

JAPANESE ENCEPHALITIS VACCINE

Japanese Encephalitis Vaccine

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Introduction

Japanese encephalitis vaccine inactivated adsorbed (JE-VC) is an inactivated Vero cell culture-derived vaccine containing inactivated Japanese encephalitis virus.^{1,2} This is the only Japanese encephalitis vaccine available in the US; other types of Japanese encephalitis vaccines may be available in other countries (e.g., live attenuated vaccine, live recombinant chimeric vaccine, inactivated mouse brain-derived vaccine).²

Uses

■ Prevention of Disease Caused by Japanese Encephalitis Virus

Japanese encephalitis vaccine inactivated adsorbed (JE-VC) is used in adults, adolescents, and children 2 months of age or older for prevention of disease caused by Japanese encephalitis virus.¹

Japanese encephalitis virus is a Flavivirus closely related to West Nile virus (WNV), St. Louis encephalitis virus, yellow fever virus, and dengue virus.² It is endemic throughout most of Asia and parts of the Western Pacific.^{2,4} It is transmitted to humans through the bite of infected mosquitoes that acquired the virus by biting infected vertebrate hosts (usually pigs or wading birds).² Humans are incidental or dead-end hosts for Japanese encephalitis virus since the level or duration of viremia is insufficient to infect mosquitoes.² Direct person-to-person transmission of Japanese encephalitis virus does not occur; however, transplacental transmission of the virus from mother to child during pregnancy can occur, and transmission of the virus through blood products or transplanted organs theoretically could occur since it has been reported with similar Flaviviruses.²

Japanese encephalitis virus is the most common vaccine-preventable cause of encephalitis in Asia.² The risk of Japanese encephalitis is very low for most travelers to Asia, but risk varies depending on the specific travel destination, duration of travel, season, activities, and accommodations.² Transmission of Japanese encephalitis may occur year-round in subtropical and tropical areas, but transmission may be seasonal in more temperate areas (with peaks occurring in the summer and fall).² Mosquitoes that transmit Japanese encephalitis virus typically breed in areas with stagnant water (e.g., flooded rice fields and marshes).² These mosquitoes are most active outdoors at night.² Activities that may increase risk of exposure include outdoor recreational activities (e.g., camping, hiking, trekking, biking, rafting, fishing, hunting, farming) and spending substantial time outdoors during the evening or night.² Accommodations without air conditioning, screens, or bed nets also increase the risk for mosquito exposure.² Travelers staying in rural areas with active Japanese encephalitis virus transmission for prolonged periods of time are at highest risk.² Travelers on brief trips may also have an increased risk of infection if they have extensive outdoor or nighttime exposure in rural areas during periods of active transmission.² Risk is minimal for short-term travel (<1 month) restricted to major urban areas.²

Japanese encephalitis virus infection usually is asymptomatic.² Less than 1% of infected persons will develop symptoms of encephalitis.² Initial symptoms are usually nonspecific and may include fever, rigors, headache, vomiting, and diarrhea; mental status changes, generalized weakness, focal neurologic deficits (e.g., hemiplegia, tetraplegia, cranial nerve palsies), and movement disorders may develop over the following days.² Seizures are common, especially in children.² Serious complications, including parkinsonian syndrome, acute flaccid paralysis, status epilepticus, brain hypoxia, increased intracranial pressure, aspiration pneumonia, and brainstem herniation can occur.² The case fatality rate for Japanese encephalitis is approximately 20–30%, and 30–50% of survivors have permanent neurologic or psychiatric sequelae.²

Clinical Experience

Safety and efficacy of a 2-dose primary vaccination series of JE-VC have been evaluated in studies involving adults, adolescents, and children 2 months of age or older residing in countries where Japanese encephalitis virus is endemic (e.g., Philippines) or residing in countries where the disease is not endemic (e.g., US, Europe, Australia).^{1,5,9,10,12,13,14,15,16}

In one randomized, observer-blinded study evaluating use of JE-VC in adults 18 years of age or older residing in nonendemic countries, only 21.1% of vaccinees in the per-protocol population had protective immunity (i.e., Japanese encephalitis virus-neutralizing antibody titers of 1:10 or greater) 10 days after the first dose of JE-VC, but 97.3% had protective immunity 7 days after the second dose of JE-VC and still had protective immunity 28 days after the second dose.^{1,5} Similar levels of protective immunity were observed 28 days after the second vaccine dose in another randomized, observer-blinded trial of adults residing in nonendemic countries.¹ In a long-term follow-up study of adults residing in nonendemic countries who received the 2-dose primary vaccination series of JE-VC, protective immunity persisted for 6, 12, 24, and 36 months after initiation of the primary series in 95, 83.4, 81.8, and 84.9%, respectively, of these adults.^{1,10} However, in another study in adults residing in nonendemic countries (western and northern Europe) who received the 2-dose primary series, only 83, 58, and 48% of vaccinees had protective immunity 6, 12, and 24 months, respectively, after initiation of the primary series.^{1,2}

An open-label, single-arm study specifically examined the immunogenicity of a 2-dose primary series of JE-VC in patients ≥65 years of age residing in non-endemic countries.¹⁶ In this study, only 65% of patients demonstrated protective immunity 42 days after the second vaccine dose.¹⁶

The impact of a delay in administration of the second dose in the primary vaccine series was assessed in a group of 100 adults living in nonendemic countries.¹ When the second dose of the primary vaccine series was given 11 months after dose 1, protective immunity was observed in 99% of patients 4 weeks after the second dose and 88.5% of patients 1 year after the second dose.¹

In an uncontrolled, open-label study evaluating JE-VC in children 2 months through 17 years of age residing in nonendemic countries who received an age-appropriate 2-dose primary series of the vaccine, 100% of patients had protective immunity when evaluated 56 days and 7 months later.^{1,12} Long-term follow-up of patients enrolled in this study found that 89.5% of patients maintained protective immunity at month 36.¹³ In a randomized, controlled, open-label study evaluating JE-VC in children 2 months of age or older residing in the Philippines where Japanese encephalitis is endemic, 0–30% of those 2 months to 1 year of age and 3.2–45.7% of those 1 through 17 years of age already had protective immunity prior to administration of JE-VC; 99.2–100% of these children had protective immunity 28 days after the second age-appropriate dose of JE-VC and 85.5–100% still had protective immunity 6 months after the second dose.^{1,14} Long-term follow-up of patients enrolled in this study found that 81.3–100% of these children maintained protective immunity 3 years after primary immunization.¹⁵

There is evidence from several studies in adults that administration of a single booster dose of JE-VC given 14–22 months after completion of the 2-dose primary vaccination series of JE-VC elicits a booster response and increases Japanese encephalitis virus-neutralizing antibody titers.^{1,6,7,8} In an uncontrolled, open-label, phase 3 study in adults residing in nonendemic countries who received a single booster dose of JE-VC 14 months after completion of the 2-dose primary series, the proportion of these adults with protective immunity increased from 69.2% immediately prior to the booster dose to 100% at 28 days after the booster dose, and 98.5% still had protective immunity 12 months after the booster dose.^{1,7} In a follow-up study, 96% of patients continued to demonstrate protective immunity 76 months after receiving the booster dose.⁸ In another study, adults with low antibody titers at 11 months after completion of the primary series received a booster dose 11 months later (22 months after completion of the primary series); all patients demonstrated protective immunity 4 weeks after the booster dose.^{1,6} Safety and immunogenicity of booster doses of JE-VC have not been evaluated in children 2 months through 16 years of age previously vaccinated with the age-appropriate 2-dose primary series of JE-VC.¹

Clinical Perspective

The Centers for Disease Control and Prevention (CDC) maintains a list of specific areas where the risk of Japanese encephalitis is present.⁴ All travelers to areas where Japanese encephalitis virus is endemic should be advised to take precautions against mosquito bites (e.g., insect repellent, permethrin-impregnated clothing, bed nets, staying in screened or air-conditioned rooms).² When deciding whether to vaccinate US travelers against Japanese encephalitis virus, health-care providers should consider the risks associated with the traveler's planned itinerary, the likelihood of future travel to high-risk areas, the high morbidity and mortality associated with Japanese encephalitis, the low probability of serious adverse effects following vaccination, and the traveler's personal perception and tolerance of risk.² Risk factors for Japanese encephalitis virus exposure include prolonged travel in endemic areas, travel during the virus transmission season, spending time in rural areas, participating in extensive outdoor activities, and staying in accommodations without air conditioning, screens, or bed nets.²

The U.S. Public Health Service Advisory Committee on Immunization Practices (ACIP) and CDC state that vaccination with JE-VC is recommended for travelers who plan to spend 1 month or longer in endemic areas, persons who frequently travel to endemic areas, and persons moving to an endemic country to take up residence.²

ACIP and CDC state that vaccination with JE-VC should be considered for short-term travelers (traveling for less than 1 month) to endemic areas who are at increased risk for Japanese encephalitis based on planned travel duration, season, location, activities, and accommodations.² Vaccination with JE-VC should also be considered for travelers to endemic areas who are uncertain of specific destinations, activities, or duration of travel.²

JE-VC vaccination is *not* recommended for short-term travelers (traveling for less than 1 month) to Asia when the visit will be restricted to urban areas or times outside a well-defined Japanese encephalitis virus transmission season.²

ACIP recommends that all laboratory personnel at risk of exposure to infectious Japanese encephalitis virus be vaccinated with JE-VC.² In laboratory settings, Japanese encephalitis virus may be transmitted through needlestick injuries or, theoretically, through mucosal or inhalational exposures.² Although vaccine-induced immunity is presumed to provide protection against percutaneous exposures, it is not known whether vaccine-induced immunity would provide protection against aerosolized Japanese encephalitis virus (especially exposures involving high concentrations of the virus) that may occur during viral purification procedures and may lead to infection through mucous membranes with direct CNS exposure (e.g., olfactory epithelium).²

Dosage and Administration

■ General

Dispensing and Administration Precautions

- Appropriate medical treatment used to manage immediate allergic reactions must be available in the event an acute anaphylactic reaction occurs following administration of Japanese encephalitis vaccine inactivated adsorbed (JE-VC).¹

Other General Considerations

- JE-VC does not provide complete protection for all individuals.¹ Taking personal measures to minimize mosquito exposure, such as wearing appropriate clothing, using insect repellents, and sleeping under mosquito nets is important.¹

■ Administration

Japanese encephalitis vaccine inactivated adsorbed (JE-VC) is administered by IM injection.¹ The vaccine should *not* be given IV, intradermally, or subcutaneously.¹ JE-VC is commercially available as a sterile 0.5 mL suspension supplied in a prefilled single-dose syringe.¹

Depending on patient age, IM injections of JE-VC should be made into the anterolateral muscles of the thigh or deltoid muscle of the arm.¹ In pediatric patients 2–11 months of age, IM injections should preferably be made into the anterolateral thigh; alternatively, the deltoid muscle can be used in those 1 to <3 years of age if muscle mass is adequate.¹ In adults, adolescents, and children 3 years of age or older, IM injections should preferably be made into the deltoid muscle.¹

Before agitation, JE-VC appears as a clear fluid with a white precipitate.¹ Immediately prior to administration, the syringe containing JE-VC should be shaken well to obtain a white, opaque, homogeneous suspension.¹ The vaccine should not be administered if it is discolored or contains particulate matter.¹

After shaking, a sterile needle should be attached to the prefilled syringe.¹ For adults, adolescents, and children 3 years of age or older, the entire contents of the syringe (0.5 mL) should be administered IM.¹ To provide the appropriate dose for pediatric patients 2 months through <3 years of age, the indicated portion of the syringe contents should be expelled through the needle into a medical waste container according to the manufacturer's directions; the needle should then be replaced with a new sterile needle and the remaining volume of vaccine in the syringe should be administered IM to the pediatric patient.¹ JE-VC should not be mixed with any other vaccine in the same syringe or vial.¹

Store JE-VC under refrigeration at 2–8°C and do not freeze.¹ Do not use the vaccine beyond the expiration date printed on the label.¹ Keep the vaccine in the original packaging to protect it from light.¹ During storage, the vaccine may appear as a clear liquid with a white precipitate.¹

■ Dosage

Prevention of Disease Caused by Japanese Encephalitis Virus

Pediatric Patients 2 Months through <3 Years of Age

For primary immunization in pediatric patients 2 months through <3 years of age, 2 doses of JE-VC should be given 28 days apart.¹ Each dose consists of 0.25 mL of the vaccine.¹ The 2-dose primary series should be completed at least 1 week prior to potential exposure to Japanese encephalitis virus.¹

Safety and immunogenicity of booster doses of JE-VC have not been evaluated in pediatric patients 2 months to <17 years of age.¹ However, the U.S. Public Health Service Advisory Committee on Immunization Practices (ACIP) and Centers for Disease Control and Prevention (CDC) state that a booster dose of 0.25 mL may be given ≥1 year after completion of the primary vaccine series if ongoing exposure or re-exposure is expected.²

Pediatric Patients 3 through <17 Years of Age

For primary immunization in pediatric patients 3 to <17 years of age, 2 doses of JE-VC should be given 28 days apart.¹ Each dose consists of the entire contents (0.5 mL) of the prefilled syringe.¹ The 2-dose primary series should be completed at least 1 week prior to potential exposure to Japanese encephalitis virus.¹

Safety and immunogenicity of booster doses of JE-VC have not been evaluated in pediatric patients 3 through <17 years of age.¹ However, ACIP and CDC state that a booster dose of 0.5 mL may be given ≥1 year after completion of the primary vaccine series if ongoing exposure or re-exposure is expected.²

Adults 17 Years of Age or Older

For primary immunization in adults 17 years of age or older, 2 doses of JE-VC should be given 28 days apart.¹ Each dose consists of the entire contents (0.5 mL) of the prefilled syringe.¹ The 2-dose primary series should be completed at least 1 week prior to potential exposure to Japanese encephalitis virus.¹

If administration of the second primary dose of JE-VC is delayed (incomplete primary immunization), there is some evidence from a study in adults that high seroconversion rates are attained if the second dose is administered within 11 months after the initial dose.¹

If the risk of exposure to Japanese encephalitis virus is ongoing or reexposure to the virus is expected, adults 17 years of age or older can receive a booster dose (0.5 mL) of JE-VC, provided it has been at least 1 year since completion of the 2-dose primary series.^{1,}

■ Special Populations

Hepatic Impairment

The manufacturer makes no specific dosage recommendations for patients with hepatic impairment.^{1,}

Renal Impairment

The manufacturer makes no specific dosage recommendations for patients with renal impairment.^{1,}

Geriatric Patients

The manufacturer makes no specific dosage recommendations for geriatric patients.^{1,}

Cautions

■ Contraindications

- Severe allergic reaction (e.g., anaphylaxis) to a previous dose of the vaccine or any component of the vaccine (e.g., protamine sulfate).^{1,}
- Severe allergic reaction to any other Japanese encephalitis vaccine.^{1,}

■ Warnings/Precautions

Hypersensitivity Reactions

Japanese encephalitis vaccine inactivated adsorbed (JE-VC) contains protamine sulfate, a compound known to cause hypersensitivity reactions in some individuals.^{1,}

Appropriate medical care should be readily available in case an anaphylactic reaction occurs.^{1,}

Limitations of Vaccine Effectiveness

JE-VC does not provide complete protection for all individuals.^{1,}

Altered Immunocompetence

The immune response to JE-VC may be diminished or suboptimal in immunocompromised individuals.^{1,}

Specific Populations

Pregnancy

There are no adequate and well-controlled studies using JE-VC in pregnant women.^{1,} In animal studies (female rats), administration of JE-VC at dosages approximately 300-fold higher than the projected human dosage (on a mg/kg basis) did not reveal evidence of impaired fertility or harm to the fetus.^{1,}

JE-VC should be used during pregnancy only if clearly needed.^{1,}

Clinicians are encouraged to report cases of inadvertent administration of JE-VC during pregnancy to 1-844-349-4276 (8443-IXIARO).^{1,}

Lactation

It is not known whether JE-VC is distributed into human milk.^{1,}

JE-VC should be used with caution in nursing women.^{1,}

Pediatric Use

Safety and efficacy of JE-VC have not been established in pediatric patients younger than 2 months of age.^{1,}

Geriatric Use

Clinical studies did not include sufficient numbers of adults 65 years of age and older to determine whether they respond differently to JE-VC than younger adults.¹

■ Common Adverse Effects

The most common adverse effects following a dose of JE-VC in pediatric patients 2 months through <1 year of age are injection site reaction (e.g., redness), fever, irritability, and diarrhea.¹

In pediatric patients 1 to <3 years of age and those 3 to <12 years of age, fever is the most frequently reported systemic reaction.¹

Among pediatric patients 12 to <18 years of age, the most common injection site reactions are pain and tenderness.¹

In adults 18 years of age and older, the most frequent injection site reactions are pain and tenderness, while the most common systemic reactions are headache and muscle pain.¹

Drug Interactions

■ Immunosuppressive Agents

Although specific data are not available regarding concomitant use of Japanese encephalitis vaccine inactivated adsorbed (JE-VC) and immunosuppressive therapy, such therapy may decrease the immune response to the vaccine.^{1,134} Vaccines may be less effective during periods of impaired immune function.¹³⁴ In such cases, non-live vaccines are often postponed, as the primary concern is reduced effectiveness rather than safety.¹³⁴ If a non-live vaccine is given while immune function is compromised, it may need to be repeated once immune function has recovered.¹³⁴

■ Vaccines

If JE-VC is administered concomitantly with another parenteral vaccine, the vaccines should be given at different injection sites using separate syringes.¹ JE-VC should not be combined with any other vaccine in the same syringe or vial.¹

Hepatitis A Vaccine

JE-VC has been administered concomitantly with hepatitis A virus vaccine inactivated (Havrix[®]) in a randomized, controlled, phase 3 study in healthy adults 18 years of age or older.^{1,11} Concomitant administration did not affect the immune response to either vaccine.^{1,11}

Description

Japanese encephalitis vaccine inactivated adsorbed (JE-VC) is a sterile suspension of purified, inactivated Japanese encephalitis virus proteins adsorbed onto aluminum hydroxide and is used to stimulate active immunity to Japanese encephalitis virus.¹

JE-VC promotes production of antibodies that neutralize live Japanese encephalitis virus.¹ Data from animal studies, clinical trials of other Japanese encephalitis vaccines, and epidemiologic studies in humans suggest that a Japanese encephalitis virus-specific neutralizing antibody titer (as measured in vitro in a 50% plaque reduction neutralization test [PRNT₅₀]) of 1:10 correlates with protective immunity against Japanese encephalitis virus infection in humans.^{1,2}

JE-VC is prepared by propagating Japanese encephalitis virus strain SA₁₄₋₁₄₋₂ in Vero cells.¹ After the virus is harvested, pooled, clarified, and concentrated, the virus suspension is treated with protamine sulfate to remove contaminating DNA and proteins and the partially purified virus is then processed through a sucrose density gradient centrifugation step and fractionated.¹ Each fraction is analyzed for the presence of the virus; fractions with the highest virus activity are pooled to give a purified virus suspension.¹ After the purified virus is inactivated with formaldehyde, the preparation is adjusted to a specified protein concentration and formulated by adding an aluminum hydroxide adjuvant.¹

Each 0.5-mL dose of JE-VC contains 6 mcg of purified, inactivated Japanese encephalitis virus proteins and 250 mcg of aluminum hydroxide.¹ Each 0.5-mL dose of the vaccine also contains formaldehyde (not exceeding 200 ppm), bovine serum albumin (not exceeding 100 ng/mL), host cell DNA (not exceeding 200 pg/mL), sodium metabisulfite (not exceeding 200 ppm), host cell protein (not more than 100 ng/mL), and protamine sulfate (not exceeding 1 mcg/mL) from the manufacturing process.¹

Advice to Patients

The following information contains important points for the clinician to discuss with patients during counseling. For more comprehensive monographs suitable for distribution to the patient, please refer to the *AHFS Patient Medication Information* monographs available from [MedlinePlus](#) (in English and Spanish; written at a 6th- to 8th-grade reading level).

- Prior to administration of each dose of Japanese encephalitis vaccine inactivated adsorbed (JE-VC), provide a copy of the appropriate CDC Vaccine Information Statement (VIS) to the patient or patient's legal representative (VIS is available at [\[Web\]](#)).^{1,3}
- Stress importance of consulting current US and international advisories regarding the prevalence of Japanese encephalitis in specific locations prior to travel.¹
- Stress importance of completing the 2-dose primary vaccination series of JE-VC at least 1 week prior to potential exposure to Japanese encephalitis virus.¹
- Advise patient and/or patient's parent or guardian that JE-VC may not fully protect everyone who receives the vaccine, and that travelers to areas with Japanese encephalitis virus should take precautions to avoid mosquito bites (e.g., use insect repellent, wear protective clothing, stay in accommodations with air conditioning, screens, or bed nets).¹

- Stress importance of informing clinicians of any reactions to a previous dose of JE-VC or to any other vaccines.^{1,†}
- Advise patients to inform clinicians of any signs and/or symptoms of severe adverse reactions or anaphylaxis (e.g., difficulty breathing, wheezing, weakness or fast heartbeat, hives) that occur after administration of JE-VC.^{1,†}
- Advise patients to inform their clinician if they are or plan to become pregnant or plan to breast-feed.^{1,†}
- Advise patients to inform their clinician of existing or contemplated concomitant therapy, including prescription and OTC drugs and dietary and herbal supplements, as well as any concomitant illnesses.^{1,†}
- Advise patients of other important precautionary information.^{1,†}

Additional Information

The American Society of Health-System Pharmacists, Inc. represents that the information provided in the accompanying monograph was formulated with a reasonable standard of care, and in conformity with professional standards in the field. Readers are advised that decisions regarding use of drugs are complex medical decisions requiring the independent, informed decision of an appropriate health care professional, and that the information contained in the monograph is provided for informational purposes only. The manufacturer’s labeling should be consulted for more detailed information. The American Society of Health-System Pharmacists, Inc. does not endorse or recommend the use of any drug. The information contained in the monograph is not a substitute for medical care.

Preparations

Excipients in commercially available drug preparations may have clinically important effects in some individuals; consult specific product labeling for details.

Japanese Encephalitis Vaccine Inactivated Adsorbed

<i>ROUTES</i>	<i>FORMS</i>	<i>STRENGTHS</i>	<i>BRAND NAMES</i>	<i>MANUFACTURER</i>
<i>Parenteral</i>	<i>Injectable suspension, for IM use</i>	<i>Each 0.5 mL dose of vaccine contains 6 antigen units of purified, inactivated JEV</i>	<i>Ixiaro[®]</i>	<i>Valneva</i>

† Use is not currently included in the labeling approved by the US Food and Drug Administration.

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