

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

NEISVAC-C® VACCINE

Meningococcal Group C-TT Conjugate Vaccine, Adsorbed

Read this carefully before you start taking **NeisVac-C® vaccine** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **NeisVac-C® vaccine**.

Serious Warnings and Precautions

- **NeisVac-C® vaccine** should under no circumstances be injected intravenously or subcutaneously.

What is NeisVac-C® vaccine 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* group C bacteria 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 infections caused by other groups of meningococci or other organisms that cause meningitis and blood poisoning. As with other vaccines, NeisVac-C® vaccine cannot completely prevent meningococcal group C infections in all people who are vaccinated.

How does NeisVac-C® vaccine work?

NeisVac-C® vaccine works by causing your body to produce its own protection (or antibodies), against these types of meningococcal bacteria. NIMENRIX cannot cause meningococcal disease.

What are the ingredients in NeisVac-C® vaccine?

One dose (0.5 mL) of the vaccine contains the following:

Medicinal ingredients: *Neisseria meningitidis* group C polysaccharide conjugated, tetanus toxoid protein adsorbed on aluminium hydroxide

Non-medicinal ingredients: sodium chloride and water for injection

NeisVac-C® vaccine comes in the following dosage forms:

The NeisVac-C® vaccine is a suspension for injection packaged in pre-filled syringes of 10 mcg meningococcal group C-TT conjugate vaccine, adsorbed.

Do not use NeisVac-C® vaccine if:

You or your child are allergic to the active substance or any of the other ingredients of this vaccine.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take NeisVac-C® vaccine. Talk about any health conditions or problems you may have, including if

you:

- Have you ever had an allergic reaction (for example, symptoms such as itchy generalized skin rash, swelling of the face and throat, difficulty in breathing, blue discolouration of the tongue or lips, low blood pressure and collapse) to any ingredient of the vaccine including tetanus toxoid?
- Have you ever had an allergic reaction to any other vaccine intended to protect against meningococcal group C infections?
- Have an infectious illness (for example, high temperature, sore throat, cough, cold or flu)?
- Have hemophilia or any other problem that may stop your blood from clotting properly?
- Have been told that you have a weak immune system for any reason? For example, have you been told that you do not produce antibodies very efficiently or that you have a complement deficiency, or are you taking medicines that reduce your immunity to infections (such as anti-cancer drugs, radiation therapy, eculizumab or high doses of corticosteroids)?
- Have had your spleen removed or been told that your spleen does not work as it should?
- You over 65 years old

Other warnings you should know about:

In babies born very prematurely (at or before 28 weeks of gestation) longer gaps than normal between breaths may occur for 2-3 days after vaccination. Parents are advised to contact their physician, if any abnormal breathing is noticed.

Breastfeeding and pregnancy

- Are you pregnant, planning to become pregnant or breastfeeding? NeisVac-C[®] vaccine may still be given to you by a doctor or nurse if the risk of infection is considered to be high.

Driving and operating machinery

- The vaccine is unlikely to affect your ability to drive or operate machinery.

Although this vaccine contains tetanus toxoid, it does not reliably protect you against tetanus (lockjaw). Therefore, routine vaccines against tetanus should still be given when they are due (your doctor or nurse will advise you when you need vaccination against tetanus).

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Although there are no known interactions with other medicines, you should tell your doctor or nurse about any other medicines which you are taking, whether prescribed or bought without prescription.

Your doctor or nurse will advise you if you should need to have NeisVac-C[®] vaccine at the same time as other injected vaccines.

NeisVac-C[®] vaccine may be given at the same time as, but as separate injections at different injection sites from vaccines that protect against polio, measles, mumps, and rubella (MMR), diphtheria, tetanus and pertussis (whooping cough), infections caused by Haemophilus influenzae (Hib), pneumococcal infections, and rotavirus infections.

NeisVac-C[®] vaccine 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.

How to take NeisVac-C® vaccine:

The NeisVac-C® vaccine is usually injected into the muscle of the arm (in children from the age of 12 months and older persons) or thigh (in children from two months old up to the age of 12 months). In children 12 to 24 months of age, the vaccine may be administered in the muscle of the arm or the thigh. 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 so when administering the vaccine.

Usual dose:

One dose of NeisVac-C® vaccine is 0.5 mL (half a millilitre – a very small amount of liquid).

Your child may receive one or two injections before they are 12 months old, and another injection at approximately 12 to 13 months of age, with an interval of at least 6 months after last NeisVac-C® vaccination.

Older children (12 months and older), adolescents and adults will receive one injection only.

Overdose:

An overdose is highly unlikely to happen because it is administered from a single-dose syringe by a doctor or nurse.

If you think you, or a person you are caring for, have taken too much NeisVac-C® vaccine, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

Missing a dose is highly unlikely, since it is administered as a single dose by a health care provider.

What are possible side effects from using NeisVac-C® vaccine?

These are not all the possible side effects you may have when taking NeisVac-C® vaccine. If you experience any side effects not listed here, tell your healthcare professional.

This vaccine cannot cause meningococcal group C disease. If you or your child experiences neck pain, neck stiffness or a dislike of light (photophobia), drowsiness or confusion, or red or purple bruise-like spots that do not fade under pressure you should contact your doctor or local Hospital Emergency Department immediately to rule out other causes.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Injection site reactions / redness, swelling, hardening at the site of injection, and tenderness, pain at the injection site	x		
Headaches and fever	x		

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
In Infants: loss of appetite, feeling or being sick, vomiting and diarrhea	x		
In Infants: crying, irritability	x		
In Infants: drowsiness and sleepiness, or impaired sleeping	x		
COMMON			
Fever	x		
Muscle pain and pains in the arms or legs	x		
Drowsiness and sleepiness, or impaired sleeping	x		
In older children: loss of appetite, feeling or being sick or diarrhea	x		
RARE			
serious allergic reactions / swelling of the lips, mouth, throat, rash and swelling of the hands, feet and ankles]			x
severe skin rashes / itching, hives and other rashes			x
Fits /seizures			x
VERY RARE			
swollen lymph glands	x		
dizziness, faints	x		
abnormal or reduced sensation		x	
loss of muscle tone or floppiness in infants			x
purple spots or blotches under the skin and may look like bruises	x		

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Suspected Side Effects for Vaccines

For the general public: Should you experience a side effect following immunization, please report it to your healthcare professional.

Should you require information related to the management of the side effect, please contact your healthcare professional. The Public Health Agency of Canada, Health Canada and [Sponsor Name] cannot provide medical advice.

For healthcare professionals: If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (<http://www.phac-aspc.gc.ca/im/ae-fi-essi-form-eng.php>) and send it to your local Health Unit.

Storage:

This medicine should be stored in the refrigerator at +2°C to +8°C (Do Not Freeze). The product may be taken out of the refrigerator and stored at room temperature for a single period of not more than 9 months, as long as this time period ends before the expiry date written on the label. The date that the product is taken out of the refrigerator should be written on the box in the space provided. If the product has not been used within 9 months of the date it was taken out of the refrigerator (or by the expiry date, whichever is sooner), the product should be discarded.

The vaccine should be used before the expiry date printed on the label.

Keep out of reach and sight of children.

If you want more information about NeisVac-C® vaccine:

- Talk to your healthcare professional

Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.pfizer.ca, or by calling -800-463-6001 (Medical Information).

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