

## 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.

### 1. Why am I using NIMENRIX?

NIMENRIX is a vaccine used to help prevent meningococcal disease, caused by four types of Neisseria meningitidis bacteria (types A, C, W and Y). NIMENRIX works by causing your body to produce its own protection (or antibodies), against these types of meningococcal bacteria.

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

### 2. What should I know before I use NIMENRIX?

Do not use if you or your child have ever had an allergic reaction to NIMENRIX or any of the ingredients listed at the end of the CMI. Talk to your doctor if you or your child have had a serious reaction to any vaccine, have fainted with a previous vaccine, have had a vaccine in the last 4 weeks, have any other medical conditions, take any other medicines, or if you are pregnant or plan to become pregnant or are breastfeeding.

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

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

Some vaccines or medicines may interfere with NIMENRIX 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 NIMENRIX?

- Your doctor or nurse will give NIMENRIX as an injection. The vaccine is injected into muscle, usually in the thigh for babies from 6 to 12 weeks of age. In children from 12 months of age and adults, NIMENRIX can be injected into the thigh or arm muscle.

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

### 5. What should I know while using NIMENRIX?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>Remind any doctor or dentist you visit that you are using NIMENRIX.</li><li>Keep a record of you or your child's vaccinations, and update this after each injection.</li><li>Keep any follow-up visits with your doctor or clinic.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>If required, ensure you or your child does not miss follow-up doses of NIMENRIX to make sure the vaccine has the best chance of providing protection against meningococcal disease.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>Be careful driving or operating machinery until you know how NIMENRIX affects you. In some people, vaccination can cause dizziness or lightheadedness.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>Be careful when drinking alcohol until you know how NIMENRIX affects you.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>NIMENRIX is usually stored in the doctor's surgery or clinic, or at the pharmacy.</li><li>However, if you need to store NIMENRIX, keep it in the fridge, stored between 2°C and 8°C.</li></ul>

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

### 6. Are there any side effects?

NIMENRIX, like all medicines and vaccines, may cause unwanted side effects in some people. Most unwanted side effects with NIMENRIX are mild and clear up within a few days. These effects, as with other vaccines, generally occur around the injection site. Very common side effects include pain, redness or swelling around the injection site, loss of appetite, fever, drowsiness or feeling tired, headache, irritability/fussiness in a child. As with all vaccines given by injection, there is a very small risk of a serious allergic reaction. 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.

# NIMENRIX

**Active ingredient(s):** Meningococcal polysaccharide groups A, C, W-135 and Y conjugate vaccine powder and solvent for solution for injection in pre-filled syringe

## Consumer Medicine Information (CMI)

This leaflet provides important information about using NIMENRIX. **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 NIMENRIX.**

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

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

## 1. Why am I using NIMENRIX?

**NIMENRIX is a vaccine used to help prevent meningococcal disease, caused by four types of Neisseria meningitidis bacteria (types A, C, W and Y).**

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

The most common types of meningococcal disease are meningitis (infection of a lining around the brain and spinal cord) and septicaemia (blood infection). Neisseria bacteria can less commonly infect the joints, lungs or other organs.

Meningococcal disease is spread by small droplets from the nose, mouth or throat. Meningococcal disease is generally serious and sometimes causes long-term effects (eg deafness, memory problems, loss of fingers or toes), or death.

As with all vaccines, NIMENRIX may not protect all people who are vaccinated.

Also, NIMENRIX does not help to protect against meningococcal disease caused by other types of Neisseria, or meningitis caused by other bacteria or viruses.

NIMENRIX can be used in infants from 6 weeks of age, children and adults and is particularly recommended for:

- Travellers to countries where meningococcal A, W or Y disease outbreaks may happen (eg parts of Africa, annual Hajj)
- Close contacts of people with meningococcal A, W or Y disease
- People with medical conditions that make them more likely to get meningococcal disease (eg. people without a functioning spleen or some people with a poor immune response to infections).

NIMENRIX may also be prescribed for other people or situations.

## 2. What should I know before I use NIMENRIX?

### Warnings

**Do not use NIMENRIX if:**

1. You or your child are allergic to NIMENRIX, or any of the ingredients listed at the end of this leaflet. 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
2. If you or your child have been given NIMENRIX before and become unwell, tell your doctor or nurse before the vaccine is given.
3. You or your child have a severe infection with a high temperature. A minor infection, such as a cold, should not be a problem, but talk to your doctor or nurse before having the vaccine.

**Check with your doctor if you:**

- You or your child have had a serious reaction to any vaccine, including:
  - an allergic reaction
  - difficulty breathing
  - swelling of the throat
  - fainting or collapse
  - shock-like state or being unresponsive
  - fits or convulsions
  - high temperature (greater than 40°C)
  - severe skin reaction at the injection site
  - crying or screaming lasting for more than 3 hours, in a child.
- You or your child have allergies to:
  - any medicines
  - any other substances, such as foods, preservatives or dyes.
- You or your child fainted with a previous vaccine. Fainting can occur following, or even before any needle injection.
- You or your child have these medical conditions:
  - low platelets or a bleeding disorder, since bleeding can occur after injection of NIMENRIX.
  - you or your child have any condition, treatment or medicines that affect the immune response to infections. You or your child may still have NIMENRIX if your doctor or nurse recommends it, but may not be protected as much as other people.
- You or your child have had a vaccine in the last 4 weeks, or have recently taken any medicines, including medicines that don't need a prescription.

Some vaccines may be affected by other vaccines or medicines. Your doctor, pharmacist or nurse will be able to tell you what to do. See Section 3. What if I am taking

other medicines? for a list of vaccines that can be given at the same time as NIMENRIX.

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.

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

Your doctor will discuss the possible risks and benefits of having NIMENRIX during pregnancy or breastfeeding.

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

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

**Some vaccines may be affected by other vaccines or medicines. Your doctor, pharmacist or nurse will be able to tell you what to do.**

NIMENRIX can be given at the same time as the following vaccines.

- **Infants from 6 weeks up to 12 months of age:**

Combined diphtheria, tetanus, acellular pertussis (DTaP), hepatitis B, inactivated polio (IPV) and Haemophilus influenzae type b (Hib) vaccines and 10-valent pneumococcal conjugate vaccine.

- **Children from 12 months of age and adults:**

Hepatitis A and hepatitis B; DTaP vaccines, including combination DTaP vaccines with hepatitis B, IPV or Hib; measles-mumps-rubella (MMR) vaccine, including in combination with varicella (MMRV); seasonal flu and 10 or 13-valent pneumococcal conjugate vaccines; human papillomavirus bivalent vaccine (HPV2) and diphtheria toxoid and acellular pertussis vaccine (Tdap) in individuals aged 9 to 25 years.

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

## **4. How do I use NIMENRIX?**

### **How is it given**

Your doctor or nurse will give NIMENRIX as an injection. The vaccine is injected into muscle, usually in the thigh for babies from 6 to 12 weeks of age.

In children from 12 months of age and adults, NIMENRIX can be injected into the thigh or arm muscle.

### **When is it given**

#### **Infants 6 weeks to less than 6 months of age:**

Your baby will receive two doses, normally given at 2 and 4 months old (2 months apart) however the first dose may be given as early as 6 weeks of age. A booster dose is recommended at 12 months of age.

#### **Infants 6 months to less than 12 months of age:**

Your baby will receive one dose given from 6 months of age. A booster dose is recommended at 12 months of age, with an interval of at least 2 months after the initial dose.

### **Children from 12 months of age and adults:**

Most people will be given one NIMENRIX injection.

Some people at increased or continued risk of meningococcal infection may be given two initial NIMENRIX injections; NIMENRIX after another meningococcal vaccine; and/or a booster dose of NIMENRIX.

Your doctor will advise if you or your child need more than one NIMENRIX injection.

### **If you or your child miss a dose**

If a dose of NIMENRIX is missed, talk to your doctor or nurse and arrange another visit as soon as possible.

### **If you use too much NIMENRIX**

For information on the management of overdose, contact the Poison Information Centre on 131126.

## **5. What should I know while using NIMENRIX?**

### **Things you should do**

**Keep a record of you or your child's vaccinations, and update this after each injection.**

**Keep any follow-up visits with your doctor or clinic.**

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

If required, ensure you or your child does not miss follow-up doses of NIMENRIX to make sure the vaccine has the best chance of providing protection against meningococcal disease.

### **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how NIMENRIX affects you.**

In some people, vaccination can cause dizziness or lightheadedness.

### **Drinking alcohol**

**Tell your doctor if you drink alcohol.**

Be careful when drinking alcohol until you know how NIMENRIX affects you.

### **Looking after your medicine**

NIMENRIX is usually stored in the doctor's surgery or clinic, or at the pharmacy.

However, if you need to store NIMENRIX,

- Keep it in the fridge, stored between 2°C and 8°C.
- Do NOT freeze NIMENRIX, store it in the bathroom, or leave it in the car.
- Store it in the original pack, to protect it from light.
- Keep it out of reach of children.

Ask your pharmacist what to do with NIMENRIX that has expired or not been used.

## 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.

Most unwanted side effects with NIMENRIX are mild and clear up within a few days. These effects, as with other vaccines, generally occur around the injection site.

### Very common side effects

Very common side effects	What to do
<b>General disorders and administration site conditions:</b> <ul style="list-style-type: none"><li>• pain, redness or swelling around the injection site</li><li>• loss of appetite</li><li>• fever</li><li>• drowsiness or feeling tired</li><li>• headache</li><li>• irritability/fussiness in a child</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

### Common side effects

Common side effects	What to do
<ul style="list-style-type: none"><li>• diarrhoea, vomiting or nausea</li><li>• bruising at the injection site</li><li>• rash (in infants)</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

### Uncommon side effects

Uncommon side effects	What to do
<ul style="list-style-type: none"><li>• warmth, itchiness, lack of sensation, or a hard lump around the injection site</li><li>• dizziness</li><li>• trouble sleeping</li><li>• decreased sensation or itchiness of the skin; rash</li><li>• pain in a muscle, arm or leg</li><li>• feeling unwell</li><li>• crying in a child</li><li>• large swelling of the vaccinated limb associated with redness may occur</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

### Serious side effects

Serious side effects	What to do
<b>Serious allergic reaction:</b> <ul style="list-style-type: none"><li>• swelling of limbs, face, eyes, inside of nose, mouth or throat</li><li>• shortness of breath, breathing or swallowing difficulties</li><li>• hives, itching (especially of the hands or feet), reddening of skin (especially around the ears), or severe skin reactions</li><li>• unusual tiredness or weakness that is sudden and severe.</li></ul>	<b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>

**Tell your doctor or pharmacist if you notice anything else that may be making you 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 NIMENRIX contains

<b>Active ingredient (main ingredient)</b>	NIMENRIX contains agents that stimulate an immune response to <i>Neisseria meningitidis</i> types A, C, W and Y.
<b>Other ingredients (inactive ingredients)</b>	The vaccine also contains sucrose and trometamol. The solvent contains sodium chloride (salt) and water for injection.

**Do not take this medicine if you are allergic to any of these ingredients.**

### What NIMENRIX looks like

NIMENRIX comes as a white powder in a vial, together with a pre-filled syringe of diluent. The powder is dissolved in the solvent by the doctor or nurse, just before injection.

Australian Registration Number:

AUST R 199742

### Who distributes NIMENRIX

Pfizer Australia Pty Ltd

Sydney, NSW

Toll Free Number 1800 675 229

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