TICK-BORNE ENCEPHALITIS VACCINE

Tick-borne Encephalitis Vaccine

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Introduction

Tick-borne encephalitis vaccine is an inactivated vaccine containing cell culture-adapted, inactivated tick-borne encephalitis virus.[1]

Uses

Prevention of Tick-borne Encephalitis

Tick-borne encephalitis vaccine is used for active immunization to prevent tick-borne encephalitis in individuals ≥1 year of age.[1]

Tick-borne encephalitis virus is a tick-borne flavivirus that is endemic in a geographic region that extends from western and northern Europe to northern and eastern Asia.[2] It is primarily transmitted through the bites of infected ticks (*Ixodes ricinus* in continental Europe and the United Kingdom or *Ixodes persulcatus* in northeastern Europe and Asia).[2] It has also been rarely acquired through the consumption of contaminated food (e.g., unpasteurized dairy products from infected animals), breastfeeding, blood transfusion, solid organ transplantation, and slaughtering of infected animals.[2]

The risk of tick-borne encephalitis is low among travelers from the United States to endemic areas, but certain factors may increase risk.[2] Ticks are typically found in woodland environments; therefore, the risk of tick-borne encephalitis is increased among people engaging in certain recreational activities (e.g., hiking, camping, cycling in woodland areas, hunting, fishing, birdwatching, collecting mushrooms or berries) and people in certain occupations (e.g., farmers, forestry workers, military personnel, researchers in rural areas).[2] Risk of tick-borne encephalitis infection is generally considered low in urban areas.[2] Because ticks are more active during warmer months, the primary transmission season for tick-borne encephalitis in the Northern Hemisphere is April through November.[2]

Approximately 75% of tick-borne encephalitis virus infections are asymptomatic; however, acute neurologic disease can occur, leading to hospitalization, permanent neurologic or cognitive sequelae, and death in some cases.[2] Symptoms typically manifest within 7–14 days if acquired from a tick bite and 2–4 days if acquired via the alimentary route.[2] Acute neurologic illness (e.g., aseptic meningitis, meningoencephalitis, meningoencephalomyelitis) or febrile illness may occur; manifestations are typically milder in children ≤15 years of age, and the risk of severe illness increases with increasing age.[2] Severe illness is also more likely in immunocompromised patients and patients infected with the Far Eastern viral subtype (typically found in China, Japan, Mongolia, and eastern Russia).[2] Specific neurologic manifestations vary but may include altered mental status, decreased concentration, memory impairment, ataxia, rigidity, tremors, and cranial nerve and limb paresis or palsies.[2] Milder symptoms include headache, fatigue, tremors, hearing loss, emotional lability, or minor problems with balance or coordination.[2]

Clinical Experience

Efficacy of the tick-borne encephalitis vaccine was primarily established using immunogenicity studies and retrospective data from a field effectiveness study conducted in Austria; additional studies were conducted to assess seropersistence and antibody response to booster dose administration.[1,3,4,5,6,7,8,9,10,11,12] In one study assessing immunogenicity of the vaccine in healthy subjects 1–15 years of age, seropositivity rates 21 days after the third vaccine dose were 99.2% among patients 1–5 years of age and 99.6% among patients 6–15 years of age.[1] One study assessing immunogenicity of the vaccine in healthy subjects 16–64 years of age found that 98.8% of patients were

seropositive 21 days after the third vaccine dose.[1] Another study assessed immunogenicity in patients ≥16 years of age and found seropositivity rates of 100 and 98.7% among patients 16–49 years of age and patients ≥50 years of age, respectively, at 21 days after the third vaccine dose.[1] In follow-up studies, seropositivity rates 3 years after the primary series of tick-borne encephalitis vaccine were 82.9–100%, depending on age; following a booster dose, all patients were seropositive.[1]

A field effectiveness study retrospectively assessed the effectiveness of tick-borne encephalitis vaccines in Austria between 2000 and 2011.[1,8,12] Two vaccines against tick-borne encephalitis were available in Austria during this period; however, Ticovac accounted for the majority of vaccine doses during this time.[1] The recommended vaccination schedule during the study period was 2 vaccine doses approximately 4 weeks apart followed by a third dose 5–12 months after the second dose and a booster dose ≥3 years after the third dose.[1] Estimated effectiveness of the vaccine for preventing hospitalization due to tick-borne encephalitis was 96.3–98.7% among patients who received at least 3 vaccine doses according to the recommended schedule.[1,12]

Clinical Perspective

According to the Centers for Disease Control and Prevention (CDC), all people traveling to areas where tick-borne encephalitis is endemic should be advised to take precautions to avoid tick bites; preventive measures include insect repellant, protective clothing, and inspecting the body and clothing for ticks during and after outdoor activities.[2] Consumption of unpasteurized dairy products should also be avoided.[2] The CDC also recommends the tick-borne encephalitis vaccine for a select group of people traveling to areas where tick-borne encephalitis is endemic.[2] The CDC maintains a list of specific areas where the risk of tick-borne encephalitis is present, but cautions that tick-borne encephalitis virus transmission can be highly variable within risk areas and from year to year.[13]

The tick-borne encephalitis vaccine is *recommended* for people who are moving or traveling to an area where tick-borne encephalitis is endemic and who are likely to have extensive exposure to ticks because of their planned outdoor activities and itinerary.[2] "Extensive exposure" can be considered based on the duration of travel as well as frequency of exposure; it may include shorter-term travel with daily or frequent exposure or long-term travel with regular (e.g., a few times a month) exposure to environments that might harbor infected ticks.[2] The tick-borne encephalitis vaccine can also be *considered* for people traveling or moving to an area where tick-borne encephalitis is endemic who might engage in outdoor activities in areas where ticks are likely to be found.[2] The decision to vaccinate such patients should be based on an assessment of their planned activities and itinerary, risk factors for a poor medical outcome (e.g., age ≥60 years), and personal perception and tolerance of risk.[2] Vaccination of laboratory workers with potential for exposure to the tick-borne encephalitis virus is also recommended.[2]

Dosage and Administration

■ General

Dispensing and Administration Precautions

- Appropriate medical treatment and supervision must be available to manage potential anaphylactic reactions following vaccination.[1]

Other General Considerations

- Complete the primary immunization series at least 1 week before potential exposure.[1]

■ Administration

Tick-borne encephalitis vaccine is administered by intramuscular injection.[1] It is available as a suspension for injection in single-dose prefilled syringes containing 0.25 or 0.5 mL of vaccine.[1]

Store the vaccine at 2–8°C; keep the syringes in the outer carton to protect from light, and do not freeze.[1] Bring the vaccine to room temperature before administration.[1] Shake well prior to administration to thoroughly mix the vaccine suspension; after shaking, the vaccine should be a homogenous, off-white, opalescent suspension.[1]

■ Dosage

Adult Dosage

> #### Prevention of Tick-borne Encephalitis
>
> *For the prevention of tick-borne encephalitis in adults, the recommended dose of the tick-borne encephalitis vaccine is 0.5 mL.[1] A primary vaccine series consists of 3 vaccine doses, with the second dose administered 14 days to 3 months after the first dose and the third dose administered 5–12 months after the second dose.[1] A booster dose may be administered at least 3 years after completion of the primary immunization series if ongoing exposure or re-exposure to the tick-borne encephalitis virus is expected.[1]*

Pediatric Dosage

> ### Prevention of Tick-borne Encephalitis
>
> *For the prevention of tick-borne encephalitis in adolescents ≥16 years of age, the recommended dose of the tick-borne encephalitis vaccine is 0.5 mL.[1] A primary vaccine series consists of 3 vaccine doses, with the second dose administered 14 days to 3 months after the first dose and the third dose administered 5–12 months after the second dose.[1] A booster dose may be administered at least 3 years after completion of the primary immunization series if ongoing exposure or re-exposure to the tick-borne encephalitis virus is expected.[1]*
>
> *For the prevention of tick-borne encephalitis in children and adolescents 1–15 years of age, the recommended dose of the tick-borne encephalitis vaccine is 0.25 mL.[1] A primary vaccine series consists of 3 vaccine doses, with the second dose administered 1–3 months after the first dose and the third dose administered 5–12 months after the second dose.[1] A booster dose may be administered at least 3 years after completion of the primary immunization series if ongoing exposure or re-exposure to the tick-borne encephalitis virus is expected.[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 reactions (e.g., anaphylaxis) to any component of the formulation.[1]

Warnings/Precautions

Management of Acute Allergic Reactions

Ensure that appropriate medical treatment and supervision are available to manage possible anaphylactic reactions following administration of the vaccine.[1]

Altered Immunocompetence

Individuals with altered immunocompetence may have a reduced immune response to the vaccine.[1]

Human Albumin

Tick-borne encephalitis vaccine contains albumin, a derivative of human blood.[1] Therefore, there is an extremely remote risk of viral disease transmission and variant Creutzfeldt-Jakob disease with this vaccine, and a theoretical risk for transmission of Creutzfeldt-Jakob disease.[1] No cases of viral disease transmission, variant Creutzfeldt-Jakob disease, or Creutzfeldt-Jakob disease have ever been identified with licensed albumin or licensed albumin-containing products.[1]

Limitation of Vaccine Effectiveness

Tick-borne encephalitis vaccine may not protect all individuals.[1]

Specific Populations

> #### Pregnancy
>
> *There are no adequate and well-controlled studies of tick-borne encephalitis vaccine in pregnant women.[1] Available human data are insufficient to establish the presence or absence of vaccine-associated risk during pregnancy, and animal studies have not been conducted.[1] The Centers for Disease Control and Prevention (CDC) states that tick-borne encephalitis can pose a risk for severe illness in pregnant persons; therefore, the benefits of vaccinating pregnant persons when the likelihood of infection is high are likely to outweigh the potential*

risks.[2]

Lactation

It is unknown whether tick-borne encephalitis vaccine is present in human breast milk; its effects on the breast-fed child or on milk production are also unknown.[1] *Consider the developmental and health benefits of breast-feeding along with the mother's clinical need for vaccination and any potential adverse effects on the breast-fed child from the vaccine or from the underlying maternal condition (i.e., susceptibility to tick-borne encephalitis).*[1]

Pediatric Use

Safety and effectiveness of tick-borne encephalitis vaccine have been established in pediatric patients ≥1 year of age; safety and effectiveness have not been established in patients <1 year of age.[1]

Geriatric Use

Clinical studies of tick-borne encephalitis vaccine did not include sufficient numbers of patients ≥65 years of age to determine whether they respond differently from younger patients.[1] *Based on limited data, response to the tick-borne encephalitis vaccine may be reduced among patients ≥50 years of age, especially those ≥65 years of age.*[2]

Hepatic Impairment

Pharmacokinetics and vaccine response have not been specifically evaluated in individuals with hepatic impairment.[1]

Renal Impairment

Pharmacokinetics and vaccine response have not been specifically evaluated in individuals with renal impairment.[1]

■ Common Adverse Effects

In studies of tick-borne encephalitis vaccine in children and adolescents 1–15 years of age, the most common adverse effects were local tenderness, local pain, headache, fever, and restlessness.[1]

In studies of tick-borne encephalitis vaccine in adolescents and adults 16–65 years of age, the most common adverse effects were local tenderness, local pain, fatigue, headache, and muscle pain.[1]

Drug Interactions

■ Immunosuppressive Agents

Individuals receiving immunosuppressive agents may have a diminished response to the tick-borne encephalitis vaccine.[2]

■ Yellow Fever Vaccine

Concomitant administration of the tick-borne encephalitis vaccine and the yellow fever vaccine does not interfere with the immune response to either vaccine.[2]

Description

Tick-borne encephalitis vaccine is an inactivated vaccine that contains cell culture-adapted, inactivated tick-borne encephalitis virus.[1] The tick-borne encephalitis virus present in the vaccine is propagated in chick embryo fibroblast cells; it is then inactivated by treatment with formaldehyde, purified by sucrose gradient centrifugation, and adsorbed onto aluminum hydroxide.[1] Vaccine doses may contain trace amounts of formaldehyde, sucrose, protamine sulfate, chick protein and DNA, neomycin, and gentamicin from the manufacturing process.[1] Administration of the tick-borne encephalitis vaccine induces the production of neutralizing antibodies against the tick-borne encephalitis virus; these antibodies are believed to confer protection from the tick-borne encephalitis virus.[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).

- Inform patient or parent/guardian of the potential benefits and risks of immunization.[1]

- Advise patient or parent/guardian that they must complete the approved 3-dose primary immunization regimen before potential exposure to tick-borne encephalitis virus.[1],
- Advise patient or parent/guardian to report any suspected adverse events to a healthcare professional.[1],
- Advise patients to inform their clinician of existing or contemplated concomitant therapy, including prescription and OTC drugs and dietary or herbal supplements, as well as any concomitant illnesses.[1],
- Advise patients to inform their clinician if they are or plan to become pregnant or plan to breast-feed.[1],
- Inform 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.

Tick-Borne Encephalitis Vaccine

ROUTES	*FORMS*	*STRENGTHS*	*BRAND NAMES*	*MANUFACTURER*
Parenteral	*Injectable suspension, for IM use*	*1.2 mcg (of inactivated virus) in 0.25 mL*	*Ticovac® (available as a pre-filled syringe)*	*Pfizer*
		2.4 mcg (of inactivated virus) in 0.5 mL	*Ticovac® (available as a pre-filled syringe)*	*Pfizer*

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

Original Publication Date: July 10, 2026.
Database Extraction: 07/08/2026 15:18:40 +0000+

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