Ticovac™ (tick-borne encephalitis vaccine) – New vaccine approval

- On August 13, 2021, Pfizer announced the FDA approval of Ticovac (tick-borne encephalitis vaccine), for active immunization to prevent tick-borne encephalitis (TBE). Ticovac is approved for use in individuals 1 year of age and older.

- TBE is a viral infection of the brain and spine, transmitted to humans through the bite of an infected tick, and less frequently by ingestion of unpasteurized milk or milk products from infected animals.

    — Although TBE is not endemic in the U.S., to date, it has been identified in more than 35 countries across Europe and Asia. The European Centre for Disease Prevention and Control currently recommends TBE vaccination for people who live in or are traveling to risk areas.

- Ticovac is the first approved vaccine for TBE in the U.S.

- The immunogenicity of Ticovac was established across three studies. In these studies, seropositivity rates were 99.5% in individuals 1 to 15 years of age and 98.7 to 100% in adults greater than 15 years of age following three Ticovac doses.

- In Austria, field effectiveness of TBE vaccines was assessed retrospectively for the period from 2000 to 2011. During this period, two TBE vaccines were available in Austria. The market coverage in Austria for TICOVAC was 95%, 90%, and 80%, in 2000, 2006, and 2011, respectively.

    — Overall, worst-case and best-case TBE vaccine effectiveness for preventing hospitalized TBE was estimated to be 96.3% and 98.7%, respectively, following at least three doses of TBE vaccine administered according to the recommended schedule in Austria.

- Warnings and precautions for Ticovac include management of acute allergic reactions; altered immunocompetence; human albumin; and limitation of vaccine effectiveness.

- The most common adverse reactions with Ticovac use were as follows:

    — 1 through 15 years of age: Local tenderness, local pain, headache, fever, and restlessness.
    — 16 through 65 years of age: Local tenderness, local pain, fatigue, headache, and muscle pain.

- The recommended dosage for Ticovac is given intramuscularly at 0.25 mL per dose for 1 through 15 years of age and 0.5 mL for each dose for 16 years of age and older. The primary vaccination schedule is provided in the table below.

    — Complete the primary immunization series at least 1 week prior to potential exposure to TBEV (tick-borne encephalitis virus).
    — A booster dose (fourth dose) may be given at least 3 years after completion of the primary immunization series if ongoing exposure or re-exposure to TBEV is expected.

	1 through 15 years of age	**16 years of age and older**
First dose	Day 0	Day 0
Second dose	1 to 3 months after the first vaccination	14 days to 3 months after the first vaccination
Third dose	5 to 12 months after the second vaccination	5 to 12 months after the second vaccination

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- Pfizer's launch plans for Ticovac are pending. Ticovac will be available as a suspension for injection supplied as a 0.25 mL or 0.5 mL single-dose in prefilled syringes.

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