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 receive 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 only. 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

NeisVac-C is a vaccine to prevent invasive meningococcal disease caused by *Neisseria meningitidis* group C. This is a type of bacteria that can cause serious infections sometimes leading to life-threatening symptoms/reactions such as meningitis and septicaemia (blood poisoning).

NeisVac-C is given to children from 2 months of age, adolescents and adults. The vaccine works by causing your body to produce its own protection (antibodies) against the group C bacteria.

This vaccine will only protect against disease caused by the *Neisseria meningitidis* group C bacteria. It will not protect against infections caused by other groups of *Neisseria meningitidis* 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 (or your child) receives 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.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before receiving the NeisVac-C vaccine if the individual receiving the vaccine (e.g., you or your child)

- has haemophilia, is taking a blood thinner or has any other problem that may stop the blood from clotting properly.
- has an acute severe illness with fever. In this case, your doctor or nurse may advise you to postpone your vaccination until you are better.
- has an autoimmune disease or a weak immune system for any reason. The vaccine may still be given, but it may provide a lower level of protection against *Neisseria meningiditis* group C. For example:
  - if you do not produce antibodies very efficiently.
  - if you take 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.
- was born very prematurely (at or before 28 weeks of gestation). There may be longer than normal gaps between breaths for 2-3 days after vaccination and this may require monitoring.
- is over 65 years old.

This vaccine cannot cause meningococcal group C disease. If you or your child experience 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.

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

Other medicines and NeisVac-C

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

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

NeisVac-C may be given at the same time, but as separate injections at different injection sites, as vaccines that protect against:

- polio
- measles, mumps, and rubella (MMR)
- diphtheria, tetanus and pertussis (whooping cough)
- *Haemophilus influenzae* type b (Hib)
- *Streptococcus pneumoniae* (pneumococcus)

NeisVac-C can be given to infants at the same time as certain types of vaccines that protect against hepatitis B infection. Your doctor, pharmacist, 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.

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, pharmacist, or nurse if the risk of infection is considered to be high.

Driving and using machines
The effects of NeisVac-C on the ability to drive and use machines have not been studied. However, some of the side effects listed in section 4 'Possible side effects' may temporarily affect you. If this occurs, wait until the effects wear off before driving or using machines.

3. How to use NeisVac-C

One dose of NeisVac-C is 0.5 ml (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.

Infants from 2 to 4 months of age
Your child should be given two doses of NeisVac-C at least two months apart.

Infants from 4 months of age, older children, adolescents and adults
One dose should be given.

In infants from 2 months up to 12 months of age
A booster dose should be given at the age of approximately 12-13 months, at least 6 months after the last NeisVac-C vaccination of the primary immunisation course.

If you (or your child) have been given more NeisVac-C than recommended
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 or your child 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 vaccines, 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 in clinical studies:

Very common (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, fatigue, drowsiness, sleepiness, crying, vomiting, decreased appetite, firmness at the site of injection
- *In children and adults:*
  - Headache

Common (may affect up to 1 in 10 people)

- *In infants / toddlers and children:*
  - Sore throat, runny nose, cough, diarrhoea
- *In infants / toddlers:*
  - Poor sleep, irritability, rash, increased sweating
- *In children and adults:*
  - Fever, feeling unwell, vomiting
- *In children:*
  - Fatigue, drowsiness, sleepiness, dizziness, nausea, belly pain, pain in the arms or legs, itching, bruising, skin inflammation
- *In adults:*
  - Muscle pain

Uncommon (may affect up to 1 in 100 people)

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

Rare (may affect up to 1 in 1000 people)

- *In infants / toddlers:*
  - Allergic reaction (including difficulty in breathing), swelling of the eye lids, bruising, stiffness of muscles and joints
- *In infants/toddlers and children:*
  - Collapse
- *In children:*

- Influenza-like illness

The following side effects have also been reported:

- Low platelets leading to bruising of skin and mucus membranes
- Febrile seizures
- Meningeal (covering of the brain) irritation
- Loss of muscle tone or floppiness in infants
- Abnormal gaps in breathing
- 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.
- Red or purple spots on skin from bleeding
- Hives

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.

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 via HPRA Pharmacovigilance. Website: www.hpra.ie.

5. How to store NeisVac-C

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

Do not use this vaccine 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.

Store 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 vaccine may be stored at room temperature (up to +25 ºC) for a maximum single period of nine months within the total shelf life. During this period the vaccine 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 vaccine 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 vaccine. At the end of this period, the vaccine 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 Al^{3+}).

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
NeisVac-C is a semi-opaque white to off-white suspension for injection, provided 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.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Pfizer Healthcare Ireland
9 Riverwalk
National Digital Park
Citywest Business Campus
Dublin 24
Ireland

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

Manufacturer

Pfizer Manufacturing Belgium N.V.
Rijksweg 12
B-2870- Puurs
Belgium

This vaccine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Austria	NeisVac-C
Belgium	NeisVac-C
Cyprus	NeisVac-C
Denmark	NeisVac-C
France	NeisVac
Germany	NeisVac-C
Greece	NeisVac-C
Hungary	NeisVac-C
Íceland	NeisVac-C
Ireland	NeisVac-C
Italy	NeisVac-C
Luxembourg	NeisVac-C
Malta	NeisVac-C
Netherlands	NeisVac-C

Poland	NeisVac-C
Portugal	NeisVac-C
Spain	NeisVac-C
United Kingdom (Northern Ireland)	NeisVac-C

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The following information is intended for healthcare professionals only:

The vaccine is for intramuscular use only. Do not administer subcutaneously or intravascularly. Separate injection sites should be used if more than one vaccine is being administered.

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

The need for booster doses in individuals 12 months of age or older when first immunised has not yet been established.

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.

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.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.