

# NeisVac-C®

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### 1. Why am I using NeisVac-C?

NeisVac-C is a vaccine used to help prevent invasive meningococcal disease caused by bacteria called *Neisseria meningitidis* group C for people from 8 weeks of age.

For more information, see Section [1. Why am I using NeisVac-C?](#) in the full CMI.

### 2. What should I know before I use NeisVac-C?

Do not use if you have ever had an allergic reaction to any vaccination or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use NeisVac-C?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with NeisVac-C and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use NeisVac-C?

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.

More instructions can be found in Section [4. How do I use NeisVac-C?](#) in the full CMI.

### 5. What should I know while using NeisVac-C?

#### Things you should do

- Tell your doctor or nurse if you or your child have been given other vaccines.
- Tell your doctor or nurse if you are pregnant or plan to become

	<p>pregnant or are breast-feeding.</p>
<p><b>Things you should not do</b></p>	<ul style="list-style-type: none"> <li>• Vaccination should not be given to an infant under 8 weeks of age.</li> <li>• Do not withhold any information from your treating health professional.</li> </ul>
<p><b>Looking after your medicine</b></p>	<p>If you are required to store Neisvac-C:</p> <ul style="list-style-type: none"> <li>• Keep NeisVac-C stored at 2°C to 8°C (in a refrigerator). Do not freeze.</li> <li>• Store it in a cool, dry place away from moisture, heat or sunlight.</li> <li>• 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.</li> </ul>

For more information, see Section [5. What should I know while using Neisvac-C?](#) in the full CMI.

## 6. Are there any side effects?

Common side effects may include pain, redness or swelling at the injection site, nausea, vomiting, diarrhoea, stomach pains or fatigue. More serious side effects may be a severe allergic reaction known as anaphylaxis, neck stiffness or easy bruising and blistering.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# NeisVac-C®

**Active ingredient(s):** *Meningococcal group C polysaccharide conjugate vaccine (tetanus toxoid protein conjugate)*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using NeisVac-C. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using NeisVac-C.**

**Where to find information in this leaflet:**

- [1. Why am I using NeisVac-C?](#)
- [2. What should I know before I use NeisVac-C?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use NeisVac-C?](#)
- [5. What should I know while using NeisVac-C?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using NeisVac-C?

**NeisVac-C is a vaccine, a type of medicine used to help 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 (commonly called meningococcal) caused by 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.

## 2. What should I know before I use NeisVac-C?

### Warnings

**Your or your child should not be given NeisVac-C if:**

1. You are allergic to any of the ingredients listed at the end 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.

Always check the ingredients to make sure you can use this medicine.

2. It has passed the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. It has expired or is damaged - return it to your pharmacist.

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

Vaccination should be delayed if you or your child has a moderate or severe fever, or a current or recent medical concern.

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.

**Check with your doctor if you or your child have any other medical conditions, including 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)
- any 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 breastfeeding – see Pregnancy and breastfeeding below.
- 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.

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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant.

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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor will advise regarding this vaccine and pregnancy.

### **3. What if I am taking other medicines?**

Tell your doctor or pharmacist if you are taking any other medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

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 at the same time can protect against:
  - polio
  - measles, mumps, and rubella (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.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect NeisVac-C.**

## 4. How do I use NeisVac-C?

### How much to be given

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.

### 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.**

## **If you miss a dose of NeisVac-C vaccination**

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 NeisVac-C**

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.

If you think that you have been given too much NeisVac-C, you may need urgent medical attention.

### **You should immediately:**

- phone the Poisons Information Centre **(by calling 13 11 26)**, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while using NeisVac-C?**

### **Things you should do**

Ensure you and your child stay up to date with required vaccinations.

### **Call your doctor straightaway if you:**

- Notice any symptoms that worry you or may be severe.
- Develop signs of an allergic reaction such as skin rash, swelling of the lips or tongue, or difficulty breathing.

### **Things you should not do**

Do not withhold any information from your treating health professional.

### **Looking after your medicine**

If you are required to store NeisVac-C:

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

a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.
- When NeisVac-C is stored at room temperature, the initial date it was taken out of 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.

Do not use this medicine after the expiry date.

**Keep it where young children cannot reach it.**

## **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

## Side effects

Side effects	What to do
<p data-bbox="204 432 754 479"><b>Injection site symptoms</b></p> <ul data-bbox="204 510 743 674" style="list-style-type: none"><li data-bbox="204 510 743 674">● redness, swelling, tenderness and pain at the site of injection</li></ul> <p data-bbox="204 701 587 748"><b>Aches and pains</b></p> <ul data-bbox="204 779 775 943" style="list-style-type: none"><li data-bbox="204 779 775 943">● pain in the arms and legs or muscle aching or weakness</li></ul> <p data-bbox="204 969 571 1077"><b>Gastrointestinal symptoms</b></p> <ul data-bbox="204 1108 659 1429" style="list-style-type: none"><li data-bbox="204 1108 659 1155">● nausea or vomiting</li><li data-bbox="204 1173 453 1220">● diarrhoea</li><li data-bbox="204 1238 536 1285">● stomach pain</li><li data-bbox="204 1303 572 1350">● loss of appetite</li><li data-bbox="204 1368 671 1415">● indigestion or reflux</li></ul> <p data-bbox="204 1442 684 1615"><b>Tiredness, alertness, and sleep related symptoms</b></p> <ul data-bbox="204 1646 770 1966" style="list-style-type: none"><li data-bbox="204 1646 395 1693">● fatigue</li><li data-bbox="204 1711 743 1758">● tiredness or sleepiness</li><li data-bbox="204 1776 751 1823">● generally feeling unwell</li><li data-bbox="204 1841 770 1888">● agitation or restlessness</li><li data-bbox="204 1906 639 1953">● irritability or crying</li></ul>	<p data-bbox="810 432 1350 875"><b>Speak to your doctor if you have any of these common side effects and they worry you. Seek appropriate medical treatment if any of these symptoms worsen.</b></p>

<b>Side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● poor sleep</li> </ul> <p><b>Skin symptoms</b></p> <ul style="list-style-type: none"> <li>● itchy skin, dermatitis, rash or skin discolouration that resembles bruising</li> </ul> <p><b>Cold and flu symptoms:</b></p> <ul style="list-style-type: none"> <li>● fever</li> <li>● coughing</li> <li>● inflamed throat or a runny or blocked nose</li> <li>● chills, swollen glands or flu-like symptoms.</li> </ul> <p><b>Other side effects</b></p> <ul style="list-style-type: none"> <li>● increased sweating</li> <li>● dizziness</li> <li>● headache</li> <li>● flushing</li> <li>● burning sensation/pins and needles</li> </ul>	

## Serious side effects

Serious side effects	What to do
<p data-bbox="204 432 531 539"><b>Severe allergy (anaphylaxis)</b></p> <ul data-bbox="204 568 754 792" style="list-style-type: none"><li>● swelling of the lips, mouth and throat which may cause difficulty swallowing or breathing</li></ul> <p data-bbox="204 815 740 922"><b>Breathing symptoms in very premature infants</b></p> <ul data-bbox="204 952 759 1308" style="list-style-type: none"><li>● interruption in breathing or longer gaps between breaths in premature infants</li><li>● rapid, shallow breathing</li><li>● shortness of breath</li></ul> <p data-bbox="204 1335 735 1442"><b>Muscle, blood and skin symptoms</b></p> <ul data-bbox="204 1471 719 1951" style="list-style-type: none"><li>● loss of muscle tone or floppiness in infants</li><li>● neck and/or joint stiffness</li><li>● easy bruising or bleeding</li><li>● severe blisters and bleeding in the lips,</li></ul>	<p data-bbox="810 432 1358 875"><b>Call your doctor straightaway, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p>eyes, mouth, nose and genitals.</p> <ul style="list-style-type: none"> <li>● red or purple bruise-like spots that do not fade under pressure</li> <li>welling of the eyelids or face resulting from fluid retention</li> </ul> <p><b>Other</b></p> <ul style="list-style-type: none"> <li>● a seizure or convulsion which may be accompanied by a very high temperature</li> <li>● intolerance or sensitivity of bright light (photophobia)</li> <li>● recurrence of nephrotic syndrome in children - a condition of the kidney - which results in swelling around the face or eyes and frothy urine</li> </ul>	

**Tell your doctor or pharmacist if you notice anything else that may be making you or your child feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What NeisVac-C contains

<b>Active ingredient (main ingredient)</b>	Each dose of NeisVac-C contains the following active ingredients: <ul style="list-style-type: none"><li>• 10 micrograms of meningococcal group C polysaccharide</li><li>• 10 to 20 micrograms of tetanus toxoid protein</li></ul>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• aluminium hydroxide</li><li>• sodium chloride</li></ul>

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|--|---|
|  | <ul style="list-style-type: none"><li>• water for injection</li></ul> NeisVac-C does not contain preservatives. |
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**Do not take this medicine if you are allergic to any of these ingredients.**

## **What NeisVac-C looks like**

NeisVac-C is supplied in a pre-filled syringe without a needle, containing one dose of 0.5 mL (AUST R 83093).

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

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

## **Who distributes NeisVac-C**

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

[www.pfizermedicalinformation.com.au](http://www.pfizermedicalinformation.com.au)

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