

NeisVac-C Vaccine

[meningococcal group C polysaccharide conjugate vaccine
(tetanus toxoid protein conjugate)]

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about the **NeisVac-C vaccine** [meningococcal group C polysaccharide chemically bonded to tetanus toxoid protein (**NeisVac-C vaccine**)]. It does not contain all of the available information. All medicines have risks and benefits. Your doctor has weighed the risks of using **NeisVac-C vaccine** against the benefit that it will have for you or your child.

It does not take the place of talking to your doctor or pharmacist. If you have any concerns about having this medicine, ask your doctor or pharmacist. Please read this leaflet carefully before receiving **NeisVac-C vaccine** as it contains information about your vaccine. It may be useful to keep this leaflet in case you need to read it again after vaccination.

What NeisVac-C vaccine is used for?

NeisVac-C vaccine is one of a general group of medicines called vaccines, which are used to protect against infectious diseases. **NeisVac-C vaccine** is used to prevent disease caused by bacteria called *Neisseria meningitidis* group C. The vaccine works by causing the body to produce its own protection (antibodies) against the group C bacteria.

The *Neisseria meningitidis* family (A, B, C, Y and W₁₃₅) can cause serious and sometimes life-threatening infections such as meningitis and septicaemia (blood poisoning). **NeisVac-C vaccine** will only protect against disease caused by the meningococci group C bacteria. It will not protect against other groups of meningococci or other organisms that cause meningitis and blood poisoning.

How does NeisVac-C vaccine work?

NeisVac-C vaccine is one of a new generation of vaccines against *Neisseria meningitidis* group C bacteria. The antigen used in this vaccine is isolated from a fermentation of these bacteria. It is a polymer of sialic acid (polysaccharide group C), hooked chemically with a non-toxic tetanus toxoid protein (GCMP-TT). This type of vaccine is called conjugate vaccine. Through the action of the tetanus toxoid component in the **NeisVac-C vaccine**, the body's immune system becomes T-cells dependent in eliciting the antibody response against the polysaccharide antigen. As a result, a stronger and longer lasting antibody protection than the non-conjugate vaccine is produced, in particular with children younger than two years as it has a booster effect by repeating injection of group C vaccine.

Before you or your child are given the NeisVac-C vaccine

The NeisVac-C vaccine should not be given to you or your child or baby if:

- you have tendency of allergic reaction or hypersensitivity to any component of the vaccine or had an allergic reaction to any other vaccine products previously received. Some of the symptoms of an allergic reaction may include skin rash,

peeling of the skin, swelling of the face, lips or tongue which may cause difficulty swallowing or shortness of breath.

- have an infectious illness (e.g, high temperature, sore throat, cough, cold or flu).
- the expiry date printed on the pack is overdue.

You must tell your doctor if you, or your child:

- have any other illness, in particular if you have blood clotting disorder, haemophilia
- are taking any prescription medicine or even non-prescription medicines
- has a medical condition, which affects the immune system, such as steroids, cyclosporin or medicines to treat cancer (including radiation). If you or your child has a weak immune system then the immune response may be lower than in other individuals with healthy immune response.
- are pregnant, planning to become pregnant or breast-feeding. Vaccination with NeisVac-C vaccine is not recommended if you are pregnant. If there is a need to consider vaccination during pregnancy, your doctor will discuss the risks and benefits with you.

How NeisVac-C vaccine is given

How much is given:

Your doctor will decide how much NeisVac-C vaccine will be given to you or your baby or child. NeisVac-C vaccine is a 0.5 mL dose. For infants from 8 weeks to less than 12 months of age who have not previously been immunised with NeisVac-C vaccine, two doses (0.5 mL/dose) of vaccine, given at least 2 months apart are recommended.

Children under 12 months of age when first given NeisVac-C need a course of 3 injections in total. The third (booster) dose should be given after your child turns 12 months.

Children over 12 months of age when first given NeisVac-C, teenagers and adults may require an additional (booster) dose.

For children 12 months and older and adults and adolescents who have not previously been immunised with NeisVac-C vaccine of a single dose (0.5 mL) of the vaccine is recommended.

Case of concomitant vaccination with other vaccines

NeisVac-C may be safely given with other routine childhood vaccinations (including oral Polio, Measles, Mumps, and Rubella (MMR), Diphtheria and Tetanus Toxoid combined with pertussis (whooping cough) and *Haemophilus influenza* (Hib) – conjugate vaccines according to normal schedule but as a separate injection at a different site of injection.

NeisVac-C and a single combined vaccine against 6 infections (including injectable polio) have been given as 2 separate injections at the same visit. This was well tolerated. Immunity against meningococcus, whooping cough and polio was strong; immunity against hepatitis B was slightly less than expected. There is no information on the use of NeisVac-C with the conjugate pneumococcal vaccine used in very young children. Discuss this with your doctor if you are concerned.

NeisVac-C vaccine contains tetanus toxoid protein used as a carrier for the group C meningococcal polysaccharide (GCMP) antigen, but this is not sufficient to protect against tetanus infection (lockjaw). Therefore, it is important that routine vaccination against tetanus is also given at the ages advised by your doctor.

How it is given:

Your family physician knows how to administer this vaccine. But the information how it should be given you should also know. NeisVac-C vaccine is 0.5 mL dose which is usually injected into the muscle of the arm (in children from the age of 12 months) or leg (in infants). The vaccine must not be injected into vein, and your doctor or trained nurse will take care to avoid doing so when administering the vaccine.

Case of overdose

There is no experience with overdose of NeisVac-C vaccine. Overdosing with the vaccine is highly unlikely, because it is administered as a single-dose syringe by a health professional (doctor or trained nurse).

While you or your child are having NeisVac-C vaccine

As with all injectable vaccines, NeisVac-C vaccine may cause unwanted reactions in some individuals. A doctor is commonly concerned after an injection of a vaccine. This may occur immediately after the injection, but usually with rapid recovery after a proper treatment.

Side effects with NeisVac-C vaccine

General:

Despite the manufacturer of the vaccine in general includes exposure to bovine materials, no evidence exists that any case of the human form of bovine spongiform encephalitis has resulted from the administration of any vaccine product. As with any medicine, some side effects may occur. Some patients may have sudden signs of allergy such as rash after repeated use of vaccine product. Your doctor is aware of this potential adverse effect. If any of the following happen, swelling of the face, lips, mouth or difficulty in breathing, tell your health professional on duty immediately. They are symptoms of a serious allergic reaction, known as "anaphylactic shock" in medical terminology. Then, your healthcare professional will take an appropriate action promptly to reverse the symptoms.

If any side effects worry you, or you have unusual symptoms as described above, please contact your doctor, nurse or pharmacist without delay. Unwanted effects occurring in more than 1 in 100 people are considered to be common, and unwanted effects occurring in fewer than 1 in 10,000 people are considered to be rare. The most common adverse reactions with NeisVac-C vaccine are summarised Table 1.

Common side effects in infants and toddlers: are fever, crying, irritability, drowsiness and sleepiness, impaired sleeping, loss of appetite, vomiting and diarrhoea. These can also be caused by other vaccines given at the same time as NeisVac-C vaccine.

Common side effects in older children and teenagers: are fever, rash, headache, muscle pain and tiredness or sleepiness.

Table 1: The most common adverse reactions

Frequency of Adverse Reactions	Adverse Reactions
Very common (>1:10)	Injection site reactions: redness, tenderness/pain, swelling Pain in limb in older children Headache Crying and irritability in infants and toddlers Drowsiness/somnolence/impaired sleeping in infants and toddlers Vomiting/nausea/diarrhoea in infants Loss of appetite in infants
Common (>1 : 100 and <1 : 10)	Fever Loss of appetite in children Vomiting/nausea/diarrhoea in children Muscle pain in older children and adults Pain in limb in children

The most common Side effects in all age groups: redness, swelling and tenderness/pain at the site of injection. Fevers may also occur following vaccination, but these are rarely severe.

Renal and Urinary disorder: Relapse of nephrotic syndrome has been reported in association with meningococcal group C conjugate vaccines

Very rarely seizures (fits) have been reported following vaccination with meningococcal group C conjugate vaccines. These have not been shown to be caused by the vaccines themselves. The majority of patients have rapidly recovered. Other very rare side effects include nausea, dizziness, swollen lymph glands, faints, abnormal or reduced sensation, itching, hives, rash, joint pain, and loss of muscle tone, or floppiness in arms or legs, in infants.

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

Product descriptions

What NeisVac-C vaccine looks like?

NeisVac-C vaccine is presented as a semi-opaque white to off-white suspension in a single dose glass syringe with grey, isoprene bromobutyl tip cap and grey, bromobutyl rubber plunger stopper. The stopper and tip cap are latex free.

What is in NeisVac-C vaccine?

The vaccine is supplied in a 1.0 mL pre-filled syringe (without an integrated needle), containing one deliverable of 0.5 mL dose. Each 0.5 mL dose of NeisVac-C contains 10 micrograms of meningococcal group C polysaccharide conjugated with 10 to 20 micrograms of tetanus toxoid protein, adsorbed to 0.5 mg of aluminium adjuvant (as aluminium hydroxide). It does not contain a preservative.

How to store NeisVac-C vaccine

NeisVac-C vaccine should be stored in a refrigerator at 2°C to 8°C. Do not freeze.

Where can you get more information?

You can get more information from your doctor or pharmacist.

Name and address of the sponsor

NeisVac-C vaccine is manufactured by :
BioScience Division
Baxter Healthcare Corporation
Beltsville, Maryland, USA.

and distributed in Australia by:
Baxter Healthcare Pty Ltd
ABN 43 000 392 781
1 Baxter Drive
Toongabbie NSW 2146, Sydney

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