Package leaflet: Information for the user
TicoVac 0.5 ml Suspension for injection in a pre-filled syringe

Tick-Borne Encephalitis Vaccine (whole virus inactivated)

Read all of this leaflet carefully before you or your child receives this vaccine because it contains important information for you or your child.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This vaccine has been prescribed for you or your child only. Do not pass it on to others.
- If you or your child get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What TicoVac 0.5 ml is and what it is used for

TicoVac 0.5 ml is a vaccine, which is used to prevent disease caused by *Tick-Borne Encephalitis (TBE) Virus*. It is suitable for persons of 16 years of age and older.

- The vaccine causes the body to make its own protection (antibodies) against the virus.
- It will not protect against other viruses and bacteria (some of which are also transmitted by tick bites) that may cause similar symptoms.

The *Tick-Borne Encephalitis Virus* can cause very serious infections of the brain or the spine and its covering. These often start with headache and high temperature. In some people and in the most severe forms, they can progress to loss of consciousness, coma and death.

The virus can be carried by ticks. It is passed on to man by tick bites. The chance of being bitten by ticks that carry the virus is very high in large parts of Europe as well as Central and Eastern Asia. People who live in or go to holidays in these parts of the world are at risk of contracting tick-borne encephalitis. The ticks are not always spotted on the skin and the bites may not be noticed.

- Like all vaccines, this vaccine may not completely protect everyone who is vaccinated.
- A single dose of the vaccine is not likely to protect you or your child against infection. You or your child need 3 doses (see section 3 for more information) to achieve an optimal protection.
- The protection does not last for life. Regular booster doses are needed (see section 3 for more information)
- There is no data on post exposure prophylaxis (vaccination after tick bite)

2. What you need to know before you or your child receives TicoVac 0.5 ml

Do not use TicoVac 0.5 ml:

- If you or your child is allergic to the active substance, any of the other ingredients (listed in section 6), formaldehyde or protamine sulfate (used during the manufacturing process) or antibiotics such as neomycin and gentamycin. For example, you or your child have had skin rash, swelling of the face and throat, difficulty in breathing, blue discolouring of the tongue or lips, low blood pressure and have collapsed.
- If you or your child ever had a severe allergic reaction after eating egg or chicken
- If you or your child has an acute illness with or without fever you or your child may have to wait before having TicoVac 0.5 ml. Your doctor could ask you or your child to wait for the injection until you or your child feel better.

Warning and precautions

Talk to your doctor, pharmacist or nurse before receiving the vaccine if you or your child:
- have a bleeding disorder or bruise easily
- have an autoimmune disease (such as rheumatoid arthritis or multiple sclerosis)
- have a weak immune system (so that you or your child do not fight infections well)
- do not produce antibodies well
- take any medicine for cancer
- take medicines called corticosteroids (that reduce inflammation)
- have any brain illness
- have neurological disorders or seizure disorders.

The vaccine may not be suitable, if any of the circumstances above apply to you or your child. Alternatively, the doctor may give you or your child the vaccine. The doctor may request to do a blood test to check whether the vaccine has worked.

Other medicines and TicoVac 0.5 ml

Tell your doctor, pharmacist or nurse if you or your child are taking or have recently taken any other medicines, including medicines obtained without a prescription. Your doctor will tell you if you or your child can have TicoVac 0.5 ml at the same time as other vaccines. If you or your child have recently had another vaccine, your doctor will decide where and when to give the TicoVac 0.5 ml vaccine.

TicoVac 0.5 ml may not provide complete protection if you or your child are under an immunosuppressive treatment.

Tell your doctor if you or your child have ever been infected with, or been vaccinated against, Yellow fever, Japanese encephalitis or Dengue viruses. This is because you or your child may have antibodies in your blood that can react with the Tick-Borne Encephalitis (TBE) Virus used in tests to measure your antibody levels. These tests could then give wrong results.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before receiving this vaccine.
Your doctor will discuss with you the possible risks and benefits. The effect of TicoVac 0.5 ml during pregnancy or while breast-feeding is not known. However, it may still be given if the risk of infection is high.

Driving and using machines

The vaccine is unlikely to affect a person being able to drive or use machines. However, you may have problems with your sight or feel dizzy.

TicoVac 0.5 ml contains potassium and sodium
Potassium and sodium are present at levels less than 1 mmol per dose, i.e. essentially "potassium- and sodium-free".

3. How to use TicoVac 0.5 ml

This vaccine is usually injected into the muscle of the upper arm. The vaccine must not be injected into a blood vessel. In exceptional cases only (if you or your child have a bleeding disorder or are receiving medication to thin the blood, called an anticoagulant), the vaccine may be administered under the skin (subcutaneously).

This vaccine should not be given to persons under 16 years of age. For this age group a TBE vaccine for children is recommended. The administration of the vaccine should be documented by the physician, and the lot number recorded.

First course of injections
The first course of injections consists of three doses of TicoVac 0.5 ml:

1. Your doctor will decide when to give the first injection.
2. The second injection will be given 1 to 3 months later. It can be given two weeks after the first dose if you need urgent protection.
3. The third injection will be given 5 to 12 months after the second injection.

- It is best to have the first and second doses in the winter. This is because the tick starts being active in spring. This allows you to develop enough protection before the tick season starts.
- The third dose completes the primary course of injections. The vaccination schedule should ideally be completed with the third vaccination within the same tick season or at the least before the start of the following tick season.
- It gives protection for up to three years.
- If you leave too much time between the 3 doses, you may not have full protection against infection.

Basic Immunisation	**Dose**	**Conventional Schedule**	**Rapid Immunisation Schedule**
1st dose	0.5 ml	Elected date	Elected date
2nd dose	0.5 ml	1 to 3 months after the 1st vaccination	14 days after the 1st vaccination
3rd dose	0.5 ml	5 to 12 months after the 2nd vaccination	5 to 12 months after the 2nd vaccination

Booster vaccinations
Persons from 16 to 60 years of age
If you are younger than 60, you will need the first booster dose 3 years after the third dose. Further booster doses should be given every 5 years.

Persons 60 years of age and older
In general, you will need booster doses - the first and all further booster doses - at three years intervals.

Booster dose ≥ 16 to < 60 years	**Dose**	**Timing**
1st booster	0.5 ml	3 years after the third dose
Sequential booster doses	0.5 ml	every 5 years

Booster dose ≥ 60 years	Dose	Timing
All booster doses	0.5 ml	every 3 years

If you leave too much time between vaccine doses, you may not be protected against TBE, however, a single catch-up dose with TicoVac is sufficient to continue the vaccination schedule if you received at least two vaccinations in the past. Restarting the entire first course of vaccinations is not required. Ask your doctor for more information.

Persons with impaired immune system (including immunosuppressive therapy)
Your doctor may consider determining the antibodies in your blood at four weeks after the second dose and administer an additional dose if there is no evidence of immune response at this time. The same applies to any of the following doses.

If you use more TicoVac 0.5 ml than you should
An overdose is highly unlikely to happen because the injection is given from a single-dose syringe by a doctor.
If you have any further questions on the use of this vaccine, ask your doctor, nurse or pharmacist.

4. Possible side effects

Like all medicines, this vaccine may cause side effects, although not everybody gets them. If any of the side effects get serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

As with all vaccines, severe allergic reactions can happen. They are very rare, but the right medical treatment and supervision must always be readily available. Symptoms of serious allergic reactions include:
- swelling of the lips, mouth, throat (which may make it difficult to swallow or breathe)
- a rash and swelling of the hands, feet and ankles
- loss of consciousness due to a drop in blood pressure

These signs or symptoms usually happen very quickly after the injection is given, while the person is still in the clinic or surgery. If any of these symptoms happen after you leave the place where your injection was given, you must see a doctor IMMEDIATELY.

The following side effects have been reported:

Very common (may affect more than 1 in 10 people):
- Pain where the injection was given

Common (may affect up to 1 in 10 people):
- Headaches
- Nausea
- Muscle and joint pains
- Feeling tired or unwell

Uncommon (may affect up to 1 in 100 people):
- Swelling of lymph glands
- Vomiting
- Fever

- Bruising at the injection site

Rare (may affect up to 1 in 1,000 people):
- Allergic reactions
- Sleepiness
- Motion sickness
- Diarrhoea
- Abdominal pain
- Redness, tissue hardening, swelling, itching, tingling and warmth at the injection site

The following additional side effects, from post marketing surveillance with a rare frequency, have also been reported:
- Shingles
- Triggering of autoimmune disorders, e.g. multiple sclerosis
- Allergic reactions
- Neurological disorders such as encephalomyelitis, inflammation of the spinal cord (myelitis, transverse myelitis)
- An illness consisting of muscle weakness, abnormal sensations, tingling in the arms, legs, and upper body (Guillain-Barré syndrome)
- Inflammation of the brain, fits, inflammation of the meninges (layers lining the brain)
- Signs of meningeal irritation like pain and stiffness of neck
- Neurological symptoms such as facial palsy, paralysis, inflammation of nerves, abnormal or reduced sensation such as tingling or numbness, stabbing or throbbing pain along one or more nerves, inflammation of the visual nerve
- Feeling dizzy
- Visual disorders/impairment, being more sensitive to light, pain in the eye
- Ringing in the ears
- Rapid beating of the heart
- Shortness of breath
- Skin reactions, (rashy and/or itchy skin), dermatitis, redness of the skin, increased sweating, inflammation of the skin
- Pain in the back, joint swelling, neck pain, musculoskeletal and neck stiffness, pain in arm and legs
- Chills, influenza-like illness, weakness, edema, unsteady walking, accumulation of fluid beneath the skin
- Joint pain at the injection site, nodule and inflammation at the injection site

In a small comparative study on the immune response after intramuscular and subcutaneous administration of TicoVac in healthy adults, the subcutaneous route led to higher local reactions at the injection site (e.g., redness, swelling, itching, and pain), particularly in women.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store TicoVac 0.5 ml

- Store in a refrigerator (2°C - 8°C). Keep the syringe in the outer carton, in order to protect from light. Do not freeze. Do not use this vaccine if you notice any visible signs of foreign particulate matter or leakage.
- Keep this vaccine out of the sight and reach of children.
- Do not use this vaccine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.
- Do not throw away any vaccines via wastewater or household waste. Ask your pharmacist how to throw away vaccines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What TicoVac 0.5 ml contains
The active substance is: *Tick-Borne Encephalitis Virus* (strain Neudörfl)
One dose (0.5 milliliters) of the vaccine contains 2.4 micrograms of *inactivated Tick-Borne Encephalitis Virus* (strain Neudörfl), which is produced in chick embryo cells.
The other ingredients are: human albumin, sodium chloride, disodium phosphate-dihydrate, potassium dihydrogen phosphate, sucrose and water for injections.
Aluminum hydroxide (hydrated) is included in this vaccine as an adsorbent. Adsorbents are substances included in certain vaccines to accelerate, improve and/or prolong the protective effects of the vaccine.

What TicoVac 0.5 ml looks like and contents of the pack
TicoVac 0.5 ml is supplied as a 0.5 milliliter (one dose) suspension for injection in a pre-filled syringe. The pack may include no needles or 1 separate needle per syringe. Needles are sterile and for single use only. Pack sizes of 1 and 10 pre-filled syringes are available. Not all pack sizes may be marketed. After shaking, the suspension is off-white and milky.

Each pre-filled syringe is packed in a blister. The opening in the blister seal is intended and allows for the equilibration of moisture during the recommended warm-up prior to the administration of the vaccine. Open the blister by removing the lid to take out the syringe. Do not press the syringe through the blister.

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This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

België/Belgique/Belgien, Luxembourg/Luxemburg, Nederland, Polska, Portugal, Slovenija	FSME-IMMUN 0,5 ml
Česká republika	FSME-IMMUN
България	FSME-IMMUN 0.5 ml
Danmark, Norge, Suomi/Finland, Ísland, Ελλάδα, Κύπρος	TicoVac
Deutschland	FSME-IMMUN 0,5 ml Erwachsene
Eesti, Italia, Latvija, Lietuva	TicoVac 0,5 ml
Hrvatska	FSME-IMMUN 0,5 ml, suspenzija za injekciju u napunjenoj štrcaljki, cjepivo protiv krpeljnog encefalitisa, inaktivirano
Ireland, United Kingdom (Northern Ireland)	TicoVac 0.5 ml
France	TicoVac 0,5 ml ADULTES
Sverige	FSME-IMMUN Vuxen
Magyarország	FSME-IMMUN 0,5 ml felnőtteknek
Malta	TicoVac 0.5 ml Suspension for injection in pre-filled syringe
Österreich	FSME-Immun 0,5 ml Erwachsene Injektionssuspension in einer Fertigspritze
România	FSME-IMMUN 0.5 ml suspensie injectabila in seringa preumpluta
Slovenská republika	FSME-IMMUN 0,5 ml Injekčná suspenzia

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The following information is intended for medical or healthcare professionals only:

The vaccine should reach room temperature before administration. Shake well prior to administration to thoroughly mix the vaccine suspension. After shaking, TicoVac 0.5 ml is an off-white, opalescent, homogeneous suspension. The vaccine should be inspected visually for any foreign particulate matter and/or variation in physical appearance prior to administration. In the event of either being observed, discard the vaccine.

After removing the syringe cap, attach the needle immediately and remove the needle shield prior to administration. Once the needle is attached, the vaccine must be administered immediately. In the exceptional cases of subcutaneous administration, an appropriate needle should be used.

Any unused product or waste material should be disposed of in accordance with local requirements.