PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

TicoVac™ 0.5 ml, suspension for injection

Each dose (0.5 ml) contains:
2.4 micrograms of inactivated *Tick-Borne Encephalitis Virus*

A list of inactive and allergenic ingredients in the preparation is provided in section 6.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

TicoVac™ 0.5 ml is an active vaccine intended to prevent a disease caused by the *Tick-Borne Encephalitis Virus*. The vaccine is intended for adolescents from the age of 16 and adults.
The vaccine causes the body to generate antibodies against the virus. It does not protect against other viruses and bacteria (some of which are also transmitted by tick bites) that may cause similar symptoms.

Therapeutic group: Encephalitis vaccine

2. BEFORE USING THE MEDICINE

X Do not use the medicine if:

X You or your child are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine (listed in section 6). For example, you or your child had a rash, swelling of the face or throat, difficulty in breathing, blue discoloring of the tongue or lips, low blood pressure and have collapsed. Pay attention to cross-sensitivity with aminoglycosides aside from neomycin and gentamycin.
X You or your child had a severe allergic reaction after eating eggs or chicken.
X You or your child have a moderate to severe acute illness (with or without fever). Delay the vaccination.

Special warnings regarding use of the medicine

Before treatment with TicoVac™, tell the doctor if:

- You or your child have bleeding problems or bruise easily
- You or your child have an autoimmune disease (such as rheumatoid arthritis or multiple sclerosis)
- You or your child have a weak immune system (i.e., you or your child do not cope well with infections)
- You or your child do not produce antibodies well
- You or your child are taking medicines for cancer
- You or your child are taking medicines called steroids (reduce inflammation)
- You or your child have any brain illness
- You or your child have a neurological disorder or seizure disorders

If any of the above-mentioned conditions applies to you or your child, the vaccine may not be suitable for you. Alternatively, the doctor may decide to give you or your child the vaccine. The doctor may request to do a blood test to check whether the vaccine has worked.

Children and adolescents

Do not give this vaccine to children under 16 years of age. This age group should be given the TicoVac™ Junior vaccine, which is intended for children.

Drug interactions

If you or your child are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.
If you or your child have recently received another vaccine, your doctor will decide where and when to give the TicoVac™ vaccine.
If you or your child are under an immunosuppressive treatment, TicoVac™ may not provide complete protection.
Tell the doctor if you or your child have been infected with, or been vaccinated against, Yellow fever, Japanese encephalitis or Dengue fever. This is because you or your child may have antibodies in the body that can react with the *Tick-Borne Encephalitis Virus* used in tests to measure the antibody levels in your body. These tests could then give wrong results.

Pregnancy and breast-feeding

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

Driving and using machinery

The vaccine is not expected to affect ability to drive or operate machinery. However, you or your child might have vision problems or may feel dizzy.

Important information about some of the ingredients of the medicine

The preparation contains potassium and sodium at levels of less than 1 mmol per dose; namely, it is considered potassium- and sodium-free.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions.
Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen of the preparation.
The dosage and treatment regimen will be determined by the doctor only.
This vaccine is generally given as an intramuscular injection in the upper arm. The vaccine must not be injected into blood vessels. In exceptional cases only (if you or your child have bleeding problems or are receiving anticoagulants for blood thinning), the vaccine can be given as a subcutaneous injection.

Do not exceed the recommended dose.

If you accidentally took a higher dosage

Since the injection is given via a pre-filled syringe that contains a single dose, it is highly unlikely to receive an overdose.
Persist with the treatment as recommended by the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of TicoVac™ may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.
As with all vaccines, a severe allergic reaction can happen. This reaction is very rare, but immediate medical treatment and supervision are required.
Symptoms of a serious allergic reaction include:

- Swelling of the lips, mouth, throat (which may make it difficult to swallow or breathe)
- A rash and swelling of the hands, legs and ankles
- Loss of consciousness due to a drop in blood pressure.

These signs and symptoms usually happen very quickly after the injection, while the person is still in the clinic. If any of these symptoms happen after you have left the place where your injection was given, refer to a doctor immediately.

Additional side effects:

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

- Pain at the injection site

Common side effects (may affect up to 1 in 10 people):

- Headaches
- Nausea
- Muscle and joint pains
- Feeling tired or unwell

Uncommon side effects (may affect up to 1 in 100 people):

- Swelling of lymph glands
- Vomiting
- Fever
- Bruising at the injection site

Rare side effects (may affect up to 1 in 1,000 people):

- Allergic reaction
- Sleepiness
- Motion sickness
- Diarrhea
- Abdominal pain
- Redness, tissue hardening, swelling, itching, tingling and warmth at the injection site

Additional side effects with a rare frequency that were reported from postmarketing surveillance of the preparation:

- Shingles
- Triggering of autoimmune diseases such as multiple sclerosis
- Allergic reactions
- Neurological disorders such as encephalomyelitis, inflammation of the spinal cord
- An illness involving muscle weakness, abnormal sensation, tingling in the arms, legs, and upper body (Guillain-Barré syndrome)
- Inflammation of the brain, fits, inflammation of the meninges
- Signs of meningeal irritation, like pain and stiffness of the 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, being more sensitive to light, pain in the eye
- Ringing in the ears
- Rapid beating of the heart
- Shortness of breath
- Skin reactions, (irritated and/or itchy skin), dermatitis, redness of the skin, increased sweating, inflammation of the skin
- Back pain, joint swelling, neck pain, musculoskeletal and neck stiffness, pain in hands and legs
- Chills, influenza-like illness, weakness, edema, unsteady walking, accumulation of fluid beneath the skin
- Joint pain at the injection site, nodules 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, subcutaneous administration caused more local reactions at the injection site (e.g., redness, swelling, itching and pain), especially in women.

If a side effect has appeared, if one of the side effects gets worse, or when you suffer from a side effect that has not been mentioned in this leaflet, you should consult the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il/

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning.
Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
Store in a refrigerator (2°C-8°C). Do not freeze. Keep the syringe in the outer package in order to protect from light.
Do not use the vaccine if you notice foreign particles or leakage.

6. FURTHER INFORMATION

- **In addition to the active ingredient, the medicine also contains:**
  Sodium chloride, Human serum albumin, Aluminium hydroxide (hydrated), Disodium phosphate-dihydrate, Potassium dihydrogenphosphate, Sucrose, Formaldehyde, Protamine sulfate, Neomycin and gentamicin, Water for injection
- **What does the medicine look like and what is the content of the package:**
  TicoVac™ is marketed as a suspension (0.5 ml) for injection in a pre-filled syringe. The package contains 1, 10, 20 or 100 pre-filled syringes. Not all package sizes may be marketed. The package may contain a needle. The needles are sterile and are intended for single use.
  Each pre-filled syringe is packaged in a blister pack. The opening in the blister pack is intended and allows for the equilibration of moisture during the vaccine incubation time until it reaches room temperature. Open the blister by removing the lid to take out the syringe. Do not press the syringe through the blister pack.
  After shaking, the suspension is off-white and milky.

License holder and address: Pfizer Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach 46725.

Manufacturer name and address:
Pfizer Manufacturing Belgium NV, Puurs, Belgium

This leaflet was checked and approved by the Ministry of Health in: August 2019

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
162-33-35413

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.