



COVID-19 VACCINATION

Moderna COVID-19 vaccine for children aged 6 to 11: information for parents and guardians

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About the vaccine

The **Moderna (Spikevax)** COVID-19 vaccine can prevent severe COVID-19 infection in children. The vaccine schedule for children is 2 doses, given 8 weeks apart. The children's dose of Moderna is half of the dose given to people aged 12 years and older.

The Moderna 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 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 due to COVID-19. Children with some chronic medical conditions (including chronic lung disease, congenital heart disease, chronic 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. Children with no history of health conditions can also become very unwell if they get COVID-19.

Some children who get COVID-19 can develop a rare but serious condition 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. Most children who have developed PIMS-TS/MIS-C are aged between 6 and 11 years.

A clinical trial showed that the Moderna COVID-19 vaccine produces a good antibody response against SARS-CoV-2 in children 6 to 11 years of age. The antibody response is higher than that in young adults, and we know the Moderna vaccine is very effective against COVID-19 in young adults. This means that the Moderna vaccine is likely to be very effective in preventing severe COVID-19 in children 6 to 11 years of age.

Children can transmit SARS-CoV-2 to others, including older family members who are at higher risk of becoming seriously ill. Children with COVID-19 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 disruptions to education, and extra-curricular and social activities, which significantly impact on the wellbeing of children and their families.

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% effective, so 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 Moderna COVID-19 vaccine has been tested in more than 4,700 children aged 6 to 11 years in the clinical trial. The trial showed that the vaccine is safe in children and most side effects were mild to moderate.

Children in the Moderna clinical trial who received the vaccine were more likely to experience side effects (relative to the placebo group) than children in the Comirnaty (Pfizer) clinical trial. Although a direct comparison has not yet been made, this suggests that side effects may be more common after the Moderna COVID-19 vaccine than the Pfizer COVID-19 vaccine in this age group. This includes side effects that can limit normal daily activities (such as a high fever, headache and tiredness), although these were uncommon after either COVID-19 vaccine in the clinical trials in this age group.

Expected side effects in the first 1 to 2 days after vaccination are just as common in children as in teenagers and young adults who received the Moderna COVID-19 vaccine. The most common side effects include injection site pain (95% of children experience this), headache (54%), muscle pain (28%), fever (24%) and nausea or vomiting (24%). These side effects usually go away on their own or can be treated with over-the-counter medication such as paracetamol or ibuprofen. Children do not usually need to see a doctor for these mild side effects after receiving a COVID-19 vaccine.

The Moderna and Pfizer COVID-19 vaccines have a very rare risk of heart inflammation (called myocarditis or pericarditis). This 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. Real-world data on the Pfizer vaccine shows that younger children are less likely to experience heart inflammation than teenagers. It is likely that this will also be the case for the Moderna COVID-19 vaccine.

Because myocarditis is rare, the clinical trial in children aged 6 to 11 years did not have enough participants to assess rates of myocarditis or pericarditis following vaccination with the Moderna COVID-19 vaccine. The benefits of vaccination outweigh this very rare risk, and vaccination is 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 Moderna 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 Moderna 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 Moderna or Pfizer COVID-19 vaccines, 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 Moderna 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 Moderna 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:

- 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 Moderna or Pfizer COVID-19 vaccines.

Children with weakened immune systems (immunocompromise)

It is strongly recommended that children with immunocompromise have a COVID-19 vaccination. The Moderna 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 children who have already had COVID-19 infection. 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, however this protection will wane over time and vaccination is important to maintain that protection.

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 past 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 Moderna COVID-19 vaccine for children aged 6 to 11 years contains a smaller dose of the active vaccine component than the vaccine 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 Moderna 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 (occurring in more than 1 in 5 children) after the **Moderna COVID-19 vaccine** in children include:

- pain, redness or swelling at the injection site
- swollen or tender lymph nodes, particularly in the armpit
- fever or chills
- tiredness
- headache
- muscle pain
- nausea or vomiting
- joint pain.

These side effects are usually mild to moderate and go away within one or two 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 **Moderna 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 or 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 (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 Moderna 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 two days after vaccination
- 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 2 doses of the Moderna 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 – for example, if your child is identified as a subgroup at risk of moderate or severe COVID-19 during a local outbreak, or before your child starts any immunosuppressive treatment or is due to travel overseas. Your provider will advise if your child's second dose should be given earlier.

The second dose is likely to increase 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 dose (rather than a shorter interval) because better immune responses are more likely after a longer interval and there is a lower risk of side effects (including myocarditis).

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/>

Consent form for Moderna COVID-19 vaccination: children aged 6 to 11 years

Before you fill out this form, make sure you read the information sheet above on the Spikevax (Moderna) 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 Moderna 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.

Child's information

Name:												
Medicare number:												
Individual Health Identifier (IHI) if applicable:												
Date of birth:												
Address:												
Gender:												
Language spoken at home:												
Country of birth:												

Is your child Aboriginal and/or Torres Strait Islander?

- Yes, Aboriginal only
- Yes, Torres Strait Islander only
- Yes, Aboriginal and Torres Strait Islander
- No
- Prefer not to answer

Parent/guardian details

Parent/guardian name:											
Phone number:											
Email address:											

Consent to receive COVID-19 vaccine

I confirm that:

- I have received and understood information provided to me on Moderna 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 Moderna 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:	

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