

PACKAGE LEAFLET

Package leaflet: Information for the user
FSME-IMMUN 0.25 ml Junior 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 FSME-IMMUN 0.25 ml Junior is and what it is used for
2. What you need to know before you or your child receives FSME-IMMUN 0.25 ml Junior
3. How FSME-IMMUN 0.25 ml Junior is given
4. Possible side effects
5. How to store FSME-IMMUN 0.25 ml Junior
6. Contents of the pack and other information

1. What FSME-IMMUN 0.25 ml Junior is and what it is used for

FSME-IMMUN 0.25 ml Junior is a vaccine, which is used to prevent disease caused by *Tick-Borne Encephalitis (TBE) Virus*. It is suitable for children above 1 to 15 years of age.

- 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 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 FSME-IMMUN 0.25 ml Junior

Do not use FSME-IMMUN 0.25 ml Junior:

- 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 FSME-IMMUN 0.25 ml Junior. 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 FSME-IMMUN 0.25 ml Junior

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 FSME-IMMUN 0.25 ml Junior 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 FSME-IMMUN 0.25 ml Junior vaccine.

FSME-IMMUN 0.25 ml Junior 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 FSME-IMMUN 0.25 ml Junior 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 (play in the street or cycle). However, you may have problems with your sight or feel dizzy.

FSME-IMMUN 0.25 ml Junior 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 FSME-IMMUN 0.25 ml Junior

This vaccine is usually injected into the muscle of the upper arm. In children under 18 months the vaccine can be injected into the thigh. It 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 aged 16 years and above. For this age group the TBE vaccine for adults 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 FSME-IMMUN 0.25 ml Junior:

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 Immunization	Dose	Conventional Schedule	Rapid Immunization Schedule
1 st dose	0.25 ml	Elected date	Elected date
2 nd dose	0.25 ml	1 to 3 months after the 1 st vaccination	14 days after the 1 st vaccination
3 rd dose	0.25 ml	5 to 12 months after the 2 nd vaccination	5 to 12 months after the 2 nd vaccination

Booster vaccinations

The first booster dose should be given no more than 3 years after the third dose. Further booster doses should be given every 5 years.

Booster dose	Dose	Timing
1 st booster	0.25 ml	3 years after the third dose
Sequential booster doses	0.25 ml	every 5 years

If you leave too much time between vaccine doses, you may not be protected against TBE, however, a single catch-up dose with FSME-IMMUN 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.

No data are available regarding a catch-up dose in children less than 6 years of age.

Children 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 FSME-IMMUN 0.25 ml Junior 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.

High temperature (fever) may happen in children. Among young children (aged 1 to 2 years) one in three has some fever after the first injection. Among children aged 3 to 15 years, less than one in 10 have fever. Usually, the fever lasts only 1-2 days. Fever happens less often after the second, third or booster injections. If necessary, your doctor can recommend a treatment to prevent or treat fever.

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
- Swelling, hardness and redness where the injection was given
- Feeling sick or vomiting, decreased appetite
- Feeling tired or unwell
- Restlessness and poor sleep (in younger children)
- Muscle pains
- Fever (see above)

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

- Swelling of lymph glands
- Stomach pain
- Joint pain
- Chills

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

- Itching at the injection site
- Abnormal and reduced sensation such as tingling or numbness along several nerves
- Feeling dizzy
- Vertigo
- Diarrhoea

- Dyspepsia
- Hives

The following additional side effects, from post marketing surveillance with a rare frequency, have also been reported:

- Allergic reactions
- Inflammation of the brain, signs of meningeal irritation like stiffness of the neck
- Neurological symptoms such as facial palsy, paralysis, inflammation of nerves
- An illness consisting of muscle weakness, abnormal sensations, tingling in the arms, legs, and upper body (Guillain-Barré syndrome)
- Visual disorders/impairment being more sensitive to light, pain in the eye
- Ringing in the ears
- Shortness of breath
- Skin reactions, (rashy and/or itchy skin), redness of the skin, increased sweating
- Musculoskeletal and neck stiffness, pain in arm and legs
- Influenza-like illness, weakness, swelling of the skin, unsteady walking
- Fits with or without fever

In a small comparative study on the immune response after intramuscular and subcutaneous administration of FSME-IMMUN 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this vaccine.

5. How to store FSME-IMMUN 0.25 ml Junior

- 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 FSME-IMMUN 0.25 ml Junior contains

The active substance is: *Tick-Borne Encephalitis Virus* (strain Neudörfl)

One dose (0.25 milliliters) of the vaccine contains 1.2 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 FSME-IMMUN 0.25 ml Junior looks like and contents of the pack

FSME-IMMUN 0.25 ml Junior is supplied as a 0.25 milliliter (one dose) suspension for injection in a pre-filled syringe without an attached needle. The pack may include 0 needles or 1 needle. Needles are

sterile and for single use only. 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.

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.

Marketing Authorisation Holder

[To be completed nationally]

{Name and address }

{Tel }

{Fax }

{E-mail }

Manufacturer

Pfizer Manufacturing Belgium, NV
Rijksweg 12,
2870,
Puurs,
Belgium

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

België/Belgique/Belgien, Luxembourg/Luxemburg, Nederland, Portugal	FSME-IMMUN 0,25 ml Junior
България, Deutschland, Polska	FSME-IMMUN 0.25 ml Junior
Česká republika	FSME-IMMUN 0.25 ml
Danmark, Suomi/Finland, Norge, Ísland	TicoVac Junior
Eesti	TicoVac 0.25 ml
Ελλάδα	TicoVac 0.25 ml Junior
Magyarország	FSME-IMMUN Junior vakcina fecskendőben
Österreich	FSME-IMMUN 0.25 ml Junior Injektionssuspension in einer Fertigspritze
France	TicoVac Enfant 0.25 ml
Ireland, United Kingdom	TicoVac Junior 0.25 ml
Sverige	FSME-IMMUN Junior
Italia	TicoVac 0.25 ml per uso pediatrico
Latvija, Lietuva	TicoVac 0,25 ml

România	FSME-IMMUN 0.25 ml Junior suspensie injectabila in seringa preumpluta
Slovenija	FSME-IMMUN 0,25 ml za otroke
Slovenská republika	FSME-IMMUN 0,25 ml Junior Injekcna suspenzia

This leaflet was last revised in {MM/YYYY}

[To be completed nationally]

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, FSME-IMMUN 0.25 ml Junior 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.