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 at least 16 years of age.

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

- The Tick-Borne Encephalitis Virus can cause very serious infections of the brain or the spine. 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 some parts of central and northern Europe. People who live in or take holidays in these parts of Europe are most at risk. The ticks are not always spotted on the skin, and the bites may not be noticed.

- Like all vaccines, TicoVac 0.5 ml may not completely protect everyone who is vaccinated.
- Also, protection does not last for life.
- A single dose of the vaccine is not likely to protect you against infection. You need 3 doses (see section 3 for more information).

2. BEFORE YOU RECEIVE TicoVac 0.5 ml

Do not use TicoVac 0.5 ml if:

- you ever had an allergic reaction to a previous dose of this vaccine or to any ingredient of the vaccine. For example, you have had skin rash, swelling of the face and throat, difficulty in breathing, blue discolouring of the tongue or lips, vomiting, high blood pressure and collapse.
- you ever had an allergic reaction to neomycin or gentamicin or to tomalidine or protamine sulphate (used during the manufacturing process).
- you ever had a severe allergic reaction after eating egg or chicken.
- you are known to be allergic to latex rubber.
- you have an infection with a fever (raised temperature) you may have to wait before having TicoVac 0.5 ml. Your doctor could ask you to wait for the injection until you feel better.

Take special care with TicoVac 0.5 ml
Talk to your doctor before having the vaccine if:

- you have an autoimmune disease (such as rheumatoid arthritis or multiple sclerosis)
- you have a weak immune system (so that you do not fight infections well)
- you do not produce antibodies well
- you take any medicine for cancer

- you take medicines called corticosteroids (that reduce inflammation)
- you have any brain illness
- If any of these apply to you, the vaccine may not be suitable. Or, the doctor may give you the vaccine but want to take a simple blood test later, to check if it has worked.

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

Tell your doctor if you have ever been infected with or been vaccinated against yellow fever, Japanese encephalitis or Dengue viruses. This is because you 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 and breast-feeding
Tell your doctor before having this injection if:

- you may be pregnant, or are planning to become pregnant;
- you are breast-feeding.

If you are given more TicoVac 0.5 ml than you should be given
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 or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, TicoVac may cause side effects, although not everybody gets them. If any of the side effects persist or worsen and worry you or if you notice side effects not listed in this leaflet, please contact your doctor.

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.

Very common side effects (affect more than 1 in 10 people)

- Pain and tenderness where the injection was given

Common side effects (affect less than 1 in 10 people)

- Headaches
- Swelling, firming or lump
- Muscle and joint pain

Uncommon side effects (affect less than 1 in 100 people)

- Swelling, hardness and redness where the injection was given
- Asthma
- Swelling of lymph glands, fever

Very rare side effects (affect less than 1 in 10,000 people)

- Feeling dizzy, muscle and joint pain in the neck region, unsteady walking, inflamed nerves, convulsions
- Blurred vision or being more sensitive to light, pain in the eye
- Tinnitus
- Diarrhoea
- Rash
- Redness and itchy skin
- Severe shivering and high temperature
- Flu-like illness, weakness, swelling
5. HOW TO STORE TicoVac 0.5 ml

- Store in a refrigerator (2°C–8°C). Keep the syringe in the outer carton, as this provides protection from light. Do not freeze. Do not use TicoVac 0.5 ml if you notice any visible signs of foreign particulate matter or leakage.
- Keep out of the reach and sight of children.
- Do not use after the expiry date stated on the carton. The expiry date refers to the last day of that month.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. FURTHER INFORMATION

What TicoVac 0.5 ml contains

One dose (0.5 milliliters) of the vaccine contains as the active ingredient 2.4 micrograms of inactivated Tick-Borne Encephalitis Virus (strain Neudörfl), which is produced in chick embryo cells. Aluminum hydroxide 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.

The other ingredients in the vaccine are human albumin, sodium chloride, disodium phosphate-dihydrate, potassium dihydrogen phosphate and water for injections. Potassium and sodium are present at levels less than 1 mmol per dose, i.e. essentially “potassium- and sodium-free.”

Trace amount of formaldehyde, neomycin, gentamicin, protamine sulfate may be present.

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 with an attached needle. Pack sizes of 1, 10, 20 or 100 pre-filled syringes are available. Not all pack sizes may be marketed. After shaking, the suspension is off-white and milky.

Marketing Authorisation Holder:
Baxter AG
Industriestrasse 67
A-1221 Vienna
Austria

Manufacturer:
Baxter AG
Industriestrasse 67
A-1221 Vienna
Austria

This medicinal product is authorised in the Member States of the EEA under the following names:

- Belgium/Belgique/België
  - FSME-IMMUN 0.5 ml Baxter

- Czech Republic
  - FSME-IMMUN 0.5 ml Baxter

- Denmark
  - TicoVac 0.5 ml

- Estonia
  - TicoVac 0.5 ml

- France
  - TicoVac 0.5 ml

- Ireland
  - TicoVac 0.5 ml

- Italy
  - TicoVac 0.5 ml

- Latvia
  - TicoVac 0.5 ml

- Lithuania
  - TicoVac 0.5 ml

- Luxembourg/Luxemburg
  - FSME-IMMUN 0.5 ml

- Magyarország
  - FSME-IMMUN 0.5 ml (lehatőtérkék)

- Netherlands
  - FSME-IMMUN 0.5 ml Baxter

- Norway
  - TicoVac

- Österreich
  - FSME-IMMUN 0.5 ml

- Poland
  - FSME-IMMUN 0.5 ml

- Portugal
  - FSME-IMMUN 0.5 ml BAXTER

- Slovenia
  - FSME-IMMUN Inject

- Slovak Republic
  - FSME-IMMUN 0.5 ml Injekčná suspenzia

- Sweden
  - FSME-IMMUN Vaxen

- United Kingdom
  - TicoVac 0.5 ml

This leaflet was last approved in March 2006

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, opaque, homogenous 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.

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

Remove needle guard as follows:
1. Hold syringe at the lower part of the needle guard fixed onto the glass recipient (Fig. 1).
2. Use the other hand to take the upper part of the needle guard between thumb and forefinger and twist to break the seal (tamper evident) (Fig. 2).
3. Remove the detached part of the needle guard from the needle by a vertical movement (Fig. 3).

Following the removal of the needle guard TicoVac 0.5 ml must be used immediately.

To avoid loss of sterility and/or clogging of the needle, it should not be left without protection for prolonged periods of time. Therefore, the needle guard should only be removed after shaking and immediately prior to use.