

## COVID-19 (SARS-CoV-2) vaccinations

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The two COVID-19 vaccines approved by the Therapeutic Goods Administration for use in Australia this year are **BNT162b2 (Pfizer/BioNTech)** and **ChAdOx1-S (AstraZeneca /University of Oxford)**. Both have provisional approval. Continued approval is dependent on evidence gained from ongoing trials and post-market assessment.

	<b>BNT162b2 (Pfizer/BioNTech) Comirnaty</b>	<b>ChAdOx1-S (AstraZeneca/University of Oxford)</b>
Age approved for	≥16 years	≥18 years
Dosing	Two doses to be given at least 21 days apart.	Two doses to be given 4–12 weeks apart.
Formulation	not a live vaccine; is a lipid nanoparticle-formulated mRNA vaccine. Includes the spike glycoprotein antigen from SARS-CoV-2 to create an immune response.	ChAdOx1-S is a viral vaccine that cannot replicate in the vaccine recipient. ChAdOx1-S is a viral vector vaccine for humans based on the chimpanzee adenovirus with a SARS-CoV-2 spike glycoprotein encoded.
Efficacy	95% against symptomatic COVID-19 at 7 days post-second dose.	70% for symptomatic COVID-19 at 12 weeks post-second dose.
Safety in pregnancy and breastfeeding	Considered safe in breastfeeding but is not routinely recommended in pregnancy. No safety data is available.	Not recommended in pregnancy and lactation due to insufficient data.
Safety in older adults	Very effective in older adults who had stable chronic medical conditions and expected to be protective regardless of frailty. Adverse effects are milder and less common in older adults (aged 55 years or over) than younger adults.	There is limited data available for the efficacy and safety in individuals over 65 years of age or in people with significant co-morbidities.
Storage	Storage of the vaccine is less than minus 60°C for transport. Chemical and physical in-use stability has been demonstrated	Storage conditions include: after first opening, use the vial within 6 hours when stored at room temperature (up to 30°C), or 48

	for 6 hours at 2 °C to 30 °C after dilution in sodium chloride 9 mg/mL (0.9%) solution for injection. Transportation is challenging for regional Australia.	hours when stored in a refrigerator (2°C to 8°C). Before opening is stored in refrigeration. These storage conditions favour transport in regional Australia.
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- At this time, there are no safety or immunogenicity data for co-administered influenza vaccine with any COVID-19 vaccines. The recommended minimum interval between a dose of seasonal influenza vaccine and a dose of BNT162b2 or ChAdOx1-S is 14 days. Routine scheduling and giving of an influenza vaccine with a COVID-19 vaccine on the same day is not recommended.
- COVID-19 vaccination is recommended for all people aged ≥16 years.
- Table 2 is a comparison of the adverse events compared to placebo reported in trials for each vaccine. Although the AstraZeneca overall adverse event percentages were higher, each had a similar increase in adverse events than placebo. The increased number in the Astra Zeneca trials could reflect how each company screened for these events.

Adverse events	Pfizer (BNT162b2)	Astra Zeneca (ChAdOx1-S)
Nausea	1.1 vs 0.3	21.9 vs 13.1
Injection site pain	11.3 vs 1.5	54.2 vs 36.7
Pyrexia (high temperature)	6.1 vs 0.3	7.9 vs 1.2
Fatigue	5.5 vs 1.4	53.1 vs 38.3
Chills	5.3 vs 0.5	31.9 vs 8.3
Pain	2.4 vs 0.2	Not reported
Myalgia	4.8 vs 0.7	44.0 vs 21.6
Arthralgia	1.1 vs 0.4	26.4 vs 12.4
Headache	5.2 vs 1.6	52.6 vs 39.0
Severe or life-threatening	0.6%	Not reported
Anaphylaxis	1 in 200 000	It could not be estimated from current data.

## References

1. **Pfizer- Biontech.** Pfizer-Biontech COVID-19 VACCINE (BNT162, PF-07302048) vaccines and biological products advisory committee briefing document. *Food and drug administration*. [Online] November 30th, 2020. <https://www.fda.gov/media/144246/download>.
2. **Australian Government, Department of health.** COVID-19 vaccination – ATAGI clinical guidance on COVID-19 Vaccine in Australia in 2021. *COVID-19 vaccination – Advice for COVID-19 vaccine providers*. [Online] February 5th, 2021.

<https://www.health.gov.au/sites/default/files/documents/2021/02/covid-19-vaccination-atagi-clinical-guidance-on-covid-19-vaccine-in-australia-in-2021.pdf>.

3. **Australian Government, Department of Health.** COVID-19 vaccination – ATAGI clinical guidance on COVID-19 Vaccine in Australia in 2021. *Australian Government, Department of Health*. [Online] [Cited: February 23rd, 2021.] <https://www.health.gov.au/resources/publications/covid-19-vaccination-atagi-clinical-guidance-on-covid-19-vaccine-in-australia-in-2021>.