Package leaflet: Information for the patient

Encepur (0.5 mL)
Suspension for injection in pre-filled syringe
Tick-borne encephalitis (TBE) vaccine (inactivated)

Read all of this leaflet carefully before you receive this vaccine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others.
- If you 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 Encepur is and what it is used for

Encepur contains inactivated virus of the type that causes tick-borne encephalitis (TBE).
The vaccine Encepur is intended for use in people from the age of 12 years to prevent disease caused by the TBE virus. TBE virus is a major cause of viral infections of the central nervous system. Most infections with this virus are caused by tick bites.

The vaccine is intended for people who are permanently or temporarily staying in areas where TBE occurs.

Vaccines belong to a group of medicines that affect the immune system (the body's natural defence against infections) to protect against diseases.
As with other vaccines, Encepur may not completely protect everyone who is vaccinated.

Encepur Children is used for children from 1 year up to and including 11 years old.

2. What you need to know before you are given Encepur

You should not be given Encepur
- if you have an acute illness that requires treatment. You should not be vaccinated until at least 2 weeks after recovery
- if you have experienced complications after previous vaccination with Encepur. In this case, you should not be vaccinated with the same vaccine until the cause of the complications has been investigated
- if you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before you receive Encepur

- Encepur may contain traces of egg and chicken protein, such as ovalbumin (a protein in egg white). If you have experienced symptoms of an anaphylactic reaction such as hives, swelling of the upper airways (lips, tongue, throat), narrowing of the airways (bronchospasm), a drop in blood pressure or rapid reduction in blood pressure that has caused an acute condition (shock) after exposure to egg or chicken protein, talk to your doctor or nurse before you receive the vaccine. In such cases, which are very rare, it is recommended that the injection be given under close supervision. In general, however, there is no increased risk associated with vaccination with Encepur if you have been diagnosed as "allergic to chicken protein" only via a questionnaire or positive skin prick test.
- Your doctor or nurse will be careful not to inject the vaccine into a blood vessel. Accidental injection into a blood vessel can, in extreme cases, provoke a shock reaction.
- As with all injected vaccines, appropriate medical treatment and monitoring must always be readily available in case of a rare anaphylactic reaction following vaccination.
- Your doctor or nurse will assess the need for vaccination if you have an existing, serious neurological illness.
- Fainting, feeling faint or other stress-related reactions can occur as a response to any needle injection. Tell your doctor or nurse if you have had this kind of reaction previously.
- TBE vaccination does not protect against other tick-borne diseases (such as Lyme disease) even if they are transferred at the same time as tick-borne encephalitis.
- The effect of Encepur may be limited or uncertain if you have a weakened immune system, for example due to HIV infection or medicines that inhibit your body's immune system.

<u>Latex-sensitive individuals:</u>

Pre-filled syringe without needle:
Although no natural rubber latex has been detected in the syringe tip cap, the safe use of Encepur in latex-sensitive individuals has not been established.

Pre-filled syringe with needle:
The needle shield contains latex. May cause serious allergic reactions. Tell your doctor before you receive Encepur if you are allergic to latex.

Other medicines and Encepur
Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines, including medicines obtained without prescription.

Separate injection sites must be used if more than one vaccine is being administered at the same time.

Pregnancy and breast-feeding
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.

No controlled clinical studies have been carried out in pregnant women. Therefore, Encepur should only be used after careful consideration of the risks and benefits for pregnant and breast-feeding women.

Driving and using machines
No studies on the ability to drive and use machines have been carried out with Encepur (see section 4, 'Possible side effects').

Some of the side effects described in section 4 may affect your ability to drive and use machines.

Encepur contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially "sodium free".
This vaccine contains trace amounts of formaldehyde, chlortetracycline, gentamycin and neomycin. Tell your doctor if you have had an allergic reaction to these ingredients.

3. How Encepur is given

Your doctor or pharmacist will explain how this vaccine will be given.

One dose of Encepur (0.5 mL) for adults and adolescents from 12 years of age.

Encepur is given as a total of 3 injections, preferably during the cold months of the year to provide protection during the risk period (spring/summer). The vaccine is given according to one of the following schedules:

Standard schedule (preferred vaccination schedule)	
Dose 1	Optional day
Dose 2	14 days to 3 months after the first dose.
Dose 3	9 to 12 months after the second dose.
Booster dose 1	3 years after the third dose.
Further booster doses	People aged 12–49 years: every 5 years People aged over 49 years: every 3 years

The second vaccination can be given 14 days at the earliest after the first vaccination.

Express vaccination schedule (when immediate protection is needed)	
Dose 1	Optional day
Dose 2	7 days after the first dose.
Dose 3	21 days after the second dose.
Booster dose 1	12 to 18 months after the third dose.
Further booster doses	People aged 12–49 years: every 5 years People aged over 49 years: every 3 years

You will be told when you need to return for your next dose.

If necessary, the vaccination schedule can be more flexible. Talk to your doctor or nurse for more information.

<u>Administration</u>

Encepur adults is administered intramuscularly, preferably in the muscle of the upper arm. If necessary, e.g. in case of haemorrhagic diathesis (increased bleeding tendency), the vaccine can be administered subcutaneously (beneath the skin).

Under no circumstances may the vaccine be administered in a blood vessel (intravascularly).

Ask your doctor, pharmacist or healthcare personnel if there is anything you are unsure about.

If you are given more Encepur than you should
The risks and types of side effects that may occur if you are given more than the recommended dose are not known.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common side effects (may affect more than 1 in 10 people)
- headache
- muscle pain
- temporary pain at the injection site
- general feeling of being unwell.

Common side effects (may affect up to 1 in 10 people)
- nausea
- joint pain
- redness of the skin at the injection site, swelling at the injection site
- fever (over 38°C)
- flu-like symptoms (sweating, fever, shivering) may develop, especially after the first vaccination, but usually subside within 72 hours.

Uncommon side effects (may affect up to 1 in 100 people)
- vomiting.

Serious allergic reactions
Serious allergic reactions for which the frequency cannot be calculated from available information are:
- generalised rash
- swelling (most notably of the head and neck, including face, lips, tongue or throat, or any other part of the body)
- stridor (a wheezing breathing sound caused by blocked/swollen airways)
- shortness of breath, difficulty breathing
- narrowing of the airways (bronchospasm)
- drop in blood pressure
- cardiovascular reactions (possibly accompanied by temporary, non-specific visual disturbances)
- low levels of platelets that are only short-lived but which can be severe.

These signs or symptoms usually happen very quickly after the injection is given, while you are still under the supervision of healthcare professionals. **If any of these symptoms occur after you have left your doctor or nurse, you must see a doctor IMMEDIATELY.**

Other side effects
Other side effects for which the frequency cannot be calculated from the available information have been reported following vaccination with Encepur. These are:

- swollen lymph nodes (glands in the throat, armpits or groin)
- numbness and tingling
- muscle pain and joint pain in the neck that may indicate meningism (irritation of the meninges (layers lining the brain) seen in, for example, meningitis). These symptoms are very rare and subside within a few days with no lasting consequences
- dizziness
- feeling faint
- fainting
- diarrhoea
- nodule due to inflammation at the injection site (granuloma), sometimes with accumulation of fluid
- tiredness
- weakness.

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 (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

Swedish Medicinal Products Agency
Box 26
S-751 03 Uppsala
www.lakemedelsverket.se

5. How to store Encepur

Keep this medicine out of the sight and reach of children.

Store in a refrigerator (2 °C - 8 °C). Protect from light.
Do not freeze. Vaccine that has been frozen must not be used.

The vaccine must be visually inspected for particles and discolouration prior to administration. Vaccine with an abnormal physical appearance must be discarded.

Use immediately after opening the container.

Do not use Encepur after the expiry date which is stated on the carton and container after ”Exp.” The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Encepur contains

- One dose (0.5 mL) contains 1.5 mg of the active substance inactivated TBE (tick-borne encephalitis) virus (strain K23) grown in primary chicken embryo cells, inactivated with formaldehyde and with aluminium hydroxide as an adjuvant. An adjuvant is a component of the vaccine different from the antigen (the active substance in vaccines) that strengthens the immune response (the body's natural protection against infections) to the antigen.
- The other ingredients (excipients) are trometamol, sucrose, sodium chloride and water for injections. The vaccine contains trace amounts of formaldehyde, chlortetracycline, gentamycin and neomycin, and may include traces of egg and chicken protein.

What Encepur looks like and contents of the pack

Encepur is an off-white, cloudy suspension for injection in a pre-filled syringe.

Encepur is available in the following pack sizes:

- Pack with 1 pre-filled syringe (with/without needle) each containing 0.5 mL suspension for injection
- Pack with 10 pre-filled syringes (with/without needles) each containing 0.5 mL suspension for injection
- Pack with 20 pre-filled syringes (with/without needles) each containing 0.5 mL suspension for injection (2 × 10 packs)

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Bavarian Nordic A/S
Philip Heymans Allé 3
DK-2900 Hellerup
Denmark

Manufacturer
Bavarian Nordic A/S
Hejreskovvej 10A
DK-3490 Kvistgård
Denmark

GSK Vaccines GmbH
Emil-von-Behring-Straße 76
D-35041 Marburg
Germany

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The following information is intended for healthcare professionals only:

Encepur is an off-white, turbid suspension for injection. The vaccine is supplied ready for use.

As with any injection of vaccines, the usual monitoring and appropriate medical treatment must be available in case of an anaphylactic reaction after administration of the vaccine.

Shake vaccine well before use.

Encepur should be administered intramuscularly, preferably in the upper arm *(deltoid muscle)* or gluteally.

The vaccine can be injected subcutaneously if necessary (for example in patients with haemorrhagic diathesis).

Must ***not*** be injected intravascularly.

The vaccine can be given at the same time as other vaccines, however another injection site must be used.

Do not mix with other fluids for injection in the same syringe.

Remaining vaccine must be disposed of.

Keep this medicine out of the sight and reach of children.
Store in a refridgerator (2°C - 8°C).
Do not freeze. Vaccine that has been frozen must not be used.

For immunisation schedule see section 3, ‘How Encepur is given’.