



Australian Government



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

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This decision guide is for you if you are considering COVID-19 vaccination and you are pregnant, breastfeeding or planning pregnancy. It contains information about the COVID-19 vaccine Comirnaty (Pfizer, Australia). This information will be updated when other vaccines become available.

## Introduction

The information below will help you to decide whether you should have a COVID-19 vaccine. If you have any questions, ask your immunisation provider, doctor or midwife.

This document will help you to learn about:

1. COVID-19 vaccine.
2. COVID-19 in pregnant women.
3. The possible benefits and possible risks of having a COVID-19 vaccine.
4. What is most relevant to you in deciding if and when to have a COVID-19 vaccine.

## The COVID-19 vaccine: Comirnaty (Pfizer, Australia)

Australia is likely to receive different COVID-19 vaccines over time. The first vaccine to become available in Australia is called Comirnaty. This vaccine has the genetic code (mRNA) for an important part of the COVID-19 virus called the spike protein. When the vaccine injection is given, your body reads the genetic code and makes copies of the spike protein. This then trains your immune system to recognise and fight against the COVID-19 virus.

It is not a live vaccine. Once injected the mRNA breaks down very quickly and is cleared away. For the best protection against COVID-19, two doses are needed, given at least three weeks apart.

## If you are breastfeeding

### Recommendation

If you are breastfeeding you can receive Comirnaty at any time. You do not need to stop breastfeeding before or after vaccination.

### Are there complications of COVID-19 in breastfeeding women?

There is no evidence that breastfeeding women have any increased risk of complications from COVID-19 compared to women who are not breastfeeding.

### Current knowledge about COVID-19 vaccine in breastfeeding women

Comirnaty has not yet been tested in breastfeeding women, but there are no concerns about its safety in breastfeeding women or their babies.

Breastfeeding women can safely receive almost all other vaccines. There is only caution with one vaccine against yellow fever, which is a live vaccine. Comirnaty is **not** a live vaccine. 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.

## If you are planning pregnancy

### Recommendations:

If you are planning a pregnancy, you can receive Comirnaty. You do not need to avoid becoming pregnant before or after vaccination. You are not required to have a pregnancy test before getting vaccinated. If you become pregnant after your first dose, you might choose to have the second dose during pregnancy (see below) or you might choose to wait until after your pregnancy. It is important to note that the first dose may only provide partial protection against COVID-19, and this protection may be short-lived. You will only have full protection after two doses.

### Current knowledge about COVID-19 vaccine in women who are planning pregnancy

There is no evidence that women who become pregnant after being vaccinated against COVID-19 have an increased risk of developing complications that affect their pregnancy or their baby's health.

## If you are pregnant

### Recommendations:

We do not routinely recommend COVID-19 vaccine in pregnancy. You and your health professional can consider it if the potential benefits of vaccination outweigh any potential risks.

You should consider having a COVID-19 vaccine during your pregnancy if:

- you have medical risk factors for severe COVID-19 (refer to the Medical conditions that increase the risk of severe COVID-19 section of this information sheet)
- you are at high risk of exposure to the virus that causes COVID-19 or very likely to be in contact with people with COVID-19.

You may prefer to wait until after your pregnancy to be vaccinated if:

- you have no risk factors for severe COVID-19
- you are not at high risk of exposure to COVID-19.

### What factors might increase your risk of getting COVID-19 or its complications?

- If you work in an occupation or environment where you are more likely to be in contact with people with COVID-19, including in:
  - border/quarantine services
  - healthcare
  - aged care
  - disability care.
- If you live in an area where COVID-19 cases are occurring.
- If you have pre-existing (pre-pregnancy) medical risk factors for severe COVID-19, for example:
  - diabetes
  - high blood pressure
  - heart disease
  - obesity (medical conditions section in this information sheet).
- If you are an Aboriginal or Torres Strait Islander person.
- If you are unable to maintain protective measures such as social distancing and use of masks.

## What factors might reduce your risk of exposure to COVID-19, or your risk of severe disease?

- If you don't have any additional risk factors for severe COVID-19.
- If you live in an area where there is no community transmission. However, this can change rapidly and it takes at least 14-21 days for any protection after vaccination to be developed.
- If you can maintain protective measures such as social distancing and use of masks.

## Possible complications of COVID-19 in pregnant women and their babies

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 3 times higher) of needing admission to an intensive care unit.
- An increased risk (about 3 times higher) of needing invasive ventilation (breathing life support).

COVID-19 also increases the risk of certain pregnancy complications including:

- A slightly increased risk (about 1.3 times higher) of having their baby born prematurely (before 37 weeks of pregnancy).
- An increased risk (about 3 times higher) of their baby needing admission to a newborn care unit.

Pregnant women with certain underlying medical conditions 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
- Overweight or obese (body mass index above 30 kg/m<sup>2</sup>)
- Pre-existing (pre-pregnancy) high blood pressure
- Pre-existing (pre-pregnancy) diabetes (type 1 or type 2)

## What do we know about COVID-19 vaccines in pregnancy?

- We do not yet have any information from clinical trials on COVID-19 vaccines in pregnant women. Trials in pregnant women are planned or underway, but it may take many months before results are known.
- In the clinical trial for Comirnaty, 23 women became pregnant while enrolled in the trial. Of these, 11 women received Comirnaty. As of 14 November 2020, their pregnancies are ongoing, and medical experts continue to follow their pregnancies. Medical experts will get more safety information on pregnant women who have chosen to have a COVID-19 vaccine since the vaccines have been available. This will likely be available from countries, like the USA or UK, in the future.
- There is no available information yet on other mRNA vaccines in pregnant women.

## Possible benefits of COVID-19 vaccination during pregnancy

- It is likely that the vaccine protects you against COVID-19 and its complications.
- Having two doses of Comirnaty can reduce your likelihood of being ill with COVID-19 by about 95%.
- If you have Comirnaty and later get infected with COVID-19, you may be much less likely to have severe illness or need to go to hospital.

## Possible harms from COVID-19 vaccination 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%)
  - 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%)

If you experience side effects, you can take paracetamol to reduce these symptoms. These symptoms may include:

- 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 Comirnaty.

2. COVID-19 may cause side effects in pregnant women or their babies that we do not yet know about:
  - Comirnaty has not yet been studied in pregnant women. We do not yet know if there are extra side effects from this vaccine in pregnant women or in their babies, although this is very unlikely. Based on our understanding of this vaccine, we do not expect it to cause any serious problems in pregnant women or their babies.
  - Other vaccines given during pregnancy such as influenza vaccine or whooping cough vaccine, do not cause more side effects in pregnant women or their babies. They do protect newborn babies from these diseases.
3. Comirnaty may be less effective in pregnant women and may not protect their babies from COVID-19
  - We do not know how effective Comirnaty is in pregnant women. It could be less effective than in non-pregnant women, however we have not seen this with other vaccines used in pregnant women. Other vaccines routinely given during pregnancy (such as flu or whooping cough vaccine) are equally effective in pregnant women compared to non-pregnant women.
  - We do not know whether receiving Comirnaty during pregnancy will provide protection to your baby against COVID-19, because this has not been studied.

## Factors to consider when deciding the timing of COVID-19 vaccination during pregnancy

If you choose to delay the second dose

- The two doses of Comirnaty should be at least 3 weeks apart.
- Having one dose of Comirnaty before or during pregnancy, and waiting until after your baby is born to have the second dose, will still be effective in boosting your protection. You will not need to repeat the first dose.

- Having one dose only provides partial protection against COVID-19. We do not know how long or great protection from one dose will be, so it is still important to get the second dose.

#### Timing in relation to other vaccines

- There should be an interval of at least 14 days between a dose of Comirnaty and any other vaccine. This applies to both doses of Comirnaty.
- This may affect the timing of the two vaccines medical professionals routinely recommend during pregnancy:
  - Influenza vaccine, which can be given at any time.
  - Whooping cough vaccine, which is ideally given between 20 and 32 weeks of pregnancy. The influenza and the whooping cough vaccines can be given together on the same day.
- If you want to get Comirnaty, talk to your immunisation provider about making a schedule for each vaccine dose you will receive during pregnancy. This will avoid any unnecessary delays.

### Making the decision – a summary

- If you have any questions about this information, ask your immunisation provider, doctor or midwife.
- If you are breastfeeding, you can receive Comirnaty at any time, and do not need to stop breastfeeding after vaccination.
- If you are planning a pregnancy, you can receive Comirnaty at any time.
- If you have an increased risk of being exposed to COVID-19, or of having severe illness, you should consider having a COVID-19 vaccine during pregnancy.
- You can choose to have a COVID-19 vaccine at any time during pregnancy; your immunisation provider can help you to decide the best time. Ensure there is a 14 day gap between having a dose of Comirnaty and any other vaccine (including influenza or whooping cough vaccines).

### Medical conditions that increase the risk of severe COVID-19

The risk of severe COVID-19 is higher in people with certain medical conditions.

#### Individuals at high risk of severe COVID-19 illness

- Organ transplant recipients who are on immune suppressive therapy.
- Those who have had a bone marrow transplant in the last 24 months.
- Those on immune suppressive therapy for graft versus host disease.
- Those who have haematological cancers, for example, leukaemia, lymphoma or myelodysplastic syndrome (diagnosed within the last 5 years).
- Those having chemotherapy or radiotherapy.

#### Individuals at moderate risk of severe COVID-19 illness

- Those with chronic renal (kidney) failure.
- Those with heart disease (coronary heart disease or failure).
- Those with chronic lung disease (excludes mild or moderate asthma).
- Those who have a non-haematological cancer (diagnosed in the last 12 months).
- Those who have diabetes.
- Severe obesity with a BMI  $\geq 40$  kg/m<sup>2</sup>.
- Those with chronic liver disease.
- Those with some neurological conditions (stroke, dementia, other).
- Those with some chronic inflammatory conditions and treatments.
- Those with other primary or acquired immunodeficiency.
- Those with poorly controlled blood pressure.

## For more information

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

- Statement from the Royal Australian and New Zealand College of Obstetricians and Gynaecologists on [COVID-19 vaccination in pregnant and breastfeeding women](#)
- [Information on COVID-19 Pfizer \(Comirnaty\) vaccine](#)
- [Preparing for COVID-19 vaccination](#)
- [After your COVID-19 vaccination.](#)