Package leaflet: Information for the patient

Encepur Children (0.25 mL)
Suspension for injection in pre-filled syringe
Tick-borne encephalitis (TBE) vaccine (inactivated)

Read all of this leaflet carefully before your child receives 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 your child only. Do not pass it on to others.
- If your child gets 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 Children is and what it is used for

Encepur Children is a vaccine that contains inactivated virus of the type that causes tick-borne encephalitis (TBE).
The vaccine Encepur Children is intended for use in children from the age of 1 year up to and including 11 years old 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 children who are permanently or temporarily staying in areas where TBE occurs.

Encepur is used for adults and adolescents over 12 years of age.

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 Children may not completely protect everyone who is vaccinated.

2. What you need to know before your child is given Encepur Children

Your child should not be given Encepur Children
- if your child has an acute illness that requires treatment. Your child should not be vaccinated until at least 2 weeks after recovery

- if your child has experienced complications after previous vaccination with Encepur Children. In this case, your child should not be vaccinated with the same vaccine until the cause of the complications has been investigated
- if your child is 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 your child receives Encepur Children.
- In general, there is no increased risk associated with vaccination with Encepur Children if your child has 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 your child has 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 your child has 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.
- Children under 3 years of age may develop high fever (≥39.5ºC).
- Fever (over 38ºC) occurs primarily after the first vaccination. This phenomenon is not as common after the second vaccination. In such cases, fever-reducing treatment should be considered (see section 4 'Possible side effects').
- The effect of Encepur Children may be limited if your child has a weakened immune system, for example due to HIV infection or medicines that inhibit the body's immune system.

<u>If your child is sensitive to latex</u>:

Pre-filled syringe without needle:
Although no natural rubber latex has been detected in the syringe tip cap, the safe use of Encepur Children 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 your child receives Encepur Children if your child is allergic to latex.

Other medicines and Encepur Children
Tell your doctor, pharmacist or nurse if your child is taking, has 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
Not applicable.

Encepur Children contains
less than 1 mmol sodium (23 mg per dose), that is to say essentially "sodium free".

This vaccine contains trace amounts of formaldehyde, neomycin, gentamycin and chlortetracycline. Tell your doctor if your child has had an allergic reaction to these ingredients.

3. How Encepur Children is given

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

Vaccination schedule

Children from the age of 1 year up to and including 11 years old should receive 1 dose (0.25 mL) in each injection.
Encepur Children is given as a total of 3 injections, preferably starting 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	Every 5 years.

The second vaccination can be brought forward and given 14 days at the earliest after the first vaccination (express vaccination schedule)

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	Every 5 years.

You will be told when your child needs to return for the next dose.

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

Administration

Encepur Children is administered intramuscularly, preferably in the muscle of the upper arm or in the thigh, depending on muscle mass. 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 your child is given more Encepur Children than they should

The risks and types of side effects that may occur if your child is 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 (in children aged 3 years and above)
- drowsiness (in children aged under 3 years)
- temporary pain at the injection site
- fever (over 38ºC) in children aged 1 to 2 years.

Common side effects (may affect up to 1 in 10 people)
- nausea
- joint pain
- muscle pain
- redness of the skin at the injection site, swelling at the injection site
- fever (over 38ºC) in children aged 3 to 11 years
- flu-like symptoms (sweating, fever, shivering), including fever may develop, especially after the first vaccination, but usually subside within 72 hours
- general feeling of being unwell
- weakness.

Rare side effects (may affect up to 1 in 1,000 people)
- diarrhoea
- vomiting.

Serious allergic reactions
Serious allergic reactions for which the frequency cannot be calculated from available information are:
- 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
- blood circulation system reactions (possibly accompanied by temporary, non-specific visual disturbances)
- low level of platelets that is only short-lived but which can be severe.

These signs or symptoms usually happen very quickly after the injection is given, while your child is still under the supervision of healthcare professionals. **If any of these symptoms occur after your child has left the doctor or nurse, your child 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 Children. These are:

- swollen lymph nodes (glands in the throat, armpits or groin)
- numbness and tingling
- joint pain and muscle 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
- fainting
- nodule due to inflammation at the injection site (granuloma), sometimes with accumulation of fluid
- seizures.

Reporting of side effects
If your child gets 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 Children

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 Children 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 Children contains

- One dose (0.25 mL) contains 0.75 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 Children looks like and contents of the pack

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

Encepur Children is provided in single-dose syringes (with or without a needle). Each syringe contains 0.25 mL. Pack sizes: 1 × 0.25 mL, 10 × 0.25 mL

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 Children 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 Children must be administered intramuscularly, preferably in the upper arm (*deltoid muscle*) or anterolaterally in the thigh (depending on muscle mass).

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 refrigerator (2°C – 8°C).
Do not freeze. Vaccine that has been frozen must not be used.

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