Prescribing Information:

TicoVac 0.5 ml Suspension for injection in a prefilled syringe
TicoVac Junior 0.25 ml Suspension for injection in a pre-filled syringe
(Tick-Borne Encephalitis Vaccine (whole Virus inactivated))

Please refer to the Summary of Product Characteristics (SmPC) before prescribing TicoVac 0.5 ml and TicoVac Junior 0.25 ml Suspension for injection in pre-filled syringe.

Presentation: TicoVac 0.5 ml is presented as a 0.5 ml suspension in pre-filled syringe. TicoVac 0.25 ml is presented as a 0.25 ml suspension in pre-filled syringe. Indications: TicoVac 0.5 ml is indicated for the active (prophylactic) immunisation of persons of 16 years of age and older against tick-borne encephalitis (TBE). TicoVac Junior 0.25 ml is indicated for the active (prophylactic) immunisation of children aged from 1 year to 15 years against tick-borne encephalitis (TBE). To be given on the basis of official recommendations regarding the need for, and timing of, vaccination against TBE.

Dosage: **Primary vaccination:** consists of three doses of TicoVac 0.5 ml or 0.25 ml (TicoVac Junior). The first dose should be given on an elected date- give the second dose 1 to 3 months later, followed by the third dose after 5 to 12 months, ideally within the same tick season. If protection is needed rapidly the second dose can be given fourteen days after the first. A booster dose should be given following official recommendations. **Children from 1 to 15 years of age and persons from 16 to 60 years of age:** the first booster dose should be given 3 years after the third dose. Sequential booster doses should be given every 5 years after the last booster dose. **Persons above 60 years of age:** In general, in individuals over 60 years of age the booster intervals should not exceed three years. Extending the interval between any of the doses (primary vaccination schedule and booster doses) may leave subjects with inadequate protection against infection. However, in the case of an interrupted vaccination schedule of at least two previous vaccinations, a single catch-up dose is sufficient to continue the vaccination schedule. For intramuscular injection only. **Contraindications:** Hypersensitivity to the active substance, any of the excipients, or production residues (formaldehyde, neomycin, gentamycin, protamine sulfate). Cross allergies with aminoglycosides other than neomycin and gentamycin should be considered. Severe hypersensitivity to egg, chick proteins (anaphylactic reaction after oral ingestion of egg protein) may cause severe allergic reactions in sensitized individuals. TBE vaccination should be postponed if the person is suffering from a moderate or severe acute illness (with or without fever). **Special warnings and precautions for use:** Appropriate emergency treatment and supervision should always be readily available in case of a rare anaphylactic event following the administration of the vaccine. Non-severe allergy to egg protein does not usually constitute a contraindication to vaccination with TicoVac. Nevertheless, such persons should only be vaccinated under appropriate supervision and facilities for emergency management of hypersensitivity reactions should be available. Intravascular administration must be avoided as this might lead to severe reactions, including hypersensitivity reactions with shock. Whenever serological testing is considered necessary in order to determine the need for sequential doses,
assays should be performed in an experienced, qualified laboratory. This is because cross reactivity with pre-existing antibodies due to natural exposure or previous vaccination against other flaviviruses (e.g. Japanese encephalitis, Yellow fever, Dengue virus) may give false positive results. Caution is required in persons with pre-existing cerebral disorders such as active demyelinating disorders or poorly controlled epilepsy or with known or suspected auto-immune disease. As with all vaccines, TicoVac may not completely protect all vaccinees against the infection that it is intended to prevent. **Drug interactions:** No interaction studies with other vaccines or medicinal products have been performed. The administration of other vaccines at the same time as TicoVac should be performed only in accordance with official recommendations. If other injectable vaccines are to be given at the same time, administrations should be into separate sites and, preferably, into separate limbs. **Fertility, pregnancy and lactation:** No data available from the use of TicoVac in pregnant women. It is unknown whether TicoVac is excreted in human milk. Therefore, TicoVac should only be administered during pregnancy and to breastfeeding women when it is considered urgent to achieve protection against TBE infection and after careful consideration of the risk-benefit relationship. **Driving and operating machinery:** TicoVac is unlikely to affect a person’s ability to drive and use machines. It should be taken into account, however, that impaired vision or dizziness may occur. **Undesirable effects:** Refer to section 4.8 of the SmPC for further information on side effects. **Very common:** Injection site reactions. **Common:** Headache, nausea myalgia, fatigue, malaise (in adults and children); arthalgia (in adults); decreased appetite, restlessness, sleeping disorder, vomiting, pyrexia, injection site reactions such as: swelling, induration, erythema (in children). **Adverse reactions from post-marketing surveillance:** *Adults*- Herpes zoster, precipitation or aggravation of autoimmune disorders, demyelinating disorders (acute disseminated encephalomyelitis, guillain-barré syndrome, myelitis, transverse myelitis), convulsions, aseptic meningitis, sensory abnormalities and motor dysfunction (facial palsy/paresis, paralysis/paresis, neuritis, hypoesthesia, paresthesia), neuralgia, optic neuritis, dizziness, tachycardia, urticaria, rash (erythematous, macula-papular), dermatitis, back pain, joint swelling, chills, injection site joint movement impairment such as joint pain, nodule and inflammation. *Children*- convulsion (including febrile), polyneuropathy, motor dysfunction (hemiparesis/hemiplegia facial paresis, paralysis/paresis, neuritis), Guillain-Barré syndrome, rash (erythematous, maculo-papular, vesicular). *Adults and children*- anaphylactic reaction, encephalitis, meningism, visual impairment, photophobia, eye pain, tinnitus, dyspnea, pruritus, erythema, hyperhidrosis, neck pain, musculoskeletal stiffness (including neck stiffness), pain in extremity, gait disturbance, influenza like illness, asthenia, edema.

**Legal category:** POM. **Package quantities, Marketing Authorisation number and basic NHS price:** TicoVac 0.5 ml – 1 pack - PL 00057/1518 - £32; TicoVac Junior 0.25 ml -1 pack - PL 00057/1519 - £28
Adverse events should be reported. Reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). Adverse events should also be reported to Pfizer Medical Information on 01304 616161.