



COVID-19 VACCINATION

Moderna COVID-19 vaccine for children aged 6 months to 5 years: information for parents and guardians

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About the vaccine

The **Spikevax (age 6 month to 5 years) (Moderna)** COVID-19 vaccine can prevent children becoming seriously ill from COVID-19. Children should have 2 doses of the vaccine, given 8 weeks apart. The vaccine for children aged 6 months to 5 years contains half of the dose given to children aged 6 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 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. Children with complex health conditions, multiple health conditions, severe immunocompromise, and disability with significant or complex health needs have a higher risk of becoming seriously ill or needing to be admitted to hospital if they get COVID-19.

A clinical trial showed that the Moderna COVID-19 vaccine provided some protection against infection with the Omicron variant of SARS-CoV-2. Children in the trial who received the vaccine were 35% to 52% less likely to get 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 dose may give some protection, it may only last for the short term. Two doses 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 Moderna COVID-19 vaccine has been tested in more than 5,500 children aged 6 months to 5 years in a clinical trial. The trial showed that the vaccine is safe in children aged 6 months to 5 years. Most side effects were mild to moderate.

Fever was more common in this age group than in older children and adults. Up to one in 4 children aged 6 months to 5 years reported a fever following their Moderna vaccine. Most fevers in children occurred within 2 days of vaccination and lasted for one day.

Other than fever, side effects in the first one to 2 days after vaccination are slightly less common in children aged 6 months to 5 years than in older children, teenagers and young adults who received the Moderna COVID-19 vaccine. The most common side effect in children aged 2 to 5 years is injection site pain (affecting 77% to 84% of children). The most common side effect in infants and toddlers aged 6 to 23 months is irritability and/or crying (affecting 82% of infants and toddlers).

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 Moderna, 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 5 years did not have enough participants to assess rates of heart inflammation after vaccination with the Moderna 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 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 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 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).

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:

- 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 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. Children with severe immunocompromise should receive 3 doses of the vaccine, with 8 weeks between each dose.

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 Moderna 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 **Moderna COVID-19 vaccine** in children include:

In young children aged 3 to 5 years:

- pain at the injection site
- fatigue or tiredness
- headache
- muscle pain
- fever

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

- irritability and/or crying
- pain at the injection site
- sleepiness
- loss of appetite
- fever

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 **Moderna 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 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 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 2 doses of the Moderna COVID-19 vaccine, 8 weeks apart, for their primary course. Children with severe immunocompromise should receive 3 doses of the Moderna COVID-19 vaccine, with each dose 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.

The second dose is required for 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.

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