

# NUVAXOVID COVID-19 VACCINE (adjuvanted)

## 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.

▼ This vaccine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

### 1. Why am I being given NUVAXOVID?

NUVAXOVID contains the active ingredient SARS-CoV-2 rS (NVX-CoV2373). NUVAXOVID is a vaccine used to prevent COVID-19 disease caused by the SARS-CoV-2 virus in people aged 12 years and older.

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

### 2. What should I know before I am given NUVAXOVID ?

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

**Talk to your healthcare provider if you have any other medical conditions, take any other medicines, have been given another vaccine or are pregnant or plan to become pregnant or are breastfeeding.**

NUVAXOVID should not be given to children under 12 years of age.

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

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

Some medicines or vaccines may interfere with NUVAXOVID and affect how it works.

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

### 4. How will I be given NUVAXOVID ?

NUVAXOVID will be given as an injection into the muscle of your upper arm by a healthcare provider. You will be given one dose followed by a second dose 3 weeks later. It is very important that you receive your second dose. A healthcare provider will observe you for at least 15 minutes after being given NUVAXOVID.

You may receive an additional dose approximately 5-6 months after the primary vaccination.

More instructions can be found in Section [4. How will I be given NUVAXOVID?](#) in the full CMI.

### 5. What should I know while being given NUVAXOVID ?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• If you receive one dose of NUVAXOVID, you should receive a second dose of the same vaccine 3 to 4 weeks later to complete the vaccination schedule.</li><li>• An additional dose of NUVAXOVID may be given approximately 6 months after the primary vaccination for people 18 years of age and older, and at least 5 months after the primary vaccination with NUVAXOVID for adolescents aged 12 to 17 years of age. (NUVAXOVID has provisional approval for this use in adolescents).</li><li>• You may not be protected against COVID-19 disease until at least seven days after your second dose.</li><li>• You may not be protected if you only receive one dose, so a second dose is important.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how NUVAXOVID affects you. Some of the side effects of COVID-19 Vaccine listed in section 6 may temporarily affect your ability to drive or use machines. Wait until these effects have worn off before you drive or use machines. Do not drive or use machines if you are feeling unwell after vaccination.</li></ul>

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

### 6. Are there any side effects?

Very common side effects of NUVAXOVID include tenderness or pain at injection site, feeling tired, feeling unwell, headache, muscle ache, joint pain, nausea and vomiting

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.



This vaccine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or in Australia directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

# NUVAXOVID COVID-19 VACCINE (adjuvanted)

**Active ingredient(s):** SARS-CoV-2 rS (NVX-CoV2373)

## Consumer Medicine Information (CMI)

This leaflet provides important information about using NUVAXOVID. **You should also speak to your healthcare provider if you would like further information or if you have any concerns or questions about receiving NUVAXOVID.**

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

- [1. Why am I being given NUVAXOVID?](#)
- [2. What should I know before I am given NUVAXOVID?](#)
- [3. What if I am taking other medicines or vaccines?](#)
- [4. How will I be given NUVAXOVID?](#)
- [5. What should I know while being given NUVAXOVID?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I being given NUVAXOVID?

**NUVAXOVID contains the active ingredient SARS-CoV-2 rS (NVX-CoV2373).**

NUVAXOVID is a protein vaccine that works by triggering your immune system to produce antibodies and specialised white blood cells to work against the virus, to protect you against COVID-19 disease.

NUVAXOVID also contains an adjuvant, a substance included in certain vaccines to accelerate, improve and/or prolong the protective effects of the vaccine.

**NUVAXOVID is a vaccine used to prevent COVID-19 disease caused by the SARS-CoV-2 virus in people aged 12 years and older.**

## 2. What should I know before I am given NUVAXOVID ?

### Warnings

**Do not use NUVAXOVID if:**

- you are allergic to SARS-CoV-2 rS (NVX-CoV2373), or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

### Check with your doctor if you :

- had a severe allergic reaction or breathing problems after any other vaccine or after being given NUVAXOVID in the past.
- fainted following any needle injection.
- have a severe illness or infection with high fever. However, you can have your vaccination if you have a mild fever or upper airway infection like a cold.
- have a weakened immune system, such as due to HIV infection or are on a medicine that affects your immune system.
- have a bleeding disorder, bruise easily or are on a blood thinning medicine.
- are taking any other medicines or have received any other vaccines or injections (see section 3).

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?

There is an increased risk of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) after vaccination with NUVAXOVID (see section 6).

These conditions can develop within a few days after vaccination and have primarily occurred within 14 days. Following vaccination, you should be alert to signs of myocarditis and pericarditis, such as breathlessness, palpitations and chest pain, and seek immediate medical attention should these occur.

If any of the above apply to you (or you are not sure), talk to your healthcare provider before you are given NUVAXOVID.

You may not be protected against COVID-19 disease until at least seven days after your second dose. As with any vaccine, NUVAXOVID may not fully protect all those who receive it, and it is not known how long you will be protected.

### Pregnancy and breastfeeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your healthcare provider for advice before you receive this vaccine. There are limited data on the use of NUVAXOVID in pregnant or breastfeeding women. Your healthcare provider will discuss with you whether you can be given the vaccine.

## Children and adolescents

NUVAXOVID should not be given to children under 12 years of age.

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

Tell your healthcare provider if you are taking, have recently taken, or might take, any other vaccines or medicines including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Medicines (including other vaccines) that may impact whether you should be given this vaccine or not, include the following (see also Section 2 above):

- medicines that weaken the immune system (such as high-dose corticosteroids, immunosuppressants or cancer medicines)
- blood thinning medicines (anticoagulant)
- any other vaccine including any other COVID-19 vaccines

**Check with your healthcare provider if you are not sure about what vaccines, medicines, vitamins or supplements you are taking or have recently taken and if these may affect NUVAXOVID.**

### 4. How will I be given NUVAXOVID?

#### How NUVAXOVID is given

NUVAXOVID will be given to you by a healthcare provider. It is injected into a muscle of your upper arm.

**You will receive two (0.5 mL per dose) injections. You will be told when you need to return for your second injection of NUVAXOVID.**

The second injection will be given 3 weeks after the first injection. A healthcare provider will observe you for at least 15 minutes after being given NUVAXOVID.

When NUVAXOVID is given for the first injection, NUVAXOVID (and not another vaccine against COVID-19) should be given for the second injection to complete the vaccination course.

- An additional dose of NUVAXOVID may be given approximately 6 months after the primary vaccination for people 18 years of age and older or at least 5 months after the primary vaccination of NUVAXOVID for adolescents aged 12 to 17 years of age. (NUVAXOVID has provisional approval for this use in adolescents).

#### If you forget to get your second injection

If you forget to go back at the scheduled time, ask your healthcare provider for advice. It is important that you return for your second injection of NUVAXOVID.

If you miss a scheduled second injection you may not achieve maximum protection.

## If you are given too much NUVAXOVID

As NUVAXOVID is given under the close supervision of a healthcare provider it is unlikely that you will be given too much.

If you are concerned that you have been given too much NUVAXOVID, tell your healthcare provider immediately.

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

### 5. What should I know while being given NUVAXOVID?

As with any vaccine, the 2-dose vaccination course of NUVAXOVID may not completely protect everyone who is vaccinated from COVID-19. It is not yet known how long you will be protected.

#### Driving or using machines

Be careful before you drive or use any machines or tools until you know how this vaccine affects you.

NUVAXOVID has no known effect on the ability to drive and use machines. However, side effects listed in section 6 may impact your ability to drive and use machines. If you feel unwell, do not drive or use machines.

#### Looking after your vaccine

Your healthcare provider is responsible for storing this vaccine and disposing of any unused product correctly.

### 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 healthcare provider if you have any further questions about side effects.

#### Very common side effects

Very common side effects	What to do
<ul style="list-style-type: none"><li>• Tenderness or pain at injection site</li><li>• Feeling tired</li><li>• Feeling unwell</li><li>• Headache</li><li>• Muscle aches</li><li>• Joint pain</li><li>• Nausea</li><li>• Vomiting</li></ul>	<b>Speak to your healthcare provider if you have any of these side effects and they worry you.</b>

## Common side effects

Common side effects	What to do
<ul style="list-style-type: none"> <li>• Redness at injection site</li> <li>• Swelling at injection site</li> <li>• Fever (temperature higher than 38°C)</li> <li>• Chills</li> <li>• Pain or discomfort in the arms, hands, legs and/or feet</li> </ul>	<p><b>Speak to your healthcare provider if you have any of these side effects and they worry you.</b></p>

## Uncommon

Uncommon side effects	What to do
<ul style="list-style-type: none"> <li>• Tenderness of lymph glands</li> <li>• Raised blood pressure</li> <li>• Rash</li> <li>• Redness</li> <li>• Itchiness at injection site</li> </ul>	<p><b>Speak to your healthcare provider if you have any of these rare side effects.</b></p>

## Other side effects (frequency unknown)

Other side effects (frequency unknown)	What to do
<ul style="list-style-type: none"> <li>• Severe allergic reaction. Possible symptoms include:               <ul style="list-style-type: none"> <li>○ Hives or rash</li> <li>○ Feeling faint or light-headed</li> <li>○ Swelling of your lips, face, or throat</li> <li>○ Wheezing</li> </ul> </li> <li>• Inflammation of the heart muscle (myocarditis) or lining around the heart (pericarditis). Possible symptoms include:               <ul style="list-style-type: none"> <li>○ Chest pain</li> <li>○ Changes in your heartbeat</li> <li>○ Shortness of breath</li> </ul> </li> </ul>	<p><b>Call your doctor, pharmacist, or nurse straight away, or go to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>
<ul style="list-style-type: none"> <li>• Decreased sense of touch or sensation</li> <li>• Tingling, prickling or pins and needles feeling</li> <li>• Ringing in the ear</li> </ul>	<p><b>Speak to your doctor if you have any of these side effects and they worry you.</b></p>

**Tell your healthcare provider 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, or the healthcare provider may report them for you.

In Australia, report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems) and include the vaccine name (NUVAXOVID COVID-19 Vaccine [adjuvanted]) and batch/lot number if available.

In New Zealand, report side effects to the New Zealand Pharmacovigilance Centre online at <https://nzphvc.otago.ac.nz/consumer-reporting/> and include the vaccine name (NUVAXOVID COVID-19 Vaccine [adjuvanted]) and batch/lot number if available.

By reporting side effects, you can help provide more information on the safety of this vaccine.

## 7. Product details

### What NUVAXOVID contains

Active ingredient (main ingredient)	SARS-CoV-2 rS (NVX-CoV2373)
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> <li>• Matrix-M adjuvant, which contains:               <ul style="list-style-type: none"> <li>○ Quillaja Saponaria saponins fraction A</li> <li>○ Quillaja Saponaria saponins fraction C</li> <li>○ cholesterol</li> <li>○ phosphatidyl choline</li> <li>○ monobasic potassium phosphate</li> <li>○ dibasic sodium phosphate dihydrate</li> <li>○ sodium chloride</li> <li>○ potassium chloride</li> </ul> </li> <li>• Dibasic sodium phosphate heptahydrate</li> <li>• Monobasic sodium phosphate monohydrate</li> <li>• Sodium chloride</li> <li>• Polysorbate 80</li> <li>• Sodium hydroxide (for pH adjustment)</li> <li>• Hydrochloric acid (for pH adjustment)</li> <li>• Water for injections</li> </ul>

**Do not receive this vaccine if you are allergic to any of these ingredients.**

NUVAXOVID contains:

- Sodium, less than 23 mg per dose, that is to say, it is essentially sodium-free (equivalent to approximately 0.2% of the recommended maximum daily intake of 2 g sodium for an adult).
- Potassium, less than 39 mg per 0.5 mL dose, that is to say, it is essentially potassium-free.

### **What NUVAXOVID looks like**

NUVAXOVID is colourless to slightly yellow, clear to mildly opalescent suspension provided in a multidose clear glass vial.

Each vial contains 5 or 10 doses of vaccine.

AUST R 355139

### **Who distributes NUVAXOVID?**

#### **In Australia:**

Bioclect Pty Ltd  
Level 29  
66 Goulburn Street  
Sydney NSW 2000

#### **In New Zealand:**

Bioclect New Zealand Limited  
Level 5, Wynn Williams House  
47 Hereford Street  
Christchurch 8013

For Medical/Technical Enquiries:

Australia: +61 2 7202 1444

New Zealand: +64 4 974 9419

Email: [info@bioclect.com](mailto:info@bioclect.com)

Website: [www.bioclect.com](http://www.bioclect.com)

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