

NeisVac-C®

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 NeisVac-C.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you or your child being given NeisVac-C against the benefits it is expected to provide.

If you have any concerns about taking this vaccination, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What NeisVac-C is used for

NeisVac-C is a vaccine, a type of medicine used to protect against infectious diseases. NeisVac-C is used to prevent invasive disease caused by bacteria called *Neisseria meningitidis* group C.

The *Neisseria meningitidis* bacteria can cause serious and sometimes life-threatening infections such as meningitis and septicaemia (blood poisoning). NeisVac-C will only protect against invasive 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.

When a person is given NeisVac-C, the immune system (the body's natural defence system) will

produce its own protection (antibodies) against disease.

Your body usually takes several weeks after vaccination to develop protection against invasive meningococcal disease. Most people will produce enough antibodies to protect them against invasive meningococcal disease. However, as with all vaccines, 100% protection cannot be guaranteed.

NeisVac-C will not give you or your child meningococcal disease.

The chance of a severe reaction from NeisVac-C is very small, but the risks from not being vaccinated against invasive meningococcal disease may be very serious.

NeisVac-C is given to children from 8 weeks of age, adolescents and adults.

Before you are given NeisVac-C

When you or your child should not be given NeisVac-C

You or your child should not be given NeisVac-C if you have an allergy to any of the ingredients listed at the bottom of this leaflet, including Tetanus Toxoid (TT) or if you or your child have shown an allergic reaction to NeisVac-C when given it previously.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing

- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Vaccination should be delayed if you or your child has a moderate or severe fever or an infectious disease. If you are not sure whether you or your child should be given NeisVac-C, talk to your doctor or nurse. A minor illness, such as a cold, is not usually a reason to delay vaccination.

Vaccination should not be given to an infant under 8 weeks of age.

Do not use NeisVac-C if it has passed the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist.

Before you are given NeisVac-C

You must tell your doctor or nurse:

- if you or your child have allergies to any other medicines
- if you or your child are unwell or have a high fever.

Tell your doctor or nurse if you or your child have or have had any of the following:

- blood clotting disorder
- if you or your child are taking anti-coagulation medicine or undergoing anti-coagulation therapy as there is a risk of bleeding at the injection site following vaccination
- a condition affecting the immune system, such as HIV infection, or if you or your child are undergoing treatment which can alter the effectiveness of

your immune system, such as cancer therapy.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

The vaccine should not be used during pregnancy unless there is a defined risk of meningococcal C disease. If there is a need to consider vaccination during pregnancy or breast-feeding, your doctor can discuss with you the risks and benefits involved.

Tell your doctor or nurse if your baby was born prematurely.

There is a higher risk of apnoea (temporarily stopping breathing) for 2-3 days after vaccination of a premature baby.

Your doctor may decide if your baby requires monitoring during this time.

Tell your doctor or go the Accident and Emergency at the nearest hospital if you or your child experiences any of the symptoms of meningococcal infection:

- neck pain or stiffness
- sensitivity to light (photophobia)
- drowsiness
- confusion
- red or purple bruise-like spots that do not fade under pressure.

NeisVac-C will not cause meningococcal group C infection but some people could already have the disease or have meningitis caused by other organisms, prior to vaccination.

Taking other medicines

Tell your doctor or nurse if you or your child have been given other vaccines.

Your doctor will advise you if you or your child need to have NeisVac-C at the same time as other injected vaccines.

NeisVac-C must not be mixed with other vaccines in the same syringe.

NeisVac-C may be given at the same time as other vaccines as long

as they are given at different places on your body and using separate syringes.

Other vaccines that can be given protect against:

- polio
- measles, mumps, and German measles (MMR)
- diphtheria, tetanus and pertussis (whooping cough)
- infections caused by Haemophilus influenzae (Hib)
- Pneumococcal infections.

NeisVac-C can be given to infants at the same time as certain types of vaccines that protect against hepatitis B infection. Your doctor will advise you if this is necessary and which vaccine might be suitable.

Immunisation with NeisVac-C is not a substitute for routine tetanus immunisation.

How NeisVac-C is given

NeisVac-C will be injected into a muscle. It is usually injected into the thigh for infants and into the arm for older children, adolescents, and adults.

The vaccine must not be injected under the skin or into a blood vessel and your doctor or nurse will take care to avoid doing this when administering the vaccine.

The dosage for infants under the age of 12 months is two separate doses, the first dose given not earlier than 8 weeks of age and with an interval of at least two months between doses.

After the infant course of two doses is completed, children should be given a single booster dose in the second year of life. This should help maintain protection. Your doctor will advise you when your child should receive this.

For children 12 months of age and older, and for adolescents and adults, a single dose of the vaccine is recommended.

If you miss a dose

Your doctor or nurse will inform you about the vaccination schedule to follow. If you or your child miss a recommended dose or stop the vaccination course, this may result in incomplete protection.

If you take too much (overdose)

An overdose is highly unlikely, as it is given as a single-dose syringe by a doctor or nurse. If the doses are given closer together than recommended or more doses than required are given side effects are more likely to occur.

Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the list of side effects.

You may not experience any of them.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital, if you notice any of the following:

- an allergic reaction such as swelling of the lips, mouth and throat which may cause difficulty swallowing or breathing
- loss of muscle tone or floppiness in infants
- interruption in breathing or longer gaps between breaths in premature infants
- a seizure or convulsion which may be accompanied by a very high temperature

- rapid, shallow breathing, weak pulse, dizziness, weakness and fainting
- Neck stiffness, intolerance of bright light and headache
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals.

The above list includes very serious side effects. You or your child may need urgent medical attention or hospitalisation.

Tell your doctor as soon as possible if you notice any of the following:

- shortness of breath
- recurrence of nephrotic syndrome in children-this is a condition of the kidney which results in swelling around the face or eyes and frothy urine
- Easy bruising or bleeding

You should tell your doctor if you notice these symptoms after vaccination

Tell your doctor or nurse if you or your child experiences any of the following and they worry you:

Common side effects

- redness, swelling, tenderness and pain at the site of injection
- pain in the arms and legs or muscle aching or weakness
- fatigue
- nausea or vomiting
- fever
- coughing, inflamed throat or a runny or blocked nose
- loss of appetite
- poor sleep
- agitation or restlessness
- tiredness or sleepiness
- irritability or crying
- diarrhoea or stomach pain
- increased sweating
- dizziness
- headache
- itchy skin, dermatitis, rash or skin discolouration that resembles bruising
- generally feeling unwell.

Less common side effects

- burning sensation/pins and needles
- fainting
- swelling of the eyelids or face resulting from fluid retention
- swelling of the feet or ankles
- flushing
- joint pain, muscle stiffness, neck or back pain
- indigestion or reflux
- chills, swollen glands or flu-like symptoms.

Tell your doctor or nurse if you notice anything else that is making you or your child feel unwell.

Other side effects not listed above may also occur in some people.

After receiving NeisVac-C

Storage

If you are required to store Neisvac-C:

Keep NeisVac-C stored at 2°C - 8°C (in a refrigerator). Do not freeze.

Keep it where children cannot reach it.

NeisVac-C can be stored out of the refrigerator, at room temperature up to 25°C for up to 9 months before the expiry date shown on the pack. A good place to store medicines is in cupboard one-and-a-half metres above the ground. Do not leave it in the car or on a window sill.

When NeisVac-C is stored at room temperature, the initial date it left the refrigerator must be recorded and the product must not be returned to the refrigerator. At the end of this period, NeisVac-C should be used or returned to a pharmacy.

Product description

What it looks like

NeisVac-C vaccine is a white to off-white suspension in a single dose glass syringe. All parts of the syringe are latex free.

Ingredients

NeisVac-C is supplied in a pre-filled syringe without a needle, containing one dose of 0.5 mL. Each dose of NeisVac-C contains the following active ingredients:

- 10 micrograms of meningococcal group C polysaccharide
- 10 to 20 micrograms of tetanus toxoid protein

plus the following inactive ingredients:

- aluminium hydroxide
- sodium chloride
- water for injection

NeisVac-C does not contain preservatives.

The product is supplied in a pack containing a single syringe.

Supplier

NeisVac-C is supplied in Australia by:

Pfizer Australia Pty Ltd
Sydney NSW
Toll Free Number: 1800 675 229
www.pfizer.com.au

Australian registration number

AUST R 83093

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