PRODUCT MONOGRAPH

FSME-IMMUN

Tick-Borne Encephalitis Virus Vaccine, Inactivated, with Adjuvant

2.4 µg (target value)/0.5 mL

Sterile Suspension for Intramuscular Injection

Vaccine for the Prevention of Tick-Borne Encephalitis

Manufactured by:
BAXTER AG
A-1220 Vienna, Austria

Imported and Distributed by:     Date of Revisions:
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CANADA

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1 FSME-IMMUN is a trademark of Baxter AG, Vienna, Austria.
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Pages 25-28 are included in this version of the monograph. If you would like to view the entire monograph, [please click here](#).
PART III: CONSUMER INFORMATION  
FSME-IMMUN  
Tick-Borne Encephalitis Virus Vaccine, Inactivate, with Adjuvant

This leaflet is part III of a three-part "Product Monograph" published when FSME-IMMUN was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about FSME-IMMUN. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS VACCINE

What the vaccine is used for:

FSME-IMMUN 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 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 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, FSME-IMMUN 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 (please refer to the vaccination schedule for more information).

What it does:

FSME-IMMUN provides protection against tick-borne encephalitis and should be given before the start of the tick activity season. The season begins in the spring and so your course of vaccination should preferably start in the winter months.

The vaccine works by causing the body to make its own antibodies, which protect against this disease.

Please note: A tick bite may also cause infection with Borrelia bacteria. The symptoms of such infections may resemble those of tick-borne encephalitis. TBE vaccines like FSME-IMMUN do not provide protection against Borrelia infections.

As with all vaccines, FSME-IMMUN may not completely protect all patients receiving the vaccine against the infection that it is intended to prevent.

When it should not be used:

Do not use FSME-IMMUN 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 discoloring of the tongue or lips, low blood pressure and collapse.
- you ever had an allergic reaction to neomycin or gentamicin or to formaldehyde or protamine sulphate (used during the manufacturing process).
- you ever had cross-allergies with aminoglycosides
- 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 FSME-IMMUN. Your doctor could ask you to wait for the injection until you feel better.

What the medicinal ingredient is:

Tick-borne Encephalitis Virus Vaccine, Inactivated, with Adjuvant

What the important nonmedicinal ingredients are:

2% Aluminum hydroxide suspension, disodium hydrogen phosphate dehydrate, 0.1% human albumin, potassium dihydrogen phosphate, sodium chloride, water for injection.

Residues of formaldehyde, gentamicin, sucrose, neomycin, and protamine sulphate may be present.

For a full listing of nonmedicinal ingredients see Part 1 of the product monograph.

What dosage forms it comes in:

Each dose contains 2.4 micrograms (target value) inactivated tick-borne encephalitis virus.

The vaccine is provided in a one-dose (0.5 mL) prefilled glass syringe for use in individuals aged 16 years and above.
WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Talk to your doctor before having the vaccine if you
• are allergic (hypersensitive) to the active substance, any of the other ingredients or neomycin, gentamycin, formaldehyde or protamine sulphate (used during the manufacturing process)
• ever had a severe allergic reaction after eating egg or chicken
• are known to be allergic to latex rubber
• have an autoimmune disease (such as rheumatoid arthritis or multiple sclerosis)
• have a weak immune system (so that you 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 (such as demyelinating disorders or poorly controlled epilepsy)

Vaccination should be postponed in patients with acute clinical conditions (with or without fever) that could be aggravated by adverse reactions to the vaccine or could impair the interpretation of possible adverse reactions to the vaccine.

INTERACTIONS WITH THIS VACCINE

Drugs that may interact with FSME-IMMUN include:
No interaction studies with other vaccines or medicinal products have been performed. The administration of other vaccines at the same time as FSME-IMMUN 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.

A protective immune response may not be elicited in persons undergoing immunosuppressive therapy or persons with an impaired immune system (for vaccination schedule please see section “proper use of this vaccines”). There are no specific clinical data on which to base dose recommendations in such patients.

PROPER USE OF THIS VACCINE

Usual dose:
Recommended dosage for FSME-IMMUN (tick-borne encephalitis virus vaccine, inactivated, with adjuvant) is summarized in the following table:

VACCINATION SCHEDULE

<table>
<thead>
<tr>
<th>Basic Immunization</th>
<th>Dose</th>
<th>Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st dose</td>
<td>0.5 mL i.m.</td>
<td>-</td>
</tr>
<tr>
<td>2nd dose</td>
<td>0.5 mL i.m.</td>
<td>1 to 3 months after the 1st vaccination</td>
</tr>
<tr>
<td>3rd dose</td>
<td>0.5 mL i.m.</td>
<td>5 to 12 months after the 2nd vaccination</td>
</tr>
</tbody>
</table>

Rapid Immunization Schedule

<table>
<thead>
<tr>
<th>Dose</th>
<th>Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.5 mL i.m.</td>
<td>2 weeks after the 1st vaccination</td>
</tr>
</tbody>
</table>

The doctor or nurse will inject the recommended dose of the vaccine.

FSME-IMMUN will be injected into the deltoid muscle of your upper arm. Intravascular administration may lead to severe hypersensitivity reactions. A complete vaccination course involves 3 doses of the vaccine. The second dose will be given between 1 to 3 months after the first dose and the third dose will be given 5 to 12 months after the second dose. A booster vaccination is then necessary every 3 to 5 years.

In order to quickly achieve protection, as may for instance be necessary when the first dose is given in the summer months, the second dose may be given 14 days after the first injection.

It is important to follow the instruction from the doctor/nurse regarding return visits for the follow-up doses.

Overdose:

An overdose is highly unlikely to happen because the injection is given from a single-dose syringe by a doctor.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

If you have any further questions on the use of this vaccine, ask your doctor or pharmacist.

Missed Dose:

If you leave too much time between the 3 doses, you may not have full protection against infection.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

As with all medicines, FSME-IMMUN may cause side effects in some persons. If any side effects worry you, or you have any unusual symptoms, 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. 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 in clinical safety studies

**Very common side effects**
Pain, where the injection was given

**Common side effects**
Headache, nausea, feeling tired or unwell, muscle and joint pains

**Uncommon side effects**
Swelling of lymph glands, vomiting, fever, injection site hemorrhage

**Rare side effects**
Allergic reactions, sleepiness or drowsiness, diarrhea, abdominal pain, dizziness characterized by a sensation of whirling motion, injection site induration, injection site swelling, injection site paresthesia, injection site warmth, injection site erythema, injection site itching

The following additional side effects have been reported under the spontaneous reporting system

- Rapid beating of the heart
- Blurred vision or being more sensitive to light, pain in the eye
- Chills, weakness, influenza-like illness, unsteady walking, local swelling
- Severe allergic (anaphylactic) reaction, and aggravation of autoimmune disease (e.g., Multiple sclerosis)
- Neck pain, muscle stiffness, pain in arms and/or legs
- Ringing in the ears (tinnitus)
- Shortness of breath
- Signs of meningeal irritation like stiffness of neck, feeling dizzy, inflamed nerves of various degrees (e.g., abnormal or reduced sensation, facial nerve paralysis, paresis), convulsion, inflammation of the brain (encephalitis)
- Damage of the myelin sheath, the material that surrounds and protects your nerve cells (demyelination)
- Rashy and/or itchy skin, hives, redness of skin, inflammation of skin, sweating
- Herpes zoster (triggered in pre-exposed patients)

If you notice any other side effects not mentioned in this leaflet, please inform your doctor or pharmacist (chemist).

*This is not a complete list of side effects. For any unexpected effects while taking FSME-IMMUN, contact your doctor or pharmacist.*

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**REPORTING SUSPECTED SIDE EFFECTS**

To monitor vaccine safety, the Public Health Agency of Canada collects information on serious and unexpected adverse events following vaccination. If you suspect you have had a serious or unexpected event following receipt of a vaccine you may notify the Public Health Agency of Canada:

By toll-free telephone: 866-844-0018
By toll-free fax: 866-844-5931
Email: cacfi@phac-aspc.gc.ca

Mail:
The Public Health Agency of Canada
Vaccine Safety Section
130 Colonnade Road
Ottawa, Ontario K1A 0K9
A/L: 6502A

*NOTE: Should you require information related to the management of side effect, please contact your health care provider before notifying the Public Health Agency of Canada. The Public Health Agency of Canada does not provide medical advice.*

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**HOW TO STORE IT**

Store your vaccine in a refrigerator between +2°C to +8°C. The vaccine should not be frozen, not even for a short period of time.

Store the vaccine out of the reach of children.

The expiry date is indicated on the label and packaging. The vaccine should not be administered after this date.

Following use, the syringe is disposed of in accordance with the relevant national regulations.

**Specific information for the health care provider**

Shake well prior to administration to thoroughly mix the vaccine suspension.

Remove needle guard as follows:

1. Hold the 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 (fig. 2).
3. Remove the detached part of the needle guard from the needle by a vertical movement (fig. 3).
Following twisting-off and removal of the needle guard, FSME-IMMUN can be used immediately. To avoid loss of sterility and/or clogging of the needle, it should not be left without protection over prolonged periods of time. Therefore, the needle guard should only be removed immediately before use.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:
http://www.baxter.com
or by contacting the sponsor, Baxter Corporation, at: 1-800-387-8399

This leaflet was prepared by Baxter Corporation

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