

Allergy, Immunodeficiency, Autoimmunity and COVID-19 Vaccination Frequently Asked Questions (FAQ)

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This information has been developed by ASCIA to answer common questions regarding COVID-19 vaccination in relation to allergy, immunodeficiency and autoimmunity, and is updated when new information is available.

Q 1: Why is COVID-19 vaccination important?

Vaccination is an important way to reduce the risk of developing infectious diseases which can easily spread. This includes COVID-19, which is caused by infection with the SARS-CoV-2 coronavirus.

Immunity occurs after the vaccine stimulates a person's immune system to make antibodies (immunoglobulins) and COVID-19 specific T cells, to help protect the body from future infections. This means that if a person is vaccinated, they will be less likely to get COVID-19. Even if a person does get infected, it is likely to be a milder illness.

Public health measures and restrictions that have been implemented by the Australian and New Zealand governments since March 2020 have reduced the spread of COVID-19 in our countries. However, the COVID-19 pandemic has been a major cause of illness and deaths worldwide, and outbreaks continue to occur.

This means that vaccination programs are required throughout the world, including Australia and New Zealand.

For updates about the COVID-19 situation in Australia and New Zealand visit:

- health.gov.au/news/health-alerts/novel-coronavirus-2019-ncov-health-alert
- <u>https://covid19.govt.nz/alert-levels-and-updates/current-alert-level/</u>

Q 2: Which COVID-19 vaccines are available in Australia and New Zealand?

The COVID-19 vaccines listed below are not live-attenuated vaccines and are safe for people with immune system disorders, including allergy, immunodeficiency or autoimmune conditions:

- **Pfizer/BioNTech Comirnaty mRNA-based COVID-19 vaccine** available in Australia and New Zealand for adults and children 5 years and over.
- Moderna Spikevax mRNA-based COVID-19 vaccine available in Australia for adults and children 6 years and over.
- AstraZeneca/Oxford Vaxzevria viral vector COVID-19 vaccine available in Australia for adults 18 years and over.
- Novavax/Biocelect Nuvaxovid spike protein based COVID-19 vaccine available in Australia for adults 18 years and over (approved January 2022).

In Australia the vaccines listed above have all been provisionally approved by the Therapeutic Goods Administration (TGA), which is part of the Australian Government Department of Health. www.health.gov.au/initiatives-and-programs/covid-19-vaccines

In New Zealand the Pfizer/BioNTech Comirnaty vaccine has been provisionally approved by Medsafe. www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-vaccines

From 10 January 2022 in Australia, and from 17 January 2022 in New Zealand, all children from five years of age are eligible for COVID-19 vaccination. The approval of mRNA vaccines in children aged from 5 to 16 years has been made following careful evaluation of the available data supporting safety and efficacy.

Since 11 October 2021, Australians who are severely immunocompromised have been able to receive a third COVID-19 vaccine dose as part of their primary vaccination course to increase their protection against COVID-19 to the highest level.

Since late October 2021 booster doses of COVID-19 vaccines for all individuals 18 years and older have been approved. Whilst the original approval was a booster dose provided at least six months after the completion of a COVID-19 vaccine primary course of two doses, this has been changed in January 2022 to four months in Australia and New Zealand.

Approval of booster doses means that COVID-19 vaccines have been found safe and effective to boost protection for individuals aged 18 years and older through a booster dose provided after the completion of a COVID-19 vaccine primary course. The primary course can be any of the COVID-19 vaccines registered for use in Australia or New Zealand.

Q 3: Does mRNA which is used in the Pfizer and Moderna vaccines integrate into our own DNA?

No. The mRNA (messenger ribonucleic acid) in the Pfizer and Moderna COVID-19 vaccines is only taken up in the body of our cells, known as the cytoplasm, and is then quickly destroyed.

The mRNA is not taken up in the nucleus of our cells, which contains our DNA (deoxyribonucleic acid). The mRNA is coded to instruct our cells to produce the non-infectious SARS-CoV-2 coronavirus spike protein, which triggers an immune response to the spike protein, ready to protect you if you encounter the SARS-CoV-2 coronavirus.

Q 4: Will we become infected with the chimpanzee adenovirus that is used in the AstraZeneca vaccine?

No. The adenovirus in the AstraZeneca COVID-19 vaccine is the vehicle (like a taxi or uber) that carries the genetic material of the non-infectious SARS-CoV-2 coronavirus spike protein into the body of our cells, known as the cytoplasm.

This causes our cells to produce the spike protein, which triggers an immune response to the spike protein, ready to protect you if you encounter the SARS-CoV-2 coronavirus. The adenovirus cannot reproduce in humans and is destroyed.

Q 5: What are common side effects of vaccines?

Vaccinations can cause short-term mild side effects in some people.

Vaccines are usually given as an injection into the upper arm and common side effects include injection site reactions, such as local pain, redness and swelling.

Other side effects include fever, joint pain, muscle aches, headache, tiredness, or worsened eczema a day after vaccination.

These common side effects indicate the start of an immune response, which helps prevent people from getting COVID-19. Side effects do not usually require any treatment, other than paracetamol for fever or discomfort.

Questions about side effects of COVID-19 vaccines are answered on the following websites:

- <u>https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/is-it-true</u>
- <u>https://covid19.govt.nz/covid-19-vaccines/</u>

Q 6: What are the signs/symptoms of allergic reactions to vaccines?

Allergic reactions to COVID-19 vaccines are rare. However, if there is a high risk of an allergic reaction to one of the vaccines, it may be possible to have another vaccine, subject to availability and medical advice.

Mild to moderate allergic reaction signs/symptoms include rapid onset swelling of face, lips and/or eyes, tingling mouth, hives (urticaria) or welts, and abdominal pain/vomiting.

A mild to moderate allergic reaction may sometimes progress to a severe allergic reaction, known as anaphylaxis.

Anaphylaxis to vaccines is extremely rare, and is indicated by any one of the following signs:

- Difficult or noisy breathing
- Swelling of the tongue
- Swelling or tightness in throat*
- Wheeze or persistent cough
- Difficulty talking or hoarse voice
- Persistent dizziness or collapse*

*Some conditions can appear like allergic reactions, including non-allergic rashes, fainting and stress responses. Any suspected allergic reactions should be reported to the vaccination centre.

Q 7: How is anaphylaxis to vaccines treated?

Anaphylaxis can be life threatening and should always be treated as a medical emergency.

Most cases of anaphylaxis to vaccines occur within 20 to 30 minutes of vaccination, and respond to one or two doses of adrenaline (epinephrine).

If someone has anaphylaxis, they need immediate treatment with adrenaline, and the ASCIA First Aid Plan for Anaphylaxis should be followed <u>www.allergy.org.au/hp/ascia-plans-action-and-treatment#r2</u>

If a person who is at risk of anaphylaxis to foods, insects or drugs, has any of the symptoms of anaphylaxis after they have the COVID-19 vaccine, they should follow their ASCIA Action Plan for Anaphylaxis.

Health professionals who give vaccines in Australia and New Zealand should **all** be trained in the emergency treatment of anaphylaxis, and adrenaline should be readily available at **all** vaccination centres.

ASCIA Action Plans for Anaphylaxis, ASCIA First Aid Plans for Anaphylaxis and adrenaline injector instructions are available on the ASCIA website <u>www.allergy.org.au/anaphylaxis</u>

ASCIA anaphylaxis e-training is available at www.allergy.org.au/about-ascia/about-ascia-e-training

Q 8: What substances in COVID-19 vaccines can cause allergic reactions?

Polyethylene Glycol (PEG) also known as macrogol, is used to manufacture the Pfizer and Moderna COVID-19 vaccines.

- Different forms of PEG are found in tablets, laxatives, hand sanitiser gels, injectable corticosteroids and progesterone, cosmetics and bathroom products.
- PEG can cause contact dermatitis in some people.
- Allergic reactions to PEG are rare, but it is recognised as a hidden allergen that can trigger anaphylaxis to multiple classes of drugs.
- It is uncertain if PEG or another ingredient may be the cause of reported vaccine anaphylaxis.
- The estimated risk of anaphylaxis to the COVID-19 vaccine is extremely low, at around one in 100,000 doses, but it may be wise for people with known PEG allergy to request the other vaccine.

Polysorbate 80 is chemically related to PEG and is an ingredient in the AstraZeneca COVID-19 vaccine.

Widespread use of COVID-19 vaccines suggests that severe allergic reactions to the Pfizer, Moderna and AstraZeneca vaccines are very rare.

Q 9: What happens if you have a reaction to the first dose of the COVID-19 vaccine?

The Pfizer, Moderna, AstraZeneca and Novavax vaccines require a second dose, which provides more long-term protection from COVID-19.

After each dose there should be an observation period of 15 minutes:

- If you have a non-allergic reaction to the first dose you can still receive the second dose. These reactions include fainting (vasovagal syncope) and skin reactions other than hives (urticaria).
- If you have a mild or moderate allergic reaction, such as a skin reaction, including hives (urticaria), to the first dose, you should receive the second dose with a longer observation period, of at least 30 minutes.
- If you have anaphylaxis to the first dose, you should be referred to a clinical immunology/allergy specialist for assessment, before a second dose is considered.

Allergic reactions to COVID-19 vaccines are rare. However, if someone has an allergic reaction to one of the vaccines, it may be possible to have another vaccine, subject to availability and medical advice.

Q 10: Are COVID-19 vaccines safe for people with allergies?

The Pfizer, Moderna, AstraZeneca and Novavax vaccines are safe for people with allergies:

- There is no evidence that people with allergic conditions such as asthma, hay fever (allergic rhinitis), food allergy or insect sting allergy are at any greater risk of vaccine allergy compared to the general population.
- Unlike some other vaccines, there is no food, gelatin or latex in the COVID-19 vaccines that are currently available, and they are not grown in eggs.
- If a person has had an allergic reaction to another vaccine, this does not mean that they will also be allergic to the COVID-19 vaccine.
- People with a known PEG allergy or previous anaphylaxis to multiple drugs (medications) should see their clinical immunology/allergy specialist to assess and confirm their allergy. The AstraZeneca or Novavax vaccine may be a suitable alternative to the Pfizer or Moderna vaccines if PEG allergy is confirmed.

Q 11: Do allergy treatments need to be stopped to have a COVID-19 vaccine?

It is important that regular hay fever (allergic rhinitis), eczema (atopic dermatitis) and asthma treatments are continued when having the COVID-19 vaccine.

However, it is recommended that allergen immunotherapy (AIT) or venom immunotherapy (VIT) injections should not be given within 48 hours of the COVID-19 vaccine injection. This avoids confusion about the cause of side effects or allergic reactions, if they occur in response to the COVID-19 vaccine or immunotherapy.

Q 12: Are COVID-19 vaccines safe for people with immunodeficiencies or autoimmune conditions?

The Pfizer, Moderna, AstraZeneca and Novavax vaccines are safe for people with immunodeficiencies, and autoimmune conditions, who are not considered to be at greater risk of vaccine allergy compared to the general population.

People with immunodeficiencies and/or autoimmune conditions should follow the usual advice from their clinical immunology/allergy specialist or rheumatologist regarding vaccinations or ask for specific advice regarding the COVID-19 vaccine.

People with immunodeficiencies should have a booster dose after completion of their primary vaccination course (whether this was two or three doses) according to current guidelines.

In Australia a third COVID-19 vaccine dose has been recommended for people who are severely immunocompromised by the Australian Technical Advisory Group on Immunisation (ATAGI), which includes people with primary immunodeficiency (PID) disorders, also known as inborn errors of immunity (IEI).

The ATAGI recommendations have been prepared in consultation with ASCIA, and are available at: <u>https://www.health.gov.au/news/atagi-statement-on-the-use-of-a-3rd-primary-dose-of-covid-19-vaccine-in-individuals-who-are-severely-immunocompromised</u>

The recommended interval for the third dose is two to six months after the second dose of vaccine. People with PID/IEI who had a second dose more than six months ago should receive a third dose whenever this is feasible.

ATAGI also recommends a third COVID-19 vaccine dose for recipients of haematopoietic stem cell transplant (HSCT) or chimeric antigen receptor T-cell (CAR-T) therapy (within 2 years of transplantation), people on some Immunosuppressive therapies and some people with advanced or untreated HIV.

Q 13: Should immunodeficiency or autoimmune treatments be stopped to have a COVID-19 vaccine?

It is important that regular treatments for immunodeficiencies and autoimmune conditions are continued, because stopping these treatments can place people with these conditions at greater risk from COVID-19.

Vaccination should occur on a different day (if possible) from regular infusion treatments, such as immunoglobulin (Ig) or immunosuppressant infusions.

For example, people on monthly intravenous immunoglobulin (IVIg) may be advised by their specialist to be vaccinated two weeks after an IVIg infusion.

This avoids confusion about the cause of side effects or allergic reactions, if they occur in response to the COVID-19 vaccine or the infusion treatment.

Q 14: Can the COVID-19 vaccine be given if a person has other medical conditions?

COVID-19 vaccines have initially been tested in healthy adults, before being tested on more vulnerable people, to provide confidence that the vaccine is safe for use in the larger general population.

If a person is being treated for other medical conditions or is in a clinical trial, they should ask their doctor for advice regarding the COVID-19 vaccine.

Surgery guidelines recommend that people do not have major surgery and vaccines within one week of each other. This is because both surgery and the vaccine can cause a fever.

Q 15: Can the COVID-19 vaccine be given at the same time as the influenza (flu) vaccine?

Yes. As international borders open, the Australian Technical Advisory Group on Immunisation (ATAGI) has issued updated advice (in December 2021) for the rollout of influenza vaccines. With borders reopening and greater population movement, a resurgence of influenza activity is expected in 2022, outside of the usual influenza season. Therefore, ATAGI now recommends that influenza vaccines can be co-administered with COVID-19 vaccines. Subject to availability of influenza vaccines, an ideal time to vaccinate could be on the same day as a COVID-19 booster vaccine. For more details see https://www.health.gov.au/news/updated-atagi-advice-on-the-administration-of-seasonal-influenza-vaccines-in-2021-december-2021

Previously the preferred minimum interval between a dose of seasonal flu vaccine and a dose of a COVID-19 vaccine was seven days. This was to avoid confusion about the cause of side effects or allergic reactions, if they occur in response to the COVID-19 vaccine or the influenza vaccine.

Q 16: Are there any people who should not receive COVID-19 vaccines?

People who have anaphylaxis in response to the first dose of the COVID-19 vaccine should be referred to a clinical immunology/allergy specialist to be assessed before they consider receiving a second dose,

People with a confirmed allergy to ingredients in a vaccine (such as PEG) should discuss having another type of vaccine that does not contain that ingredient with their clinical immunology/allergy specialist.

Q 17: How long does immunity due to the COVID-19 vaccine last?

COVID-19 vaccine clinical trials show that the vaccines are very effective in preventing people from getting severe disease. However, there is limited information from clinical trials to tell us how long the immunity due to vaccination lasts and if vaccinated people can still spread the virus to other people. Developments in this area are being closely monitored.

Q 18: Do people still need to have the vaccine if they have already had COVID-19?

It is possible for people who have already had COVID-19 to have the vaccine. The vaccine can offer more protection or boost any antibodies (immunoglobulins) that the body has already made in response to COVID-19. Vaccination is therefore recommended even if a person has already had COVID-19.

Q 19: Will COVID-19 vaccines be effective against new variants of the SARS-CoV-2 coronavirus?

Clinical trials have shown that the vaccine stimulates the immune system to make antibodies (immunoglobulins) that are able to respond to a variety of mutations.

Technology used in vaccine development is adaptable to change if this occurs, in the same way that the influenza vaccine ingredients also change each season. Developments in this area are being closely monitored.

Q 20: How are COVID-19 vaccines recorded?

In Australia COVID-19 vaccinations will be recorded in an individual's Immunisation History Statement: https://www.servicesaustralia.gov.au/individuals/services/medicare/australian-immunisation-register/how-getimmunisation-history-statement

In New Zealand COVID-19 vaccinations will be recorded on the National COVID-19 Immunisation Register (CIR): <u>https://covid19.govt.nz/covid-19-vaccines/how-to-get-a-covid-19-vaccination/book-your-covid-19-vaccination/getting-proof-of-your-vaccination/</u>

Q 21: What other measures can prevent the spread of COVID-19?

Until we know more about how vaccines prevent the spread of COVID-19, and how long immunity lasts due to the vaccine, it is important that the following measures continue to be followed, even if you are vaccinated.

If you follow the actions listed below this will help reduce the spread of COVID-19 and other infections.

✓ Get vaccinated

Vaccination reduces the risk of developing COVID-19 and the spread of COVID-19.

✓ Wash hands regularly

It is important to wash hands regularly to reduce the spread of COVID-19 and other infections, even if you are vaccinated.

- Cover your mouth when you cough or sneeze and practice physical distancing Cover your mouth when you cough or sneeze and keep a physical distance from other people, to reduce the risk of inhaling droplets or aerosols that contain virus.
- Stay home if you are unwell and follow regulations
 People who are unwell should stay home, avoid contact with other people and follow local health regulations.
- ✓ Be aware of COVID-19 symptoms

If you have COVID-19 symptoms or have had contact with a person who has COVID-19, get tested and follow local health regulations.

✓ Seek medical help

If you have a positive COVID-19 test result, seek medical help and follow local health regulations.

For further information go to www.allergy.org.au/members/covid-19

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