



Pfizer COVID-19 vaccine for children aged 6 months to 4 years: information for parents and guardians

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About the vaccine

The **Comirnaty (age 6 month to 4 years) (Pfizer)** COVID-19 vaccine can prevent children becoming seriously ill from COVID-19. Children should have 3 doses of the vaccine, with 8 weeks between each dose. Each dose for children aged 6 months to 4 years contains about one third of the dose given to children aged 6 years and older.

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 with your immunisation provider or your GP before your child receives the vaccine.

Benefits of the vaccine

Although most children who get COVID-19 have a mild illness, some children can become very unwell. Some children have a higher risk of serious illness from COVID-19. This includes children with complex or multiple health conditions, severe immunocompromise, or disability with significant or complex health needs.

In a clinical trial, children in the trial who received the Pfizer vaccine were about 80% less likely to get symptomatic COVID-19 than children who did not have the vaccine.

Protection against COVID-19 starts from about 2 to 3 weeks after the first dose. While one or two doses may give some protection, it may be short-lived. Three doses of the Pfizer vaccine will improve protection.

It is possible that your child could still get sick from COVID-19 after vaccination. But evidence shows 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 3,000 children aged 6 months to 4 years in a clinical trial. The trial showed that the vaccine is safe in children aged 6 months to 4 years. Most side effects were mild to moderate.

Side effects are less common in children aged 6 months to 4 years than in older children, teenagers and young adults who received the Pfizer COVID-19 vaccine. The most common side effects in children aged 2 to 4 years are injection site pain (affecting around 30% of children) and tiredness (affecting around 30% of children). The most common side effects in infants and toddlers aged 6 to 23 months are irritability (affecting around 50% of infants and toddlers), drowsiness (affecting 20% to 27% of children) and decreased appetite (affecting around 20% of children).

If your child experiences any discomfort or fever after vaccination, you can give them over-the-counter medication such as paracetamol or ibuprofen as required. Children do not usually need to see a doctor for these mild side effects after receiving a COVID-19 vaccine.

Some COVID-19 vaccines, including the Pfizer vaccine, have a very rare risk of heart inflammation (called myocarditis or pericarditis). These conditions are most commonly seen in adolescents and young adults, and are very rare in children under 12 years of age. The clinical trial in children aged 6 months to 4 years did not have enough participants to assess rates of heart inflammation after vaccination with the Pfizer COVID-19 vaccine. The benefits of vaccination are considered to outweigh this potential risk for infants and children in this age group who are at increased risk of severe illness from COVID-19.

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

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 mRNA vaccine** (that is, the Moderna or Pfizer COVID-19 vaccines)
- **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 to take extra precautions after vaccination, 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).

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, but you should seek advice from a GP, immunisation specialist or cardiologist about the best timing of vaccination and whether any additional precautions are recommended:

- myocarditis or pericarditis (heart inflammation) within the last 3 months
- acute rheumatic fever within the last 3 months
- acute heart failure.

Infants and children with congenital heart disease can be vaccinated without delay in the majority of cases. Parents should check with their cardiologist if they have doubts or questions.

Children with weakened immune systems (immunocompromise)

It is strongly recommended that children with immunocompromise have a 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 preventive measures after vaccination, such as physical distancing.

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 high-risk infants and children who have already had COVID-19. You should wait 3 months after a confirmed infection before your child receives a COVID-19 vaccine dose. Your child is likely to be protected from reinfection for at least

3 months after infection. But this protection will reduce over time and vaccination is important to maintain protection.

Children who have recently received another vaccine

It is preferable to separate the Pfizer vaccine from other vaccines by 7 to 14 days.

Tell your immunisation provider if your child has received another vaccine within the past 14 days.

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 (occurring in more than 1 in 5 children) after the **Pfizer COVID-19 vaccine** in children include:

In young children aged 3 to 5 years:

- pain at the injection site
- fatigue or tiredness

In infants and very young children aged 6 months to less than 3 years:

- irritability
- sleepiness
- loss of appetite

About one in 100 children may experience swollen or tender lymph nodes, particularly in the armpit or groin.

These side effects are usually mild to moderate and go away within one or 2 days.

If your child experiences pain at the injection site, fever, headaches or body aches after vaccination, they can take paracetamol or ibuprofen. These help to reduce some of the 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** reported in other age groups 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, or reduced level of consciousness
- shortness of breath or chest pain
- 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, such as headache, fever or chills

For non-urgent symptoms, you can see your regular healthcare provider (such as 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 preventive 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 any side effects 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 (such as 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, AND
- you are sure that they don't have any respiratory symptoms (such as a runny nose, cough, sore throat, loss of smell or loss of taste).

Check the current guidelines in your state or 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, such as 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 3 doses of the Pfizer COVID-19 vaccine, 8 weeks apart, for their primary course.

The dosing interval can be shortened to a minimum of 4 weeks in certain situations. Your provider will advise if your child's second dose should be given earlier.

All 3 doses are required for the best protection against COVID-19. Unless there are special circumstances, it is better for your child to get each dose 8 weeks apart (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.

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/>

Consent form for Pfizer COVID-19 vaccination: children aged 6 months to 4 years

Before you fill out this form, make sure you read the information above on the Comirnaty (Pfizer) COVID-19 vaccine.

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Consent checklist	Yes	No
1. Has your child recently been sick with a cough, sore throat or fever, or been feeling unwell in any way?	<input type="checkbox"/>	<input type="checkbox"/>
2. Has your child had COVID-19 before?	<input type="checkbox"/>	<input type="checkbox"/>
3. Has your child had a COVID-19 vaccination before?	<input type="checkbox"/>	<input type="checkbox"/>
4. Has your child had a serious reaction to a vaccine or medication?	<input type="checkbox"/>	<input type="checkbox"/>
5. Does your child have a weakened immune system (immunocompromise) or any immune disorders?	<input type="checkbox"/>	<input type="checkbox"/>
6. Does your child have a bleeding disorder or other blood disorder, or take any medicine to thin their blood?	<input type="checkbox"/>	<input type="checkbox"/>
7. Has your child ever had any problems with their heart?	<input type="checkbox"/>	<input type="checkbox"/>
8. Are you a parent/guardian/substitute decision maker who has the authority to provide consent for vaccination on behalf of this child?	<input type="checkbox"/>	<input type="checkbox"/>

If you answered **Yes** to any of questions 1 to 7, your child may still be able to receive the Pfizer COVID-19 vaccine. However, you should talk to your child's GP, immunisation specialist or cardiologist first to discuss the best timing of vaccination and whether any additional precautions are needed.

Consent to receive COVID-19 vaccine

I confirm that:

- I have received and understood information provided to me on Pfizer COVID-19 vaccination for the child named above.
- None of the above conditions apply to this child, or I have discussed these conditions and any other special circumstances with my regular health care provider and/or vaccination provider.
- I am the child's parent, guardian or substitute decision maker.
- I have the authority to provide consent for this child and I agree to the child named above receiving the Pfizer COVID-19 vaccine.

Parent/guardian/substitute decision maker's name:	
Parent/guardian/substitute decision maker's signature:	
Date:	

For provider use:

Name:													
Medicare number:													

Dose 1:

Date vaccine administered:	
Time received:	
COVID-19 vaccine brand administered:	
Batch no:	
Serial no:	
Site of vaccine injection:	
Name of vaccination service provider:	

Dose 2:

Date vaccine administered:	
Time received:	
COVID-19 vaccine brand administered:	
Batch no:	
Serial no:	
Site of vaccine injection:	
Name of vaccination service provider:	

Dose 3:

Date vaccine administered:	
Time received:	
COVID-19 vaccine brand administered:	
Batch no:	
Serial no:	
Site of vaccine injection:	
Name of vaccination service provider:	

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