



Australian Government



COVID-19 vaccination decision guide for people who are pregnant, breastfeeding or planning pregnancy

Version 5.1

19 August 2021

The Department of Health will publish updated versions of this guide as more information and new vaccines become available.



This decision guide contains information about COVID-19 vaccines recommended for people who are pregnant, breastfeeding or planning pregnancy. Updates will be made to this guide as new information becomes available.

Key points

- Pregnant people are a priority group for COVID-19 vaccination and should be routinely offered Comirnaty at any stage of pregnancy.
- Those who are trying to become pregnant do not need to delay vaccination or avoid becoming pregnant after vaccination.
- Real-world evidence has shown that Comirnaty is safe for those who are pregnant and breastfeeding.
- COVID-19 Vaccine AstraZeneca can be considered for those who are pregnant, breastfeeding or planning pregnancy, if they cannot access Comirnaty and if the benefits of vaccination outweigh the risks for that individual.
- Those who are pregnant have a higher risk of severe illness from COVID-19.
- Their babies also have a higher risk of being born prematurely.
- COVID-19 vaccination may provide indirect protection to babies by transferring antibodies through the placenta (for those who are pregnant) or through breastmilk (for those who are breastfeeding).

What are the current recommendations for COVID-19 vaccine in pregnant people?

Pregnant people are a priority group for COVID-19 vaccination and should be routinely offered Comirnaty at any stage of pregnancy. Pregnant people have a higher risk of severe illness from COVID-19 and their babies have a higher risk of being born prematurely. Vaccination is the best way to reduce these risks.

To ensure adequate protection, pregnant people are recommended to complete the routine schedule of Comirnaty, which is two doses, 3-6 weeks apart. The recommended interval between COVID-19 vaccine and any other vaccine given during pregnancy is seven days. In special circumstances this interval can be shortened (including same day administration), such as after a tetanus prone wound or during an outbreak of influenza or COVID-19.

Brand preference recommendations

Comirnaty is the preferred COVID-19 vaccine for people under 60 years in Australia, and for those people who are pregnant, breastfeeding or planning pregnancy. This is for two reasons:

- Research has shown that Comirnaty is safe for pregnant people. This research has not yet been carried out for COVID-19 Vaccine AstraZeneca.
- COVID-19 Vaccine AstraZeneca is associated with a rare risk of a clotting condition called thrombosis with thrombocytopenia syndrome (TTS) which appears to be more common in people under 60 years of age.

Comirnaty is registered for use in people aged 12 and older. It works by delivering the genetic code (mRNA) for an important part of the COVID-19 virus called the spike protein. After vaccination your body reads the genetic code and makes copies of the spike protein. This trains your immune system to recognise and fight against the COVID-19 virus.

For further information about Comirnaty refer to [Information on COVID-19 Pfizer \(COMIRNATY\) vaccine](#).

Recommendations for pregnant people who cannot access Comirnaty (Pfizer) vaccine

There are very limited data on the safety of COVID-19 Vaccine AstraZeneca in pregnancy. Pregnant people are a priority group for vaccination and are preferred to receive an mRNA COVID-19 vaccine where possible (e.g. Comirnaty), since there is evidence to support the safety of these vaccines in pregnancy, and on the basis of their age. Those who are breastfeeding or planning pregnancy are also preferred to receive Comirnaty on the basis of their age.

However, if Comirnaty is not accessible, COVID-19 Vaccine AstraZeneca can be considered if the benefits to the individual outweigh the potential risks, e.g. in outbreak settings. There are no theoretical safety concerns associated with COVID-19 Vaccine AstraZeneca specific to pregnancy, breastfeeding or planning pregnancy.

Recommendations for pregnant people who have already received a dose of COVID-19 Vaccine AstraZeneca

Pregnant people who have already received a first dose of COVID-19 Vaccine AstraZeneca can receive either Comirnaty or COVID-19 Vaccine AstraZeneca for their second dose, although Comirnaty is preferred. While generally it is recommended that the same vaccine brand is used for both doses, the reason for a preference for Comirnaty use in pregnant people is there is more information regarding safety of Comirnaty in pregnant people compared with AstraZeneca.

You and your provider may wish to consider the following factors:

- There is a growing body of evidence supporting the safety of mRNA COVID-19 vaccines in pregnancy.
- There are still very limited data on the safety of viral vector vaccines (such as COVID-19 Vaccine AstraZeneca) in pregnancy.
- There is comparatively less data on the safety and efficacy of mixed vaccine schedules than completing the series with the same vaccine.

Why have the recommendations for pregnant people changed?

Pregnant people were not included in the first clinical trials for COVID-19 vaccines, so at the time of initial guidance there was limited evidence confirming the safety of COVID-19 vaccines during pregnancy. The initial advice from immunisation expert groups was therefore cautious, and COVID-19 vaccines were not routinely recommended in pregnancy.

Over time, 'real-world' evidence from other countries has accumulated and reports show that mRNA COVID-19 vaccines, such as Comirnaty, are safe to use in pregnant people. Emerging research also demonstrates that pregnant people have a similar immune response to mRNA vaccines compared to non-pregnant people, and are therefore likely to have similar protection against COVID-19. Furthermore, research shows that the antibodies produced by vaccination cross the placenta and may provide some protection to newborn babies.

What are the risks of COVID-19 in pregnancy?

Pregnant people with COVID-19 have a higher risk of certain complications compared to non-pregnant people with COVID-19 of the same age, including:

- an increased risk (about 5 times higher) of needing admission to hospital¹
- an increased risk (about 2-3 times higher) of needing admission to an intensive care unit^{2,3}
- an increased risk (about 3 times higher) of needing invasive ventilation (breathing life support).^{2,3}

COVID-19 during pregnancy also increases the risk of complications for the newborn, including:

- a slightly increased risk (about 1.5 times higher) of being born prematurely (before 37 weeks of pregnancy)²
- an increased risk (about 3 times higher) of needing admission to a hospital newborn care unit.²

Some pregnant people are more likely to have severe illness from COVID-19 compared to pregnant people *without* these conditions. The conditions are:

- being older than 35 years
- being overweight or obese (body mass index above 30 kg/m²)
- having pre-existing (pre-pregnancy) high blood pressure
- having pre-existing (pre-pregnancy) diabetes (type 1 or type 2).

Are mRNA COVID-19 vaccines (like Comirnaty) safe in pregnancy?

Yes, mRNA vaccines have been shown to be safe in pregnant people, based on accumulated real-world evidence from other countries. A US study of over 35,000 pregnant people who had an mRNA COVID-19 vaccine showed that the side effects following vaccination were very similar in pregnant people when compared to non-pregnant people⁴. Pregnant people appeared slightly more likely to report pain at the injection site but were less likely to report generalised symptoms such as fever or tiredness. Fever of 38°C or above was reported in fewer than 1% of pregnant people who had Comirnaty after the first dose, and fewer than 5% after the second dose. The findings from this large study are supported by other smaller studies.^{5,6}

This study also reported the pregnancy outcomes for 827 people whose pregnancies were completed. They did not identify any safety concerns for those who received an mRNA COVID-19 vaccine in pregnancy. Complications such as premature delivery, stillbirth, small for gestational age infants and congenital anomalies occurred at a similar rate as what is seen in the general population.⁴

A number of smaller studies have shown that receiving an mRNA vaccine during pregnancy does not increase the risk of pregnancy complications for those who are pregnant or their babies.⁵⁻⁸ Animal studies of Comirnaty have not shown any negative effects on fertility or pregnancy.⁹

Overall the data on COVID-19 vaccines in pregnant people are still limited, but growing. A clinical trial of Comirnaty is underway in the US and further real-world evidence is being gathered.¹⁰

There are still very limited data on the safety of viral vector vaccines (such as COVID-19 Vaccine AstraZeneca) in pregnancy.

What are the possible harms from vaccination with Comirnaty during pregnancy?

1. You may experience side effects after vaccination. Common side effects reported after Comirnaty in its clinical trial in people aged 18-55 include:
 - pain at the injection site (in about 84%) – pregnant people appear more likely to report injection site pain compared with non-pregnant people⁴
 - tiredness (in about 62%)
 - headache (in about 52%)
 - muscle pain (in about 37%)
 - chills (in about 35%)
 - joint pain (in about 22%)
 - fever (in about 16%)
 - diarrhoea (in 10%).

Fever is considered undesirable in early pregnancy, but most people who have COVID-19 vaccination will not have a fever. As paracetamol is safe to use in pregnancy you can take it to reduce the symptoms if you experience the following side effects:

- fever
 - pain at the injection site
 - headache
 - muscle pain
 - joint pain
 - chills.
2. COVID-19 vaccination may cause rare side effects in pregnant people or their babies that we do not yet know about:
 - Real-world evidence is available from a study of over 35,000 pregnant people who had an mRNA COVID-19 vaccine. This study did not find any side effects specific to pregnant people or their babies. However, it is still possible that there are very rare side effects that have not been detected in this study.

Are there any benefits for my baby from having a COVID-19 vaccine during pregnancy?

Pregnant people with COVID-19 have a higher risk of stillbirth or premature (early) delivery.² Their babies are also more likely to show distress during delivery, or to need treatment in a newborn intensive care unit. COVID-19 vaccination during pregnancy may reduce the risk of premature delivery of the baby, if it prevents infection in the mother.

Several studies have shown that the antibodies induced by COVID-19 vaccine can cross the placenta, particularly in those vaccinated early in pregnancy, and who received both doses prior to delivery.^{5,6,8,11,12} These antibodies may provide your baby with some protection against COVID-19 for the first few months of life. However, there have not yet been any studies to confirm such protection.

When is the best time to have a COVID-19 vaccine if I am pregnant?

Currently we do not know if there is an optimal time to have a COVID-19 vaccine during pregnancy, either for the benefit of the mother or to protect her baby. Therefore, it is recommended to have a COVID-19 vaccine as soon as you are offered one. Comirnaty can be given at any stage of pregnancy.

Can I just have one dose during pregnancy, and delay the second dose?

Having only one dose will provide partial protection against COVID-19, and we do not yet know how long this protection will last. Having the second dose is important to gain optimal protection against COVID-19. Two doses of Comirnaty provides good protection against COVID-19, including against the Delta strain. A single dose is not as effective at preventing infection but does reduce the risk of severe illness. Now that there is good data on the safety of mRNA vaccines in pregnant people, it is recommended to have 2 doses of Comirnaty, 3 – 6 weeks apart. If you choose to delay the second dose, you will not need to repeat the first dose.

Can Comirnaty be given at the same time as influenza or whooping cough vaccines?

It is not routinely recommended to co-administer COVID-19 vaccine with other vaccines. The minimum recommended interval between COVID-19 vaccine and any other vaccine (including influenza vaccine) is 7 days. However, this interval can be shortened (including same day administration) in special circumstances, such as a tetanus prone wound or outbreak of influenza or COVID-19.

What are the recommendations for breastfeeding people?

Comirnaty is the preferred vaccine for people under 60 years of age, which includes those who are breastfeeding. You do not need to stop breastfeeding before or after vaccination.

Can breastfeeding people have COVID-19 Vaccine AstraZeneca?

If Comirnaty is not available, you can consider having COVID-19 Vaccine AstraZeneca after talking to your healthcare provider about the benefits and potential rare risks. COVID-19 Vaccine AstraZeneca has not been formally studied in those who are breastfeeding, however there are no theoretical safety concerns for its use while breastfeeding. It is not a live vaccine and cannot cause COVID-19 in your infant.

Is Comirnaty safe in breastfeeding people?

There is limited research on the safety of COVID-19 vaccines in those who are breastfeeding, however, there are no theoretical safety concerns. Several small studies have shown that those who are breastfeeding have similar side effects after having an mRNA COVID-19 vaccine compared to the general population.^{5,6,13}

The mRNA in Comirnaty is rapidly broken down in the body and we do not think that it passes into breastmilk. Even if it did, it would be quickly destroyed in the baby's gut and is therefore extremely unlikely to have any effect on your baby.

Are there any benefits for my baby from having COVID-19 vaccine while breastfeeding?

Several small studies have shown that the antibodies induced by COVID-19 vaccine pass into breastmilk.^{5,6,13,14} This may provide your baby with some protection against COVID-19, however there have not yet been any studies to confirm such protection.

What are the recommendations for people planning pregnancy?

Comirnaty is recommended for people who are planning pregnancy. You do not need to avoid becoming pregnant before or after vaccination. Getting vaccinated before conceiving means you are likely to have protection against COVID-19 throughout your pregnancy. Vaccination does not affect fertility. You are not required to have a pregnancy test before getting vaccinated. If Comirnaty is not available, you can consider having COVID-19 Vaccine AstraZeneca after talking to your healthcare provider about the benefits and potential rare risks.

For more information

For more information about COVID-19 and COVID-19 vaccines, refer to:

- [Joint statement between RANZCOG and ATAGI about COVID-19 vaccination for pregnant women](#)
- [Information on COVID-19 Pfizer \(Comirnaty\) vaccine](#)
- [Preparing for COVID-19 vaccination](#)
- [After your COVID-19 vaccination – Comirnaty](#)

References

1. Magnus MC, Oakley L, Gjessing HK, et al. Pregnancy and risk of COVID-19. *medRxiv*. March 2021:2021.03.22.21254090. doi:10.1101/2021.03.22.21254090
2. Allotey J, Stallings E, Bonet M, et al. Clinical manifestations, risk factors, and maternal and perinatal outcomes of coronavirus disease 2019 in pregnancy: Living systematic review and meta-analysis. *BMJ*. 2020;370:3320. doi:10.1136/bmj.m3320
3. Zambrano LD, Ellington S, Strid P, et al. Update: Characteristics of Symptomatic Women of Reproductive Age with Laboratory-Confirmed SARS-CoV-2 Infection by Pregnancy Status — United States, January 22–October 3, 2020. *MMWR Morb Mortal Wkly Rep*. 2020;69(44):1641-1647. doi:10.15585/mmwr.mm6944e3
4. Shimabukuro TT, Kim SY, Myers TR, et al. Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons. *N Engl J Med*. April 2021. doi:10.1056/nejmoa2104983
5. Gray KJ, Bordt EA, Atyeo C, et al. Coronavirus disease 2019 vaccine response in pregnant and lactating women: a cohort study. *Am J Obstet Gynecol*. 2021;0(0). doi:10.1016/j.ajog.2021.03.023
6. Collier AY, McMahan K, Yu J, et al. Immunogenicity of COVID-19 mRNA Vaccines in Pregnant and Lactating Women. *JAMA*. May 2021. doi:10.1001/jama.2021.7563
7. Shanes ED, Otero S, Mithal LB, Mupanomunda CA, Miller ES, Goldstein JA. Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Vaccination in Pregnancy: Measures of Immunity and Placental Histopathology. *Obstet Gynecol*. 9900;Latest Articles. https://journals.lww.com/greenjournal/Fulltext/9900/Severe_Acute_Respiratory_Syndrom_e_Coronavirus_2.206.aspx.
8. Beharier O, Plitman Mayo R, Raz T, et al. Efficient maternal to neonatal transfer of antibodies against SARS-CoV-2 and BNT162b2 mRNA COVID-19 vaccine. *J Clin Invest*. May 2021. doi:10.1172/JCI150319
9. World Health Organization. *MRNA Vaccines against COVID-19: Pfizer-BioNTech COVID-19 Vaccine BNT162b2: Prepared by the Strategic Advisory Group of Experts (SAGE) on Immunization Working Group on COVID-19 Vaccines.*; 2020. <https://apps.who.int/iris/handle/10665/338096>.
10. Study to Evaluate the Safety, Tolerability, and Immunogenicity of SARS CoV-2 RNA Vaccine Candidate (BNT162b2) Against COVID-19 in Healthy Pregnant Women 18 Years of Age and Older - Full Text View - ClinicalTrials.gov. <https://clinicaltrials.gov/ct2/show/NCT04754594>. Accessed June 5, 2021.
11. Prabhu M, Murphy EA, Sukhu AC, et al. Antibody Response to Coronavirus Disease 2019 (COVID-19) Messenger RNA Vaccination in Pregnant Women and Transplacental Passage Into Cord Blood. *Obstet Gynecol*. 2021:10-1097.
12. Mithal LB, Otero S, Shanes ED, Goldstein JA, Miller ES. Cord blood antibodies following maternal coronavirus disease 2019 vaccination during pregnancy. *Am J Obstet Gynecol*.

April 2021. doi:10.1016/j.ajog.2021.03.035

13. Perl SH, Uzan-Yulzari A, Klainer H, et al. SARS-CoV-2–Specific Antibodies in Breast Milk After COVID-19 Vaccination of Breastfeeding Women. *Jama*. 2021.
14. Kelly JC, Carter EB, Raghuraman N, et al. Anti–severe acute respiratory syndrome coronavirus 2 antibodies induced in breast milk after Pfizer-BioNTech/BNT162b2 vaccination. *Am J Obstet Gynecol*. 2021.