



Australian Government



Information on COVID-19 Pfizer (Comirnaty) vaccine

About the vaccine

Comirnaty (Pfizer Australia Pty Ltd) is a vaccine that can prevent people from becoming ill from COVID-19. Comirnaty does not contain any live virus, and it cannot give you COVID-19. It contains the genetic code for an important part of the SARS-CoV-2 virus called the spike protein. After getting the vaccine, your body makes copies of the spike protein, and your immune system will learn to recognise and fight against the SARS-CoV-2 virus, which causes COVID-19.

To prevent COVID-19, everyone aged 16 years and older should get vaccinated, with a few exceptions specified in this information sheet. Vaccination is voluntary.

You can discuss any concerns or questions you have about COVID-19 vaccination with your immunisation provider and/or your GP before you receive the vaccine.

Benefits of the vaccine

A very large clinical trial showed that Comirnaty is effective in preventing COVID-19 in people aged 16 years and older. People who had two doses of Comirnaty were about 95 per cent less likely to get COVID-19 than people who did not get the vaccine. It was equally effective in people over the age of 65 years, and as people with some stable pre-existing medical conditions.

Protection against COVID-19 starts from about 2–3 weeks after the first dose. While one dose may give some protection, it may only last for the short-term. Two doses will give optimal protection. No vaccine is 100 per cent effective, so it is possible that you can still get sick from COVID-19 after vaccination. We do not know how long the protection from Comirnaty will last. We will learn more about this over time.

We currently do not know how effective COVID-19 vaccines are at preventing spread of the virus. This means that SARS-CoV-2 could potentially still infect a vaccinated person. Even if they have no symptoms or only mild symptoms they could still pass it on to others.



This is why it is important to continue other preventative measures like:

- physical distancing
- hand washing
- wearing a face mask
- COVID-19 testing and quarantine/isolation as required by your state/territory.

If you have been vaccinated with two doses of Comirnaty, you should still get a COVID-19 test if you have symptoms that meet testing criteria according to your local health authority (e.g. fever, cough, sore throat).

Who can receive this vaccine

People aged 16 years and older can receive this COVID-19 vaccination.

Certain groups of people are prioritised to receive vaccines first because they are at higher risk of exposure to the COVID-19 virus (e.g. workers in border or quarantine facilities, a healthcare facility or aged-care facility) or severe illness and death from COVID-19 (e.g. are older or have underlying medical conditions).

Who should not receive this vaccine

You should not receive this vaccine if you have had:

- anaphylaxis (a type of severe allergic reaction) to a previous dose of the same COVID-19 vaccine, or
- anaphylaxis after exposure to any component of a COVID-19 vaccine.

Precautions for vaccination

If **you have a history of anaphylaxis** (a type of severe allergic reaction) to any substance, or you **have an adrenaline autoinjector** (e.g. an EpiPen), you will need to stay for 30 minutes of observation after you have your vaccine. In the very rare cases where severe allergic reactions were reported after Comirnaty, these reactions usually occurred in the first 30 minutes after vaccination.

If **you have a bleeding disorder** or you are **taking a blood-thinning medication** (anticoagulant), tell your immunisation provider. Your immunisation provider can help determine whether it is safe for you to have an intramuscular injection, and to decide the best timing for injection.

Special circumstances to discuss before vaccination

People with weakened immune systems (immunocompromise)

People with immunocompromise includes those who have a medical condition that weakens their immune system or may be taking medications that suppress their immune system.

The Australian Government strongly recommends people with immunocompromise receive COVID-19 vaccination. Comirnaty is not a live vaccine. It is safe in people with immunocompromise.

People with immunocompromise, including those living with HIV, have a higher risk of severe illness from COVID-19, including a higher risk of death.

Clinical trials for Comirnaty did not include people with immunocompromise, except for a small group of people with stable HIV. We do not know if Comirnaty is as effective in people with immunocompromise compared to the rest of the population. It is possible that Comirnaty might not be as effective in people with immunocompromise as it is in the general population. It is

important to continue other preventative measures such as physical distancing after vaccination.

Women who are pregnant, breastfeeding or planning pregnancy

If you are breastfeeding, you can have Comirnaty. You do not need to stop breastfeeding after vaccination. If you are planning pregnancy, you can also have Comirnaty. You do not need to have a pregnancy test before vaccination.

Pregnant women are not routinely recommended to have Comirnaty, but can consider vaccination particularly if they are at higher risk of getting COVID-19 e.g. due to their occupation, or if they have risk factors for severe illness, e.g. due to pre-existing medical conditions.

If you are pregnant, your healthcare provider can help you to assess the benefits and risks of vaccination.

People with a history of COVID-19

If you have had COVID-19, tell your immunisation provider. Your provider may advise to wait for up to six months before having a COVID-19 vaccine.

Comirnaty and children

Comirnaty has only been provisionally approved for use in people aged 16 years or older, and cannot be given to younger people. Clinical trials are currently testing Comirnaty in older children, but we do not yet have the results of this trial. The risk of COVID-19, especially severe disease, in children is lower than in older adolescents and adults.

Ensuring the safety of Comirnaty

Increased funding for vaccine research, and access to very large numbers of volunteers for research studies have meant Comirnaty and other COVID-19 vaccines have been developed quickly. A large clinical trial involving around 44,000 people confirmed Comirnaty to be safe and effective.

The Therapeutic Goods Administration (TGA) assesses all vaccines in Australia. This ensures that in order for a vaccine to be approved it is safe, effective and manufactured to a very high quality standard. A description of the process for approval of COVID-19 vaccines is available on the [TGA website](#).

The safety of COVID-19 vaccines will be monitored continuously throughout the COVID-19 vaccination program. Suspected side effects can be reported to your vaccination provider or other healthcare professional. They will then make a formal report on your behalf to your state or territory health department or directly to the Therapeutic Goods Administration (TGA).

If you would prefer to report it yourself, please visit the [TGA website](#) for information on how to report suspected side effects associated with COVID-19 vaccines.

WHAT TO EXPECT ON COVID-19 VACCINATION DAY AT YOUR RESIDENTIAL AGED CARE FACILITY

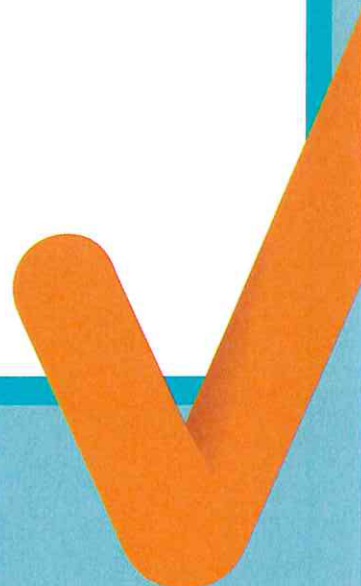
Information for residents, families, carers and loved ones

The Australian Government has a strategy to deliver COVID-19 vaccines to everyone living in Australia.

Residential aged care workers and residents will be among the first people who can choose to receive a COVID-19 vaccine. This is part of the first phase ([Phase 1a](#)) of [Australia's COVID-19 vaccine national roll-out strategy](#).

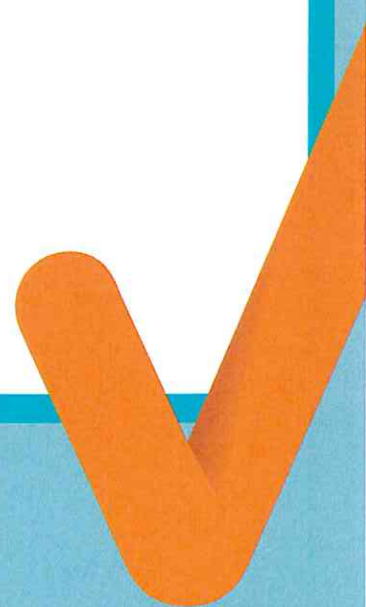
COVID-19 vaccination for residential aged care workers and residents will be done at residential aged care facilities. Your residential aged care facility will let you know when your vaccination day will be.

This document gives you, your family, carers and loved ones information about what you can expect in the lead up to, and on your vaccination day.



Before vaccination day

- The Australian Government will organise for vaccines to be delivered to your residential aged care facility.
- The Australian Government has also recruited a clinical workforce who will visit your residential aged care facility and administer the vaccine to residents and staff. These clinical workers will work very closely with your facility in the lead up to vaccination day to plan and make sure the vaccination day runs safely and efficiently.
- Your residential aged care facility will ask you, and your substitute decision maker (if one is in place), to consent to receiving the COVID-19 vaccine.
 - Information is available to you so you can make an informed decision about COVID-19 vaccination. If you haven't already been provided with this information by your facility, you can find a copy on the [Department of Health's website](#).
 - Before giving consent, you, your family, carers and decision makers can also choose to engage with clinical staff at your facility, a GP or other health professionals to discuss the benefits and risks of vaccination, and whether it is suitable for you to receive the COVID-19 vaccine.
- Clinical staff at your facility will check your health to make sure it is suitable for you to receive the vaccine. If your facility has any concerns about your health they will consult a GP. You can also choose to talk to your GP at any time about your health and COVID-19 vaccination.
- If you consent to receiving the COVID-19 vaccine your residential aged care facility will register you to receive the vaccine. Your facility will manage all of the arrangements for the vaccination day with the vaccine workforce.
- The COVID vaccine does not need to be prescribed for you by your GP.
- You have the right to access an aged care advocate. This service through OPAN is free, confidential and independent of the government and aged care providers. Aged Care Advocates in your state or territory are available on 1800 700 600 or at opan.com.au



On the day of vaccination

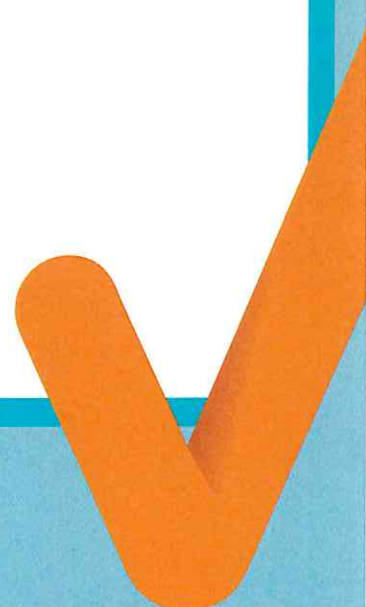
- If you intend to receive the vaccine, clinical staff at your facility will check to make sure you are well on vaccination day. If you develop a medical issue on the day of vaccination your residential aged care facility may consult with a GP to determine whether your vaccination can go ahead, or if it needs to be delayed until a later date.
- You may choose to have a support person come to your residential aged care facility on the vaccination day to help and support you. This could include someone to translate information or provide reassurance if you feel concerned.
- As with any vaccine, you may have some side effects after receiving a COVID-19 vaccine. Information about what to expect after your vaccination will be given to you by the clinical worker administering your vaccine. This information is also available on the [Department of Health's website](#).
- After your vaccination, staff at your residential aged care facility will be monitoring you closely. If you feel unwell after receiving your vaccine make sure you let them know.

Keep up to date with trusted information

You can find more information, including translated information on the Department of Health's [COVID-19 vaccines website](#). You can also subscribe to receive [COVID-19 vaccines updates](#).

You can also call the National Coronavirus Helpline on 1800 020 080, and ask for an interpreter if needed.

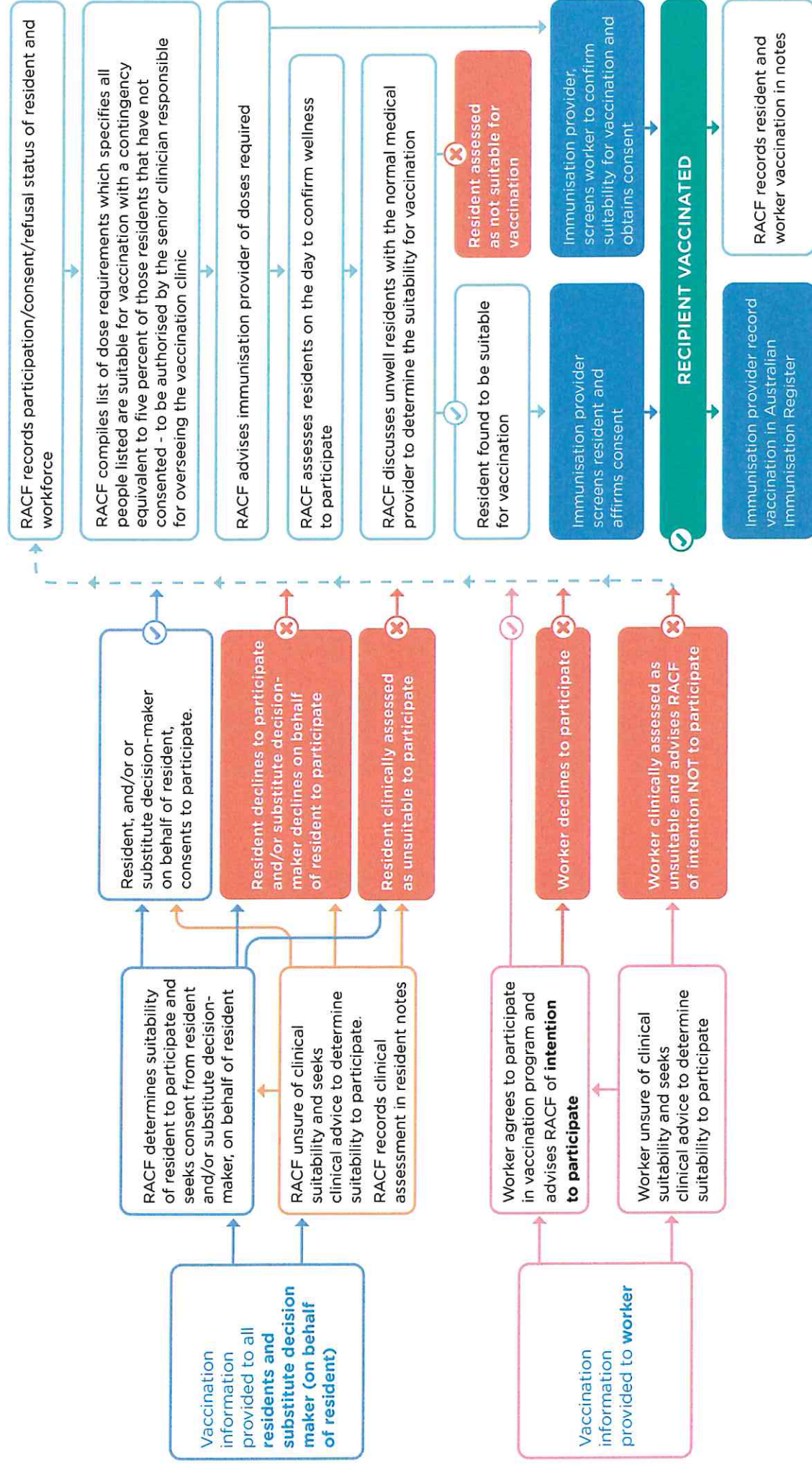
The [Older Persons Advocacy Network](#) (OPAN) is available if you want to talk about any issues or concerns you have in relation to COVID-19 or if you need help engaging with your aged care provider. Call 1800 237 981, 6am-10pm (AEDT), 7 days a week or email covid@opan.com.au.



CONSENT PROCESS

COVID-19 vaccine program for aged care

Prioritising Residential Aged Care



CONSENT GUIDANCE MATERIAL FOR RESIDENTIAL AGED CARE

National COVID-19 Vaccination Program

COVID-19 is a very contagious virus that can cause serious respiratory infection, particularly in older people. Immunisation is a safe and effective way to help protect you and the residents in your care from serious disease caused by the COVID-19 virus.

Getting vaccinated is voluntary, but strongly encouraged.

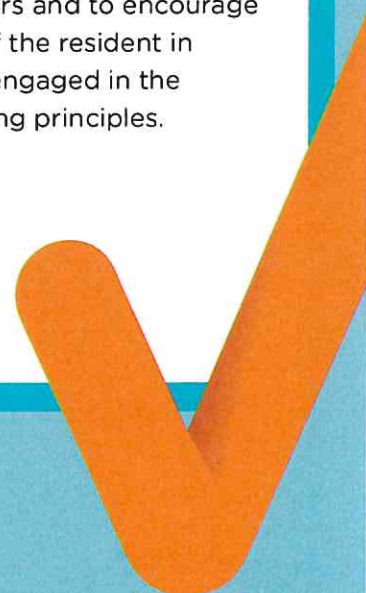
Prioritising residential aged care workers and residents

Residential aged care workers and residents will be among the first people who can choose to receive a COVID-19 vaccine. This is part of the first phase (Phase 1a) of [Australia's COVID-19 vaccine national roll-out strategy](#).

Consent

As with all other vaccines, valid consent is required before administering each COVID-19 vaccine dose. Written consent is not mandatory, but it is preferable. The Australian Government has prepared a written consent form which can be used to provide consent to participate in the vaccination program.

For some residents, consent will need to be sought from a substitute decision maker and through a supported decision making process. Decisions by substitute decision makers should take into account the individual's wishes and preference around vaccination. This includes considering their decisions to have vaccinations for themselves previously. Even when someone has a level of cognitive decline, the preference is to discuss with them their wishes and preferences in relation to vaccination. Facilities should seek to engage early with substitute decision makers and to encourage that decision on vaccination occur in line with the known or likely preferences of the resident in preparation of the vaccine program. Wherever possible, the resident should be engaged in the discussions and decision to have a vaccine, in line with supported decision making principles.



Prioritising Residential Aged Care

Residents, their family, carers and decision makers may wish to engage with clinical staff at the facility, their GP, or other health professionals to discuss the risks and benefits of vaccine, and the clinical suitability of the resident to receive the vaccine, to ensure consent is informed. The COVID-19 vaccine does not need to be prescribed by a GP for residents and workers.

For further information about consent, refer to the [Australian Immunisation Handbook - Preparing for vaccination - Valid consent](#).

A decision to not get vaccinated will not affect anyone's access to safe, quality residential aged care. The Charter of Aged Care Rights supports older people in their decisions about their care and is available [here](#).

Guidance Materials

This pack contains guidance materials, including a consent form and vaccine information sheet, which can be provided to workers, residents, families, carers, guardians, advocates and others to inform participation in the National COVID-19 Vaccination Program. Some materials have been developed for all Australians, by the Australian Technical Advisory Group on Immunisation (ATAGI). ATAGI advises the Minister for Health on a range of immunisation issues, including COVID-19.

The guidance materials include:

- Consent form (ATAGI) – for workers and residents wanting to participate in the COVID-19 Vaccination Program, it is recommended a consent form is completed
- Information on COVID-19 Pfizer (Comirnaty) vaccine – fact sheet
- Pre vaccine information (ATAGI)
- Post vaccine information (ATAGI)
- Consent – patient resource (ATAGI)
- Consent – process map

The information in this pack should be provided to the resident, along with substitute decision makers, to assist them make informed decisions about COVID-19 vaccine, in-line with the wishes and preferences of the person they are acting on behalf of.

For advice on how to best support residents living with dementia or cognitive impairment contact the National Dementia Helpline on 1800 100 500 (Monday-Friday 8:00am-8:00pm). The Older Persons Advocacy Network (OPAN) provides free, confidential and independent advocates who can discuss an older person's rights surrounding COVID-19 vaccination. OPAN is available on 1800 700 600.

Learn more at the Department of Health's [COVID-19 vaccines website](#) and subscribe to the [COVID-19 vaccines update](#).



Australian Government



After your COVID-19 vaccination

About the vaccine

Today you have received the Comirnaty (Pfizer Australia Pty Ltd) vaccine.

This vaccine can prevent people from becoming ill from COVID-19. Comirnaty does not contain any live virus, and it cannot give you COVID-19. It contains the genetic code for an important part of the SARS-CoV-2 virus called the spike protein. After getting the vaccine, your body makes copies of the spike protein, and your immune system will learn to recognise and fight against the SARS-CoV-2 virus.

What to expect after vaccination

As with any vaccine, you may have some side effects after receiving a COVID-19 vaccine.

Common side effects after **Comirnaty** include:

- pain or swelling at the injection site
- tiredness
- headache
- muscle pain
- chills
- fever
- joint pain.

Less common side effects after **Comirnaty** include:

- redness at the injection site
- nausea
- enlarged lymph nodes
- feeling unwell
- pain in limb
- insomnia
- itching at the injection site.



These side effects are usually mild and usually go away within one or two days. If you experience pain at the injection site or fever, headaches or body aches after vaccination, you can take paracetamol or ibuprofen. These help reduce the above symptoms (you do not need to take paracetamol or ibuprofen before vaccination). If there is swelling at the injection site, you can use a cold compress.

Rare side effects that have been reported after **Comirnaty** are:

- Severe allergic reaction (anaphylaxis)
- Temporary one-sided facial drooping (also called Bell's palsy).

You should seek medical attention after vaccination if:

- You think you are having an allergic reaction. Call 000 if you experience severe symptoms, such as difficulty breathing, wheezing, a fast heartbeat or collapsing.
- You are worried about a potential side effect or have new or unexpected symptoms.
- You have an expected side effect of the vaccine which has not gone away after a few days.

For symptoms which are not urgent, you can see your regular healthcare provider (usually your GP).

Vaccine safety monitoring and reporting side effects

Suspected side effects can be reported to your vaccination provider or other healthcare professional. They will then make a formal report on your behalf to your state or territory health department or directly to the Therapeutic Goods Administration (TGA).

If you would prefer to report it yourself, please visit the [reporting suspected side effects associated with a COVID-19 vaccine webpage](#) on the TGA website and follow the directions on the page.

COVID-19 testing after vaccination

Some side effects from COVID-19 vaccination might be similar to symptoms of COVID-19 (e.g. fever), though Comirnaty does not contain any live virus and cannot cause COVID-19. You may not need to get a COVID-19 test or isolate if you develop general symptoms like fever, headache or tiredness in the first two days after vaccination and if you are sure that you don't have any respiratory symptoms (e.g. runny nose, cough, sore throat, loss of smell or loss of taste). However, you should check the current guidelines in your state/territory for the most up-to-date information. This advice may change in the event of a COVID-19 outbreak in your local area. You may still need to get a COVID-19 test if you meet other criteria, e.g. you are a close contact of a known COVID-19 case. If in doubt, seek medical assessment.

Remember your second appointment

It is important that you receive two doses of Comirnaty (Pfizer), at least three weeks apart. Maximum protection against COVID-19 will not occur until at least a week after your second dose.

How is the information you provide at your appointment used

For information on how your personal details are collected, stored and used visit <https://www.health.gov.au/covid19-vaccines>