Australian Government

COVID-19 VACCINATION

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

Version 4.1

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

This decision contains information about Comirnaty (Pfizer), the COVID-19 vaccine recommended for women who are pregnant, breastfeeding or planning pregnancy. Updates will be made to this guide as new information becomes available.

Key points

- Pregnant women should be routinely offered Comirnaty at any stage of pregnancy.
- Women 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 pregnant women and breastfeeding women.
- Pregnant women 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 pregnant women) or through breastmilk (for breastfeeding women).

Comirnaty (Pfizer) COVID-19 vaccine

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

- Research has shown that Comirnaty is safe for pregnant and breastfeeding women. 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 16 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.

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

Pregnant women should be routinely offered Comirnaty at any stage of pregnancy. Pregnant women 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 women are recommended to complete the routine schedule of Comirnaty, which is two doses, three 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.

Why have the recommendations for pregnant women changed?

Pregnant women 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 women. Emerging research also demonstrates that pregnant women have a similar immune response to mRNA vaccines compared to non-pregnant women, 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 women with COVID-19 have a higher risk of certain complications compared to non-pregnant women with COVID-19 of the same age, including:

- An increased risk (about 5 times higher) of needing admission to hospital.[1]
- 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 women are more likely to have severe illness from COVID-19 compared to pregnant women *without* these conditions. The conditions are:

- Being older than 35 years
- Being overweight or obese (body mass index above 30 kg/m^2)
- 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 women, based on accumulated real-world evidence from other countries. A US study of over 35,000 pregnant women who had an mRNA COVID-19 vaccine showed that the side effects following vaccination were very similar in pregnant women when compared to non-pregnant women[4]. Pregnant women 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 women 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 women whose pregnancies were completed. They did not identify any safety concerns for women 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 to 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 women or their babies[5–8]. In the clinical trial for Comirnaty, 23 women became pregnant during the study period, of which 11 had received Comirnaty.[9] Information about the outcomes of their pregnancies is awaited.

Animal studies of Comirnaty have not shown any negative effects on fertility or pregnancy.[9]

Overall the data on COVID-19 vaccines in pregnant women 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 women appear more likely to report injection site pain compared to non-pregnant women.[4]
    - 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. If you experience the following side effects, you can take paracetamol to reduce these symptoms:

- fever
- pain at the injection site
- headache
- muscle pain
- joint pain
- chills

Paracetamol is safe in pregnancy. It is not recommended to take paracetamol *before* having a COVID-19 vaccine.

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

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

Pregnant women 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. Now that there is good data on the safety of mRNA vaccines in pregnant women, it is recommended to have 2 doses of Comirnaty, 3 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 women?

Comirnaty is recommended for breastfeeding women. You do not need to stop breastfeeding before or after vaccination.

Is Comirnaty safe in breastfeeding women?

There is limited research on the safety of COVID-19 vaccines in breastfeeding women, however, there are no theoretical safety concerns. Several small studies have shown that breastfeeding women 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 women planning pregnancy?

Comirnaty is recommended for women 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.

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

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