Comirnaty ® Tozinameran [mRNA] COVID-19 Vaccine - Pfizer for Persons 12 years and over

Version 26 of COVID-19 Vaccine Administration Protocol (CVAP) Tozinameran [mRNA] Comirnaty ® COVID- 19 Vaccine - Pfizer for persons aged 12 years and over.

Key changes in this version:

Update booster recommendations to align with recent ATAGI statement

Areas Applicable	NT Wide
Health Professionals authorised by this SSTP	Nurses Midwives Aboriginal and Torres Strait Islander Health Practitioners
Scheduled Substance(s)	SARS-COV-2 (COVID-19) vaccine. Comirnaty® COVID-19 Vaccine Tozinameran [mRNA] multi-dose vial containing up to 6 doses of 30 micrograms after dilution
Indication	Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2, in individuals 12 years of age and older including in pregnancy **NOTE:** Bivalent vaccines are preferred over original (ancestral) vaccines in people aged 12 years and older. Refer to Australian Technical Advisory Group on Immunisation - ATAGI
Contraindications and/or Exclusions*	**Contraindications** • People under 12 years old • Anaphylaxis to the active substance or to any of the excipients including a previous dose of an mRNA COVID-19 vaccine (Spikevax® or Comirnaty®) (including Polyethylene Glycol) • Any person who has an episode of rheumatic fever within the last 3 months or has current active inflammatory markers **Exclusions** • Administration of vaccine to individuals with an acute severe febrile illness or acute infection should be deferred until they are symptom- free (minor infection or low grade fever should not delay vaccination). **Precautions** • Specific allergies - individuals with a history of allergy to previous doses of a COVID-19 vaccine or any component of COVID-19 vaccines or with a history of anaphylaxis to other drugs or vaccines may need prior assessment before receiving a COVID-19 vaccine. Refer to ATAGI advice for further information.

	• People with confirmed SARS-CoV-2 infection should wait a minimum of six (6) months after their diagnosis (either by PCR test or Rapid Antigen Test) before they receive any subsequent dose of COVID-19 vaccination. • Vaccination can occur prior to 6 months in exceptional circumstances such as prior to starting an immunosuppressant, prior to overseas travel or if someone cannot reschedule vaccination easily (such as due to an infrequent outreach vaccinating schedule). • Individuals with a cardiac condition may require consultation with a medical officer or cardiologist as outlined in ATAGI advice Please refer to the Product Information for list of precautions Comirnaty-BNT162b2-PI Template (tga.gov.au)
Dose and Route*	Single dose if 30 micrograms (0.3mL after dilution) given intramuscularly (IM) - preferred route is in the deltoid muscle of the upper arm*. *preferred route is in the deltoid muscle of the upper arm. However alternate sites, such as vastus lateralis muscle of the thigh or ventrogluteal muscle of the hip, may also be used at clinician's discretion.
Administration	N/A
Dose Frequency*	**Primary series** • 2 dose course given 8 weeks apart. ○ The dose interval can be shortened to 3 weeks for people at higher risk of severe infection from COVID-19 infection (such as older adults or people with underlying medical conditions), in an outbreak setting or prior to international travel. • An additional vaccine (3 dose primary series) is required for people who are immunocompromised, as defined in the ATAGI guidelines – the third dose can be **given 2 months after the 2nd dose** **Booster doses** • Booster frequency should be in accordance with the Australian Technical Advisory Group on Immunisation ATAGI advice as in place from time to time **SARS-CoV-2 infection** If a person has a confirmed SARS-CoV-2 infection, any due dose can be given to the person 6 months after the infection. **Note for all populations** • If the second dose of the primary series is administered later than the recommended interval, no additional vaccine dose needs to be given. • A second dose of a COVID-19 vaccine administered <14 days after the first dose is considered an invalid dose. An additional COVID-19 vaccine dose should be administered as a replacement dose. **Mixed schedules** The same brand should be used for the 2 doses of the primary vaccination course except if • there is a medical contraindication/ precaution or

	• if a vaccine brand is not available or • the person is not accepting of the 2nd dose of the same brand. The 2nd dose needs to be given 8-12 weeks after the first dose i.e Spikevax® or Vaxzevria®
Dilution	Please follow instructions in the product information for dilution Comirnaty-BNT162b2-PI Template (tga.gov.au)
Drug Interactions*	**No interaction studies have been performed.** There is no known impact of timing of COVID-19 vaccines and other vaccines on effectiveness. As such time COVID 19 vaccines and influenza or other immunisations on the Australian Immunisation Register can be administered without consideration of timing such as on the same day. There is a potential for an increase in mild or moderate adverse events when more than one vaccine is given at the same time.
Monitoring requirements*	Ensure vaccines are not expired and have been stored in accordance to Product Information. • Once removed from the freezer, the unopened thawed vial can be stored at 2-8°C for up to one month (31 days) and up to 2 hours at temperatures 30 °C or lower, prior to use. • Discard any unused vaccine 6 hours after dilution. Follow usual health service post-vaccination monitoring Adverse events following vaccination are notifiable conditions in the NT and need to be reported to Public Health Unit. Follow established procedure if an adverse reaction occurs. https://www.health.gov.au/health-topics/immunisation/health-professionals/reporting-and-managing-adverse-vaccination-events
Health Professional Accreditation Requirements	Health professionals using this guideline must meet the requirements outlined by the NT Chief Health Officer: ***Nurses and Midwives***: • Be registered with the Nursing and Midwifery Board of Australia with no conditions, undertakings or notations which may limit delivery of clinical services directly to patients ***Aboriginal Health Practitioners:*** • Be registered with the Aboriginal and Torres Strait Islander Health Practice Board of Australia with no conditions or undertakings which may limit delivery of clinical services directly to patients **All health professionals following this protocol must:** • Maintain continuing professional development related to skills and competencies required for the delivery of medicines and COVID-19 vaccines including the use of multi-dose vials and management of anaphylaxis • Hold a current Cardiopulmonary Resuscitation (CPR) certificate

<table>
<tr><td></td><td colspan="3">All health professionals administering vaccines from this protocol must have completed:
A program of study for the administration of vaccines accredited by Health Education Services Australia (HESA) or;
A program of study approved by the Chief Health Officer or;
completed the assessment of an immuniser program of study that meets the curriculum content requirements of the National Immunisation Education Framework for Health Professionals</td></tr>
<tr><td>Documentation
(including necessary information to the patient)</td><td colspan="3">The health professional must:
Complete all clinical documentation requirements as outlined by the Health Service.
Enter the patient details and vaccine brand name, dose, site of administration and batch number in the Australian Immunisation Register within 24 hours and no later than 10 days after administration</td></tr>
<tr><td>Related Documents</td><td colspan="3">Australian Product Information – COMIRNATY ® (BNT162b2 [mRNA]) COVID-19 VACCINE
Comirnaty-BNT162b2-PI Template (tga.gov.au)
https://www.health.gov.au/resources/collections/covid-19-vaccination-provider-resources
ATAGI Clinical guidance on use of COVID-19 vaccine in Australia (most recent version)
ATAGI Provider guide to COVID-19 vaccination of people with immunocompromised (most recent version)
ATAGI updated recommendations for a winter dose of COVID-19 vaccine
ATAGI statement on SARS-CoV-2 Omicron variant and COVID-19 booster doses
ATAGI check list for administration sites
Australian Immunisation Handbook
Pre Vaccination Screening Checklist
COVID-19 Vaccination Eligibility Declaration Form for People certain conditions or on therapies leading to severe immunocompromise
Immunisation: Health Professionals; NT Upskilling Courses
Australian Immunisation Handbook: After Vaccination Australian Government COVID 19 Vaccination Training Program
COVID-19 vaccination decision guide for women who are pregnant, breastfeeding or planning pregnancy</td></tr>
<tr><td rowspan="2">Chief Health Officer</td><td>Signature</td><td>Name</td><td>Date</td></tr>
<tr><td>EDOC 2023/386213</td><td>Adjunct Professor Christine Connors</td><td>22/12/2023</td></tr>
<tr><td>Period of effect</td><td colspan="3">This SSTP remains in force until 22/12/2025 unless revoked earlier.</td></tr>
</table>

References:

* The drug information provided is to act as a guide to outline the limits of legal dealing with the named scheduled substances. Further information reference should be made to the full manufacturer's product info and other reliable sources of medicines information. If contraindications or interactions are present refer to medical officer before administration