Australian Government

COVID-19 VACCINATION

Pfizer COVID-19 vaccine for children aged 5 to 11: information for parents and guardians

Version 1

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About the vaccine

The **Comirnaty (Pfizer)** COVID-19 vaccine can prevent children from becoming ill from COVID-19. The vaccine schedule for children is 2 doses, given 8 weeks apart. This interval can be shortened in special circumstances to a minimum of 3 weeks.

The Pfizer COVID-19 vaccine does not contain any live virus and cannot cause 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 child's body makes copies of the spike protein. Your child's immune system will then learn to recognise and fight against the SARS-CoV-2 virus, which causes COVID-19. The body breaks down the genetic code quickly.

Vaccination is voluntary and free. You can discuss any concerns or questions you have about COVID-19 vaccination for your child with your immunisation provider or your GP before they receive the vaccine.

Benefits of the vaccine

Although most children who get COVID-19 have a mild illness, some children, including those with no history of health conditions, can become very unwell with COVID-19. Children with some medical conditions (including chronic lung disease, congenital heart disease, neurological disease, obesity and immunocompromise) have a higher risk of becoming seriously ill or needing to be admitted to hospital if they get COVID-19.

In the United States, almost 6,000 cases have been reported of a rare but serious condition associated with COVID-19 called paediatric inflammatory multisystem syndrome temporally

associated with SARS-CoV-2 (PIMS-TS). This is also known as multisystem inflammatory syndrome in children (MIS-C). Most children with PIMS-TS/MIS-C need to be treated in hospital and a small proportion of children with PIMS-TS/MIS-C have died. Most people who contracted PIMS-TS/MIS-C were aged between 5 and 11 years.

A clinical trial showed that the Pfizer COVID-19 vaccine is effective in preventing COVID-19 in children aged 5 to 11 years. Children who had 2 doses were about 91 percent less likely to get sick from COVID-19 than children who did not get the vaccine.

Children can transmit the virus to others, including older family members who are at higher risk of becoming seriously ill. Infected children often miss out on school and other activities.

When children are vaccinated, the risk that they will become infected and spread COVID-19 to family members, friends and others around them is reduced. Reducing the spread of COVID-19 may help to minimise school closures and other disruptions to extra-curricular and social activities which significantly impact on the wellbeing of children and their families.

Getting your child vaccinated will also help with the return to normal activities without disruptions, like needing to isolate after contact with someone with COVID-19, and will support the safe enjoyment of other activities, like overseas travel.

Protection against COVID-19 starts from about 2 to 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 improved protection.

No vaccine is 100 per cent effective, so it is possible that your child could still get sick from COVID-19 after vaccination. Evidence shows, however, that people who are vaccinated are much less likely to get seriously ill from COVID-19 or need to go to hospital.

Safety of the vaccine

The safety of the Pfizer COVID-19 vaccine has been tested in more than 3,500 children aged 5 to 11 years in the clinical trial and a safety expansion group. The trial showed that the vaccine is safe in children and most side effects were mild.

The Pfizer COVID-19 vaccine for children aged 5 to 11 years is a smaller dose (one third of the active component of the vaccine) than the vaccine for people aged 12 years and over.

In the United States, vaccination of children aged 5 to 11 years with the Pfizer COVID-19 vaccine started on 4 November 2021. As at 9 December 2021, more than 5 million children in this age group have received at least one dose and more than 2 million have received both doses of the Pfizer COVID-19 vaccine. No specific safety concerns have been identified in this age group in this large, real-world population, where the number of children vaccinated is already greater than the approximately 2.3 million children aged 5–11 years in Australia.

Expected side effects in the first one to two days after vaccination are less common in children than in teenagers and young adults. The most common side effects include a sore arm, headache and fatigue. These usually go away on their own or are treated with over the counter medication like paracetamol or ibuprofen. Children don't usually need to see a doctor for these mild side effects after receiving a COVID-19 vaccine.

The Pfizer COVID-19 vaccine has a very rare risk of heart inflammation (called myocarditis or pericarditis). Myocarditis and/or pericarditis occurs very rarely in younger people, including adolescents and children 12 years of age and older, who have had the Pfizer Comirnaty vaccine

or the Moderna Spikevax vaccine. It is more common after dose 2 and in males. In the USA, from data reported through to 11 June 2021, the rate of myocarditis/pericarditis in female adolescents aged 12-17 years was 9.1 per million doses, and in male adolescents aged 12-17 years 66.7 per million doses of an mRNA COVID-19 vaccine given. The rate and severity of myocarditis in children is expected to be lower than that in adolescents, and more mild. Myocarditis is more commonly seen in males under 30 years of age after the second dose. Most people who have had these conditions after their vaccine have recovered fully.

The clinical trial in children aged 5 to 11 years did not have enough participants to assess rates of myocarditis or pericarditis following vaccination with the Pfizer COVID-19 vaccine, but no specific safety concerns have been identified so far from millions of doses of this vaccine administered overseas to children aged 5 to 11 years. The benefits of vaccination outweigh this very rare risk, and vaccination is still recommended for all eligible age groups.

The Therapeutic Goods Administration (TGA) assesses all vaccines in Australia. For a vaccine to be approved, the TGA must assess that 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 at: www.tga.gov.au.

The safety of COVID-19 vaccines has been, and will continue to be, monitored throughout the COVID-19 vaccination program, including for children.

For current information on the frequency and severity of myocarditis and pericarditis after the Pfizer COVID-19 vaccine, see the Australian Technical Advisory Group on Immunisation (ATAGI) weekly COVID-19 meeting updates, available at: www.health.gov.au/committees-and-groups/australian-technical-advisory-group-on-immunisation-atagi#statements.

Who should not receive this vaccine?

Your child should not receive the Pfizer COVID-19 vaccine if they have had:

- **anaphylaxis** (a type of severe allergic reaction) to a previous dose of the Pfizer COVID-19 vaccine
- **anaphylaxis after exposure to any component of the vaccine**, including polyethylene glycol (PEG)
- **any other serious adverse event** that an experienced immunisation provider or medical specialist has confirmed was caused by a previous dose of the Pfizer COVID-19 vaccine, without another cause identified.

Precautions for vaccination

Children with certain conditions may need additional precautions such as staying for 30 minutes of observation after having their vaccine or consulting an allergy specialist. Tell your immunisation provider if your child has had:

- an **allergic reaction to a previous dose** or to a component of the Pfizer COVID-19 vaccine
- **anaphylaxis to other vaccines or to other medicines** – your provider can check to ensure there are no common components with the COVID-19 vaccine your child is receiving
- **confirmed mastocytosis** with recurrent anaphylaxis that requires treatment.

Tell your immunisation provider **if your child has a bleeding disorder** or is **taking a blood-thinning medication** (anticoagulant). This will help them determine whether it is safe for your child to have an intramuscular injection and help decide the best timing for injection.

Special circumstances to discuss before vaccination

Children with heart conditions

Children with a history of any of the following conditions can receive the Pfizer COVID-19 vaccine. You should seek advice, however, from a GP, immunisation specialist or cardiologist about the best timing of vaccination and whether any additional precautions are recommended.

- Recent (within the past 3 months) myocarditis or pericarditis (heart inflammation)
- Acute rheumatic fever (with active heart inflammation) or acute rheumatic heart disease
- Acute decompensated heart failure.

Tell your doctor if your child has had myocarditis or pericarditis diagnosed after a previous dose of the Pfizer COVID-19 vaccine.

Children with weakened immune systems (immunocompromise)

It is strongly recommended that children with immunocompromise receive COVID-19 vaccination. The Pfizer COVID-19 vaccine is not a live vaccine. It is safe in children with immunocompromise.

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

Some children with immunocompromise may have a reduced immune response to the vaccine, so it is important to consider other preventative measures, such as physical distancing, after vaccination.

Children with a history of COVID-19

If your child has had COVID-19 in the past, tell your doctor or immunisation provider. COVID-19 vaccination is still strongly recommended in children who have already had COVID-19 infection. COVID-19 vaccination can be given after recovery from the infection, or can be deferred for up to six months after the acute illness (confirmed with a COVID-19 test). This is because evidence suggests that past infection reduces the risk of reinfection for at least six months.

Children who have recently received another vaccine

Children can safely receive other vaccines any time before, after or at the same time as their COVID-19 vaccine. If your child has recently received another vaccine (within the last 7 days), it is best to let your immunisation provider know so they can correctly assess any side effects.

Children who turn 12 before their second dose

The Pfizer COVID-19 vaccine for children aged 5 to 11 years contains a smaller dose of the active vaccine component compared with the dose for people aged 12 years and over. It is important that your child gets the correct vaccine for their age. If they received their first dose when they were 11 years old, and had their 12th birthday before their second dose, it is safe for them to receive the Pfizer COVID-19 vaccine for people aged 12 years and over for their second dose. This is also the usual practice for other types of vaccines where there are different dose strengths for different age groups.

What to expect after vaccination

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

Common side effects after the **Pfizer COVID-19 vaccine** in children include:

- pain, redness or swelling at the injection site
- tiredness
- headache
- fever and chills.

Less common side effects after the **Pfizer COVID-19 vaccine** in children include:

- joint pain
- muscle pain
- vomiting.

These side effects are usually mild and go away within one or two days.

If your child experiences pain at the injection site or fever, headaches or body aches after vaccination, they can take paracetamol or ibuprofen. These help to reduce some of the above symptoms (paracetamol or ibuprofen does not need to be taken before vaccination). If there is swelling at the injection site, a cold compress can be applied.

Rare side effects reported after the **Pfizer COVID-19 vaccine** include:

- severe allergic reaction (anaphylaxis)
- myocarditis (inflammation of the heart muscle)
- pericarditis (inflammation of the outer lining of the heart).

You should seek medical attention after vaccination if your child has:

- symptoms of a severe allergic reaction, such as difficulty breathing, wheezing, a fast heartbeat, or if your child collapses
- chest pain, pressure or discomfort, irregular heartbeat, skipped beats or 'fluttering', fainting, shortness of breath, pain with breathing
- new or unexpected symptoms, or if you are worried about a potential side effect
- an expected side effect of the vaccine that has not gone away after a few days, like headache, fever or chills.

For non-urgent symptoms, you can see your regular healthcare provider (e.g. your GP).

Vaccinated people can still get COVID-19. Even if they have no symptoms, or only mild symptoms, they could still pass the virus on to others. This is why it is important after vaccination to continue other preventative measures, such as:

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

If your child has been vaccinated, they should still get a COVID-19 test if they have symptoms that meet your local health authority's testing criteria.

Vaccine safety monitoring and reporting side effects

You may be contacted by SMS or email in the week after your child has received each dose of the vaccine to see how they are feeling. This is part of our ongoing monitoring of the safety of COVID-19 vaccines.

You can report suspected side effects that your child experiences to your vaccination provider or other healthcare professional. They will then make a formal report on your child's behalf to your state or territory health department and/or the TGA.

If you would prefer to report it yourself, please visit www.tga.gov.au/reporting-suspected-side-effects-associated-covid-19-vaccine and follow the directions on the webpage.

COVID-19 testing after vaccination

Some side effects from COVID-19 vaccination might be similar to symptoms of COVID-19 (e.g. fever). However, the Pfizer COVID-19 vaccine does not contain any live virus and cannot cause COVID-19.

Your child may not need to get a COVID-19 test or isolate if:

- they develop general symptoms like fever, headache or tiredness in the first 2 days after vaccination
- you are sure that they 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 if there is a COVID-19 outbreak in your local area. Your child may need to get a COVID-19 test if they meet other criteria, e.g. if they are a close contact of a known COVID-19 case. If in doubt, seek medical assessment.

Remember your next appointment

It is important that your child receives 2 doses of the Pfizer COVID-19 vaccine, 8 weeks apart, for their primary course. The dosing interval can be shortened to a minimum of 3 weeks in certain situations, e.g. as part of a local outbreak response or before your child starts any immunosuppressive treatment. Your provider will advise if your child's second dose should be given earlier.

The second dose is likely to prolong the duration of protection against COVID-19. Unless there are special circumstances, it is better for your child to get their second dose 8 weeks after the first (rather than a shorter interval) because better immune responses are more likely after a longer interval.

How your information is used and recorded

For information on how your child's personal details are collected, stored and used visit www.health.gov.au/using-our-websites/privacy/privacy-notice-for-covid-19-vaccinations.

If your child is getting their vaccination in a pharmacy, the pharmacy must share some of your child's personal information with the Pharmacy Programs Administrator so they can claim payment from the Australian Government. More information about why this is needed and what information is shared is provided at the link above.

By law, the person giving your child's vaccination must record it on the Australian Immunisation Register. You can view your child's vaccination record online through your:

- Medicare account
- MyGov account
- My Health Record account (you can register for this with a Medicare number or an Individual Healthcare Identifier).

Further information

If you would like more detailed information about vaccinating your child against COVID-19, the following websites have some useful information:

Is it true? Get the facts on COVID-19 vaccines: www.health.gov.au/initiatives-and-programs/covid-19-vaccines/is-it-true

FAQs about COVID-19 and COVID-19 vaccination in children: www.ncirs.org.au/covid-19/covid-19-and-children-frequently-asked-questions

Information about COVID-19 vaccination in children: https://mvec.mcri.edu.au/references/covid-19-vaccination-in-children/

COVID-19 vaccines for children and teens (CDC): www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/children-teens.html