IMMUNIZATION PROTOCOL FOR PHARMACISTS

INACTIVATED JAPANESE ENCEPHALITIS VACCINE

I. ORDER FOR ADMINISTRATION

1. Screen for contraindications.
2. Provide a current Vaccine Information Statement (VIS), answering questions.
3. Obtain a signed Vaccine Administration Record (VAR).
4. Do not remove vaccine from refrigerator until ready to reconstitute it with the diluent supplied.
5. Reconstitute only with the 1.3 ml of diluent supplied. Shake vial thoroughly.
6. After reconstitution the vaccine should be stored at 2°– 8°C (35° – 46°F) and used within 8 hours.
7. Give Japanese encephalitis vaccine subcutaneously as a three dose series of 1.0 ml to individuals ≥18 years of age on days 0, 7 and 30.
   a. May be given simultaneously with all other vaccines, including travel vaccines.

Pharmacist signature Date

Electronic copy of this protocol available at
http://www.oregon.gov/dhs/ph/imm/provider/pharmpro.shtml

Original provided courtesy of the Oregon State Public Health Division DHS Immunization Program

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II. LICENSED INACTIVATED JAPANESE ENCEPHALITIS VACCINE

Product Name	Vaccine components	Acceptable Age Range	Preservatives
JE-VAX® (sanofi-pasteur)	Nakayama-NIH strain of JE virus (grown in mice through intracerebral inoculation), gelatin, formaldehyde, polysorbate 80 and <50 ng of mouse protein	≥1 year of age	0.007% thimerosal

III. INDICATIONS FOR USE

Japanese encephalitis (JE) vaccine is indicated for active immunization against JE for persons one year of age or older.

A. Travelers:

1. JE-Vax® should be considered for use in persons who plan to reside in or travel to areas where JE is endemic or epidemic during a transmission season.

2. JE-Vax® is not recommended for all persons traveling to or residing in Asia. The incidence of JE in the location of intended stay, the conditions of housing, nature of activities, duration of stay, and the possibility of unexpected travel to high-risk areas are factors that should be considered in the decision to administer vaccine.

3. In general, vaccine should be considered for use in persons spending a month or longer in epidemic or endemic areas during the transmission season, especially if travel will include rural areas (see CDC's Health Information for International Travel).

B. Vaccination is recommended for all laboratory workers with a potential for exposure to infectious JE virus.

IV. VACCINE SCHEDULE FOR JE--VAX®

Dose and Route: 1.0 ml (0.5ml for children ≤ 3 years of age) subcutaneous(SC)

DOSE	RECOMMENDED AGE	DOSAGE SCHEDULE	BOOSTER
3	≥18 years [1]	Three dose series on days 0, 7 and 30 [2]	**After 2 years** [3]

[1]While this vaccine is licensed for persons ≥1 year of age, Oregon pharmacist's, by law, currently can't administer this vaccine to persons <18 years of age.

[2]An abbreviated schedule of days 0, 7 and 14 can be used when the longer schedule is impractical or inconvenient because of time constraints. (Two doses administered a week apart will confer short-term immunity among 80% of vaccinees. However this schedule should be used only under unusual circumstances and is not routinely recommended). The last dose should be administered at least 10 days before the commencement of travel to ensure an adequate immune response and access to medical care in the event of delayed adverse reactions.

[3]A booster dose of 1.0 ml (0.5 ml for children from 1- 3 years of age) may be given after 2 years. In the absence of firm data on the persistence of antibody after primary immunization, a definite recommendation cannot be made on the spacing of boosters beyond 2 years.

V. CONTRAINDICATIONS & PRECAUTIONS

Contraindications	Precautions
1. Adverse reactions to a prior dose of JE vaccine manifesting as generalized urticaria and angioedema.[1,2] 2. Proven or suspected hypersensitivity to proteins of rodent or neural origin.[2] 3. Hypersensitivity to thimerosal.	1. Vaccinees should be observed for 30 minutes after vaccination and warned about the possibility of delayed generalized urticaria, often in generalized distribution or angioedema of the extremities, face, and oropharynx, especially of the lips. 2. Because of the possibility of delayed allergic reactions, vaccinees should be advised to remain in areas where they have ready access to medical care for 10 days after receiving a dose of JE vaccine and to seek medical attention immediately upon onset of any reaction.

	3. Altered immune states: The only data on the use of inactivated JE vaccine in patients with altered immune states come from a small study among children. These data did not suggest a changed pattern of adverse reactions or immune response after vaccination. 4. Simultaneous administration of other vaccines or drugs: No data exist on the effect of concurrent administration of other vaccines, drugs (e.g., chloroquine, mefloquine), or biologicals on the safety and immunogenicity of JE vaccine. However, the package insert on product information indicates that where possible, JE vaccine should be administered concurrently with other vaccines.
[1]These reactions may occur within minutes following vaccination. Most reactions occur within 48 hours but may occur as long as 2 weeks after vaccination. [2]JE vaccine is produced in mouse brains.	

VI. ADVERSE REACTIONS

1. JE vaccine is associated with a moderate frequency of local and mild systemic adverse effects.

2. Tenderness, redness, swelling and other local effects occur in about 20% (<1% to 31%) of vaccinees.

3. Systemic side effects, principally fever, headache, malaise, rash, and other reactions, such as chills, dizziness, myalgia, nausea, vomiting and abdominal pain occur in about 10% of vaccinees.

4. Less than 5% of US travelers immunized with a three-dose regimen of the vaccine reported headache, flu-like symptoms, fever, and other systemic complaints. Hives and facial swelling were reported in 0.2% and 0.1% of vaccinees, respectively. Local soreness occurred in 5.9% and local redness in 2.9%.

5. Generalized urticaria or angioedema may occur shortly after vaccination or up to 17 days (usually within 10 days) of vaccination.

VII. ADVERSE EVENT 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.org. In addition, a copy of the completed VAERS form should be sent to the patient's primary provider, per ORS 855-041-0510

VIII. OTHER CONSIDERATIONS

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

2. The decision to use JE-VAX 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. 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.

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.

XI. STORAGE & HANDLING

The vaccine should be stored between 2°– 8°C (35°– 46°F).
After reconstitution the vaccine should be stored between 2°– 8°C (35°– 46°F) and used within 8 hours.
DO NOT REFREEZE VACCINE BEFORE OR AFTER RECONSTITUTION.
Unused vaccine should be discarded 8 hours after reconstitution.

X. REFERENCES

Sanofi pasteur. JE-Vax® package insert. Available at : www.vaccineshoppe.com/US_PDF/680-30_4345.pdf

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

CDC. Japanese encephalitis. In: *Health Information for International Travel 2008*. Atlanta: U.S. Department of Health and Human Services, Public Health Service, 2007:190–200. Available at wwwn.cdc.gov/travel/yellowBookCh4-JapaneseEncephalitis.aspx