decision to use IXIARO® should balance the risks for exposure to the virus and for developing illness, the availability and acceptability of repellents and other alternative measures, and the side effects of vaccination.3

3. Assessments should be interpreted cautiously because risk can vary within areas and from year to year.

4. Risk of JE for travelers to highly endemic areas during the transmission season can reach 1 per 5,000 per month of exposure; the risk for most short term travelers may be 1 per million or less.2

5. Advanced age may be a risk factor for developing symptomatic illness after infection. JE acquired during pregnancy carries the potential for intrauterine infection and fetal death. These special factors should be considered when advising elderly persons and pregnant women who plan visits to areas where JE is endemic.

1 CDC. Use of Japanese Encephalitis Vaccine in Children, Recommendations of the Advisory Committee on Immunization practices (ACIP), MMWR 2013; 62(45); 898-900. Available at: http://www.cdc.gov/mmwr/pdf/wk/mm6245.pdf
3 Advisory Committee on Immunization Practices (ACIP) MMWR, 2010: 59 (RR-1)
IX. STORAGE AND HANDLING

IXIARO®

1. Store in refrigerator at 2° to 8°C (35°F-46°F)
2. Do not freeze.
3. Shake well before use: Cloudy solution.
4. Store in original package to protect from light.
5. Do not use after the expiration date shown on the label.

X. ADVERSE EVENTS REPORTING

Adverse events following immunization must be reported to the Vaccine Adverse Events Reporting System (VAERS) at 1-800-822-7967. Forms and procedures can be found at the VAERS website: www.vaers.hhs.gov. In addition, a copy of the reporting form should be reported to the patient’s primary provider, per Oregon Revised Statute (ORS) 855-019-0280(4)

REFERENCES

3. IXIARO package insert, 05-2013, Available at: 


8. JE-VAX (No longer manufactured) package insert, 12-2005, Available at: 

9. CDC. Inactivated Japanese encephalitis virus vaccine, Recommendations of the Advisory Committee on Immunization Practices (ACIP), MMWR 1993; 42 (RR-1) Available at: www.cdc.gov/mmwr/PDF/rr/rr4201.pdf

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 or 711 for TTY. For other questions, consult with the vaccine recipient’s primary health care provider or a consulting physician.

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