

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 vaccine, 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 adults aged 18 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 18 years.

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.

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 ?

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|----------------------------------|--|
| Things you should do | <ul style="list-style-type: none">• If you receive one dose of NUVAXOVID, you should receive a second dose of the same vaccine 3 weeks later to complete the vaccination schedule.• You may not be protected against COVID-19 disease until at least seven days after your second dose.• You may not be protected if you only receive one dose, so a second dose is important. |
| Driving or using machines | <ul style="list-style-type: none">• 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. |

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.

NUVAXOVID COVID-19 VACCINE (adjuvanted)

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

This vaccine has **provisional approval** in Australia to prevent COVID-19 disease caused by SARS-CoV-2 virus in people aged 18 years and older. This approval has been granted on the basis of short-term efficacy and safety data. Evidence of longer term efficacy and safety from ongoing clinical trials and vaccination in the community continues to be gathered and assessed.

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 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 18 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).

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.

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

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 18 years.

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.

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">• Tenderness or pain at injection site• Feeling tired• Feeling unwell• Headache• Muscle aches• Joint pain• Nausea• Vomiting | Speak to your healthcare provider if you have any of these side effects and they worry you. |

Common side effects

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

Uncommon

| Uncommon side effects | What to do |
|-----------------------|------------|
|-----------------------|------------|

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

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

What NUVAXOVID contains

| | |
|---|---|
| Active ingredient (main ingredient) | SARS-CoV-2 rS (NVX-CoV2373) |
| Other ingredients (inactive ingredients) | <ul style="list-style-type: none"> • Matrix-M adjuvant, which contains: <ul style="list-style-type: none"> • Quillaja Saponaria saponins fraction A • Quillaja Saponaria saponins fraction C • cholesterol • phosphatidyl choline • monobasic potassium phosphate <ul style="list-style-type: none"> • potassium chloride • Dibasic sodium phosphate heptahydrate |

| | |
|--|--|
| | <ul style="list-style-type: none"> • Monobasic sodium phosphate monohydrate • Sodium chloride • Polysorbate 80 • Sodium hydroxide (for pH adjustment) • Hydrochloric acid (for pH adjustment) • Water for injections |
|--|--|

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

NUVAXOVID contains:

- approximately 3.75 micrograms of sodium per 0.5 mL dose, equivalent to approximately 0.2% of the recommended maximum daily intake of 2 g sodium for an adult.
- Potassium, less than 39 micrograms 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 10 doses of vaccine. (AUST R 355139).

Who distributes NUVAXOVID

In Australia:

Bioclect Pty Ltd
Suite 5 02 Level 5
139 Macquarie 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

Website: www.bioclect.com

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