

Package leaflet: Information for the user

NeisVac-C 0.5 ml Suspension for injection in pre-filled syringe

Meningococcal Group C Polysaccharide Conjugate Vaccine Adsorbed

Read all of this leaflet carefully before you or your child start taking 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 vaccine has been prescribed for you or your child. 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 NeisVac-C is and what it is used for
2. What you need to know before you take NeisVac-C
3. How to use NeisVac-C
4. Possible side effects
5. How to store NeisVac-C
6. Contents of the pack and other information

1. What NeisVac-C is and what it is used for

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

The *Neisseria meningitidis* group C bacteria can cause serious infections such as meningitis and septicaemia (blood poisoning). These infections are sometimes life-threatening.

This 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 cannot completely prevent meningococcal group C infections in all people who are vaccinated.

2. What you need to know before you use NeisVac-C

Do not use NeisVac-C

- if you have ever had an allergic reaction to a previous dose of this vaccine or to any ingredient of the vaccine including tetanus toxoid (listed in section 6). The symptoms of an allergic reaction include skin rash, swelling of the face and throat, difficulty in breathing, blue discolouration of the tongue or lips, low blood pressure, and collapse.
- if you have ever had an allergic reaction to any other vaccine intended to protect against meningococcal group C infections.

Vaccination with NeisVac-C may have to be delayed if you have an acute illness with or without fever. In this case, your doctor or nurse may advise you to postpone your vaccination until you are better.

Warnings and precautions

Talk to your doctor, pharmacist, or nurse before using NeisVac-C.

Take special care with NeisVac-C:

- if you have haemophilia, are taking a blood thinner or have any other problem that may stop your blood from clotting properly
- if you have been told that you have an autoimmune disease or that you have a weak immune system for any reason. For example:
 - Have you been told that you do not produce antibodies very efficiently?
 - Are you taking medicines that reduce your immunity to infections (such as anti-cancer drugs or high doses of corticosteroids)?
- if you have had your spleen removed or have been told that your spleen does not work as it should
- if you suffer from a kidney disease in which large amounts of protein appear in the urine (called nephrotic syndrome)
There have been reports that this condition may reappear after vaccination. Your doctor or nurse will advise you if you can still have NeisVac-C. What he says will depend on the exact type of kidney problem you have.
- if you are over 65 years old.

In these cases, talk to your doctor or nurse before receiving this vaccine, as it may not be suitable for you. You may still be given the vaccine but it may not provide very high protection against infections caused by the group C bacteria.

This medicinal product contains less than 1 mmol sodium (23 milligrams) per dose, i.e. essentially “sodium-free”.

Other medicines and NeisVac-C

Tell your doctor, pharmacist or nurse if you are taking/using, have recently taken/used or might take/use any other medicines.

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

NeisVac-C may be given at the same time as, but as separate injections at different injection sites, to vaccines that 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 or nurse will advise you if this is necessary and which vaccine might be suitable.

NeisVac-C can also be given at the same time as oral vaccines that protect against rotavirus infections.

Please tell your doctor, pharmacist or nurse if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before taking this vaccine.

NeisVac-C may still be given to you by a doctor or nurse if the risk of infection is considered to be high.

Driving and using machines

The vaccine is unlikely to affect a person's ability to drive or operate machinery.

3. How to use NeisVac-C

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

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.

For infants from 2 to 4 months of age, two doses of NeisVac-C should be given at least two months apart. For infants from 4 months of age, older children, adolescents and adults one dose should be given.

After completion of the primary immunisation course in infants aged from 2 months up to 12 months of age a booster dose should be given at the age of approximately 12-13 months with at least an interval of 6 months after the last NeisVac-C vaccination. The need for booster doses in subjects aged 12 months or more when first immunised has not yet been established.

NeisVac-C must not be mixed with other vaccines in the same syringe. Separate injection sites should be used if more than one vaccine is being administered

If you are given more NeisVac-C than you should be given

There is no experience with overdose of NeisVac-C vaccine. However, an overdose is highly unlikely to happen because the injection is given from a single-dose syringe by a doctor or nurse.

If you miss a dose of NeisVac-C or stop the vaccination course

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

If you have any further questions on the use of this vaccine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, NeisVac-C can cause side effects although not everybody gets them.

As with all injectable vaccines, allergic reactions can happen. Although they are very rare, they can be serious. To cover this possibility, effective medical treatment and supervision should always be readily available for the appropriate length of time after vaccination.

Signs and symptoms of serious allergic reactions include:

- swelling of the lips, mouth, and throat, which may cause difficulty in swallowing or breathing
- a rash and swelling of the hands, feet, and ankles
- loss of consciousness due to a drop in blood pressure.

These signs or symptoms usually develop quickly after the injection is given, while the person affected is still in the clinic or doctor's surgery. If any of these symptoms occur after leaving the place where the injection was given, you must consult a doctor or nurse IMMEDIATELY.

The following side effects have been reported:

Very common side effects (may affect more than 1 in 10 people)

- *In all age groups:*
 - Redness, swelling, tenderness, and pain at the site of injection
- *In infants / toddlers:*
 - Fever, irritability, drowsiness, sleepiness, crying, vomiting, decreased appetite, hardening at the site of injection
- *In children and adults:*
 - Headache

Common side effects (may affect less than 1 in 10 people)

- *In infants / toddlers and children:*
 - Sore throat, runny nose, cough, diarrhea, rash
- *In infants / toddlers:*
 - Poor sleep, irritability, sweating
- *In children and adults:*
 - Fever, feeling or being sick, vomiting
- *In children:*
 - Fatigue, drowsiness, sleepiness, dizziness, nausea, belly pain, pain in the arms or legs, itching, purple spots under the skin, rash

Uncommon side effects (may affect less than 1 in 100 people)

- *In infants / toddlers and children:*
 - Local swelling, flushing, chills
- *In infants / toddlers:*
 - Belly pain, indigestion, feeling or being sick, pain in the arms or legs, skin redness
- *In children and adults:*
 - Swollen lymph glands
- *In children:*
 - Irritability, weakness, stiffness of muscles and joints, neck pain, muscle and joint pain, back pain, allergic reaction (including difficulty in breathing), abnormal or reduced sensation, fainting, crying, fits (seizures), decreased appetite, swelling of the eye lids, blocked nose, rash, sweating
- *In adults:*
 - Influenza-like illness

Rare side effects (may affect less than 1 in 1000 people)

- *In infants / toddlers:*
 - Allergic reaction (including difficulty in breathing), swelling of the eye lids, collapse, skin inflammation, purple spots under the skin, stiffness of muscles and joints
- *In children:*
 - Influenza-like illness

The following side effects have also been reported:

- Loss of muscle tone or floppiness in infants
- Meningeal irritation
- Fits (seizures)
- Red or purple bruise-like spots or blotches under the skin
- Skin rashes that can cover much of the body and lead to blistering and peeling. The inside of the mouth and the eyes can also be affected.
- Severe allergic reaction
- Swelling of the lips, mouth and throat, which may cause difficulty in breathing

If you have previously been told by your doctor or nurse that you suffer from nephrotic syndrome there may be an increased chance that this condition will reoccur within a few months after vaccination. Nephrotic syndrome is a kidney disease which may result in swelling, particularly around the face or eyes, protein in the urine, making it appear frothy, and/or weight gain. You should tell your doctor or nurse if you notice similar symptoms after vaccination.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, pharmacist or nurse.

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.

This vaccine cannot cause meningococcal group C disease. If you or your child experiences any of the following symptoms of meningococcal infection, i.e.

- neck pain
- neck stiffness
- a dislike of light (photophobia)
- drowsiness
- confusion
- red or purple bruise-like spots that do not fade under pressure

you should contact your doctor, nurse or local Accident and Emergency Department immediately.

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.

United Kingdom

Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Malta

ADR Reporting

Website: www.medicinesauthority.gov.mt/adrportal

5. How to store NeisVac-C

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

Do not use this medicine after the expiry date which is stated on the carton. Unless the day is indicated, the expiry date refers to the last day of that month.

This medicine should be stored in the refrigerator at +2°C to +8°C. Do not freeze. Keep the syringe in the outer carton in order to protect from light.

The product may be stored at room temperature (up to +25°C) for a maximum single period of nine months within the total shelf life. During this period the product may be put back into the refrigerator at 2-8 °C. The starting date for storage at room temperature and the revised expiry date should be stated on the product package. Under no circumstances must the revised expiry date for storage at room temperature exceed the expiry date set in accordance with the total shelf life of the product. At the end of this period, the product should be used or discarded.

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 NeisVac-C contains

The active substance in one dose (0.5 millilitres) of the vaccine is of 10 micrograms of *Neisseria meningitidis* group C (strain 11) polysaccharide (de-O-acetylated). This is linked to 10 – 20 micrograms of a protein called tetanus toxoid, and is adsorbed on hydrated aluminium hydroxide (0.5 milligrams Al³⁺).

The other ingredients are sodium chloride (cooking salt), water for injections and hydrated aluminium hydroxide. Hydrated aluminium hydroxide is included in this vaccine as an adsorbent to improve and/or prolong the protective effects of the vaccine.

What NeisVac-C looks like and contents of the pack

The NeisVac-C suspension for injection is semi-opaque white to off-white. Upon storage, a white deposit and clear supernatant can be observed. Therefore the vaccine must be shaken to homogeneity before use. If foreign particles or discolouration are detected in the syringe, the vaccine should be discarded by the Health Care Professional.

NeisVac-C is supplied as a 0.5 millilitre (one dose) suspension for injection in a pre-filled syringe. Pack sizes of 1, 10 or 20 pre-filled syringes are available. However, not all pack sizes may be marketed.

Each pre-filled syringe is packed in a blister. The opening in the blister seal is intended and allows for the equilibration of moisture during the recommended warm-up prior to the administration of the vaccine. Open the blister by removing the lid to take out the syringe. Do not press the syringe through the blister.

The pack of 1 may include up to two needles of different sizes. Where two needles are provided it is recommended to use the smaller needle for injection in children and the larger needle for vaccination in adults. The primary packaging is latex-free.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Pfizer Limited
Ramsgate Road
Sandwich
Kent
CT13 9NJ
United Kingdom

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

Manufacturer

Pfizer Manufacturing Belgium N.V.
Rijksweg 12
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Belgium

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	NeisVac-C
Belgium	NeisVac-C
Bulgaria	NeisVac-C
Cyprus	NeisVac-C
Czech Republic	NeisVac-C
Denmark	NeisVac-C
Estonia	NeisVac-C
France	NeisVac
Germany	NeisVac-C
Greece	NeisVac-C
Hungary	NeisVac-C
Íceland	NeisVac-C
Ireland	NeisVac-C
Italy	NeisVac-C
Latvia	NeisVac-C
Lithuania	NeisVac-C
Luxembourg	NeisVac-C
Malta	NeisVac-C
Netherlands	NeisVac-C
Norway	NeisVac-C
Poland	NeisVac-C
Portugal	NeisVac-C
Romania	NeisVac-C
Slovakia	NeisVac-C
Spain	NeisVac-C

United Kingdom

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