

Patient Information on the COVID-19 vaccination in autoimmune inflammatory rheumatic diseases (AIRD) 29 October 2021

Why is it important for me to have the vaccine?

Some diseases (including rheumatoid arthritis) are caused by the body's immune system, which usually protects us from infection. When the immune system is affected by arthritis or drugs to treat the condition, the risk from COVID-19 may be increased.

If you get vaccinated, you will be less likely to get COVID-19. Even if you are infected, it is more likely to be a milder illness.

People who catch COVID-19 can become very unwell. Many people will need hospital treatment even if they do not have a health condition.

What vaccines are available?

Three COVID-19 vaccines are currently available in Australia – AstraZeneca (Vaxzevria/Oxford) vaccine, Pfizer (Comirnaty) and Moderna (Spikevax) vaccine. All of these are suitable for rheumatology patients whose immune system may not be strong. The AstraZeneca vaccine is a viral vector vaccine. The Pfizer and Moderna vaccines use messenger RNA (mRNA).

The COVID-19 vaccines available in Australia are safe for people with arthritis and people taking drugs that suppress the immune system, even if the condition is active. This is because none of these is a "live" vaccine.

Which vaccine should I have?

The Australian Technical Advisory Group on Immunisation (ATAGI) currently recommends the use of the Pfizer or Moderna vaccine over the AstraZeneca vaccine in people aged 12-60 years.

The AstraZeneca vaccine can be used in adults aged 18-60 years where the benefits are likely to outweigh the risks for that individual and the person has made an informed decision based on an understanding of the risks and benefits.

People over the age of 60 can receive any of the COVID-19 vaccines (provided that they don't have the conditions listed below) as the benefits of the AstraZeneca vaccine continue to outweigh the risk of adverse effects in this age group.

The Pfizer or Moderna vaccines are the preferred vaccine in patients with: a history of cerebral venous sinus thrombosis (CVST), a past history of heparin-induced thrombosytopenia (HIT), a past history of idiopathic splanchnic (mesenteric, portal, splenic) vein thrombosis and antiphospholipid syndrome with thrombosis.

People who have had their first dose of the COVID-19 AstraZeneca vaccine without any serious adverse events or allergic reactions can safely be given their second dose. This includes adults under the age of 60.

The Pfizer and Moderna vaccines should not be given if you have had a serious adverse event (including myocarditis and/or pericarditis) or an allergic reaction to a previous dose. In some people with rare inflammatory heart disorders (e.g., recent or current myocarditis, endocarditis,

pericarditis or rheumatic fever) or severe heart failure, the mRNA vaccines (Moderna and Pfizer) may not be suitable. Discuss with your specialist if you have concerns. Note that the mRNA vaccines are safe to use in people with most common forms of heart disease (including angina or a history of heart attacks).

When will people with rheumatology conditions receive the vaccine?

In Australia anyone aged ≥12 years can now receive the vaccine.

Protection from COVID-19

All the vaccines are very good at stopping severe symptoms and hospitalisation caused by COVID-19 after 2 doses.

All the vaccines require a second dose:

- AstraZeneca usually 4-12 weeks after the first dose.
- Pfizer vaccine usually 21 days after the first dose.
- Moderna vaccine usually 28 days after the first dose.

The first dose does provide some protection. The second dose gives more long-term protection from COVID-19.

What is a third primary dose and how is it different to a booster dose?

A third primary dose is given 2-6 months after the second dose in people who may not have had a strong immune response to the 2 initial doses due to their medical conditions and/or medications. This third primary dose "completes the primary course" for these people. Some people with AIRD on immunosuppressant therapy will fall into this category.

A third primary dose is different to a booster dose. A booster dose refers to an additional vaccine dose after the primary vaccine course is complete which for most people is 2 doses. This is usually given 6 months after the second dose.

At this stage there are no recommendations for booster doses for people who receive a third primary dose as part of their primary vaccine course, however this may change with time as more information is available.

Do I need a third primary dose?

Not all people with rheumatological diseases will need a third dose, however ATAGI are recommending a third dose for people who might not have had a complete response to the first two doses due to the use of the following immunosuppressive therapies:

- High dose corticosteroid treatment equivalent to >20mg/day of prednisone for ≥14 days in a month, or pulse corticosteroid therapy
- Multiple immunosuppressants where the combination is considered to be severely immunosuppressive
- At least one of the following conventional synthetic DMARDs:
 - methotrexate (>0.4mg/kg/week)
 - o leflunomide
 - o mycophenolate
 - azathioprine (>3mg/kg/day)
 - o cyclosporine
 - o cyclophosphamide
 - o tacrolimus
- At least one of the following biological or targeted synthetic DMARDs:
 - o janus kinase (JAK) inhibitor (for e.g., baricitinib, tofacitinib, upadacitinib)
 - abatacept

o rituximab

Some other treatments or combinations of treatments and/or conditions might also qualify for a third vaccine dose - ask your specialist if you are uncertain.

- Pfizer or Moderna are preferred for the third dose however you can receive AstraZeneca for your third dose if you have already been vaccinated with AstraZeneca or if you have had a significant adverse reaction after a previous Pfizer or Moderna dose.
- The third dose is usually given 2-6 months after the second dose of vaccine.
- Talk to your rheumatologist about the timing of your medicines around your third primary dose as you did with the previous doses.

The ATAGI recommendations can be found here; https://www.health.gov.au/news/atagi-statement-on-the-use-of-a-3rd-primary-dose-of-covid-19-vaccine-in-individuals-who-are-severely-immunocompromised

Will the drugs that I take for my condition affect the way the vaccine works?

Some people who are taking drugs that suppress the immune system may be given advice to continue avoiding exposure to COVID-19 after they have had the vaccine. This is because their medications could mean their immune system does not respond as strongly to the vaccine as people who don't take these drugs. This does not mean you should stop your treatment, because this can result in a flare of your condition which puts you at greater risk from COVID-19. Everyone in Australia will need to follow Government advice on reducing the spread of COVID-19, even after they have had the vaccine.

Can I have other vaccines (e.g. influenza vaccine) at the same time as the COVID-19 vaccine? The administration of any other vaccine on the same day as the COVID-19 vaccine is generally not recommended. The preferred minimal interval between the COVID-19 vaccine and the influenza vaccine is 7 days (previously 14 days). In some situations a shorter interval is acceptable (including co-administration) You do not need to delay your influenza vaccine until you complete the course of two COVID-19 vaccines.

Should I delay my rituximab treatment so that I can have the COVID-19 vaccine?

To ensure the best response to the COVID-19 vaccine, it is recommended that vaccination is performed towards the end of a rituximab dosing cycle or before initiation of rituximab therapy. Please discuss the timing with your rheumatologist.

Should I continue to take methotrexate when I have the COVID-19 vaccine?

There is some evidence that responses to the COVID-19 vaccine are reduced in people treated with methotrexate. Therefore, interruption of methotrexate therapy during COVID-19 vaccination may be considered, but only in patients with stable rheumatic disease at low risk of flare, or those for whom protection from COVID-19 is of particular importance. **This decision to hold methotrexate for one or two doses following each vaccination should be individualised and discussed with your treating rheumatologist.**

More information on the use of other immunomodulatory medicines with the COVID-19 vaccine is available here: https://drive.google.com/file/d/16uiV5Ug51NiuPi5m1TolsXMfrhxbggFX/view

Can I have denosumab (Prolia) at the same time as the COVID-19 vaccine?

There is currently no evidence to support separating the doses of denosumab and the COVID-19 vaccine. If they are to be given on the same day, it would be advised to use different injection sites for to minimise the possibility of an injection site reaction.

Can I have surgery after having the COVID-19 vaccine?

Surgery guidelines recommend people do not have major surgery and vaccines within one week of each other. This is because both surgery and the vaccine can cause a fever.

Can I have the COVID-19 vaccine if I am pregnant or breastfeeding?

The Australian Government recommends the use of either the Pfizer or Moderna vaccine in pregnant women at any stage of their pregnancy. This is because the risk of severe outcomes from COVID-19 is significantly higher for pregnant women and their unborn baby. Women who are trying to become pregnant do not need to delay vaccination or avoid becoming pregnant after vaccination. More information can be found here;

https://www.health.gov.au/resources/publications/covid-19-vaccination-atagi-clinical-guidance-on-covid-19-vaccine-in-australia-in-2021

All 3 vaccines can be given to women who are breastfeeding. **Breastfeeding women do not need to stop breastfeeding to receive the vaccine.** More information can be found here; https://ranzcog.edu.au/RANZCOG_SITE/media/RANZCOG-MEDIA/News/RANZCOG-ABA-NZBA-COVID-19-vaccination-and-breastfeeding-infographic-final.pdf You can talk to your midwife and/or rheumatology healthcare team if you are not sure what to do.

Can children have the COVID-19 vaccine?

All children ≥ 12 years are eligible to receive the COVID-19 vaccine. Only the Pfizer and Moderna vaccines are approved for use in children ≥12 years. More information can be found here: <u>ATAGI statement on the use of COVID-19 vaccines in all young adolescents in Australia | Australian Government Department of Health</u>

Are there any side effects?

Some people will get mild side effects. These can include pain where the injection goes in, tiredness, headache and aching of muscles. Serious reactions like allergic reactions are extremely rare. People with a history of severe allergic reactions can be vaccinated but should be monitored for 30 minutes after receiving the vaccine. If you have any concerns about the vaccine, ask your doctor, nurse or pharmacist.

You should seek medical advice as soon as possible if:

- You have any of the following symptoms, particularly around 4 to 42 days after vaccination with AstraZeneca: headache that persists beyond 48 hours after vaccination or appears later than 48 hours after vaccination. Simple painkillers may alleviate headache initially, but it persists, blurred vision, weakness of face or limbs, confusion or seizure, shortness of breath, chest pain, persistent abdominal pain, leg swelling or a pin-prick rash or bruising not at the injection site that cannot be explained.
- You experience chest pain, pressure or discomfort, irregular heartbeat, skipped beats or 'fluttering', fainting, shortness of breath or pain when breathing after the Pfizer or Moderna vaccine.

If I didn't have a side effect does this mean that the vaccine didn't work?

Not everybody will have side effects from the COVID-19 vaccine. If you don't get any side effects this does not mean that the vaccine did not work.

What about reports of blood clots (thrombosis) with the AstraZeneca vaccine?

ATAGI and the Thrombosis and Haemostasis Society of Australia and New Zealand (THANZ) released a statement on the 23 May 21 regarding thrombosis with thrombocytopenia syndrome (TTS) with the AstraZeneca vaccine. This statement outlines that there is unlikely to be an increased risk of TTS in people with the following conditions, and people in these groups can receive the AstraZeneca vaccine:

- History of blood clots in typical sites
- Increased clotting tendency that is not immune mediated
- Family history of blood clots
- History of ischaemic heart disease or stroke
- Current or past thrombocytopenia (low platelet count)

 Those receiving anticoagulation therapy (for e.g. apixaban, dabigatran, rivaroxaban, warfarin)

However, if you have a history of; CVST, HITT, idiopathic splanchnic (mesenteric, portal, splenic) vein thrombosis and antiphospholipid syndrome with thrombosis, the Pfizer or Moderna vaccine is recommended.

TTS can now be treated very effectively. Due to better awareness, early diagnosis and appropriate treatment, the outcome and prognosis of the majority of those who have experienced this syndrome is good. More information can be found here; https://www.health.gov.au/news/joint-statement-from-atagi-and-thanz-on-thrombosis-with-thrombocytopenia-syndrome-tts-and-the-use-of-covid-19-vaccine-astrazeneca

Should I take aspirin before having my COVID-19 vaccine to reduce my risk of getting blood clots?

There is no evidence that taking low-dose aspirin before having a COVID-19 vaccine will reduce your risk of blood clots.

What should I do if I take "blood thinners"?

Continue to take your medicines as prescribed by your doctor. There is no reason to stop or change your dose of blood thinners before the COVID-19 vaccine.

Do you still need to have the vaccine if you have had COVID-19?

It is possible for people who have already had COVID-19 to have the vaccine for it. It is not known yet how long the antibodies made by your body in response to COVID-19 last, so a vaccine could offer more protection or boost any antibodies your body has already made.

Please encourage your household members and other close contacts to have the COVID-19 vaccine once they are eligible as this may offer you further protection from getting COVID-19. This is known as the "ring" vaccination concept.

An Australian Government COVID vaccine fact checker is available at; https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/is-it-true

More information for your treating doctors can be found here. https://drive.google.com/file/d/16uiV5Ug51NiuPi5m1TolsXMfrhxbqgFX/view
https://app.magicapp.org/#/guideline/LqRV3n/rec/EZ6z8E/practical
https://www.health.gov.au/news/atagi-statement-on-the-use-of-a-3rd-primary-dose-of-covid-19-vaccine-in-individuals-who-are-severely-immunocompromised

The ARA will update this advice as new information becomes available.

The information in this document has been obtained from various sources and has been reviewed by the Australian Rheumatology Association. It is intended as an educational aid and does not cover all aspects of the topic. This information is not intended as medical advice for individual problems nor for making an individual assessment of the risks and benefits. It can be reproduced in its entirety but cannot be altered without permission from the ARA