Comirnaty ® Tozinameran [mRNA] COVID-19 Vaccine - Pfizer for Children aged 5 – 11 years

Version 6 of *COVID-19 Vaccine Administrative Protocol (CVAP) Tozinameran [mRNA] Comirnaty ® COVID-19 Vaccine - Pfizer for persons aged 5 to 11 years*

Key updates in this version:

- **Booster dose recommended for eligible populations.**

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 ® (Tozinameran) [mRNA] COVID-19 Vaccine multi-dose vial containing up to 10 doses of 10 micrograms after dilution
Indication	• Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2, in individuals 5 to 11 years of age as a two dose schedule. • Booster dose for the following population children aged 5-11 years: o those who are severely immunocompromised o those who have a disability with significant or complex health needs o those who have complex and/or multiple health conditions that increase the risk of severe COVID-19
Contraindications and/or Exclusions*	**Contraindications** • People under 5 years old • People 12 years and older • 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) **Exclusions** • Administration of vaccine to individuals with an acute severe febrile illness or acute infection (minor infection or low grade fever should not delay vaccination) should be deferred until they are symptom-free. **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 six 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 a consultation with a medical officer or cardiologist as outlined in ATAGI advice. Please refer to the Product Information for list of precautions Comirnaty-Tozinameran-PI Tozinameran (tga.gov.au)
Dose and Route*	Single dose if 10 micrograms (0.2mL after dilution with 1.3mL sodium chloride 9 mg/mL (0.9%) solution) given intramuscularly in the deltoid muscle of the upper arm* Note If a child turns 12 after their first dose they should receive a 30mcg dose (0.3mL) of Comirnaty® using the formulation for people 12+ years. *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.
Dose Frequency*	**Dose scheduling for children aged 5-11 years** **Primary series** • 2 dose course given 8 weeks apart. • The interval for second doses for children at higher risk of COVID-19 (e.g. some underlying medical conditions) may be shortened from 8 to 3 weeks in the context of ongoing community transmission. A list of underlying medical conditions associated with a higher risk of severe COVID-19 are available. **Children aged 5-11 years with certain conditions or on therapies leading to severe immunocompromise, as defined in ATAGI recommendations.** Primary series is a 3 dose course • Dose 1 and 2 given at least 21 days apart • Dose 3 given 2 months after the second 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 **Note for all populations** • If the second dose is administered later than the recommended interval, no additional vaccine dose needs to be given. • A replacement dose should be administered if the second dose of the primary series was administered 14 days or earlier following the first dose.
Dilution	Please follow instructions in the product information for dilution

	Comirnaty-Tozinameran-PI Tozinameran (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. 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 10 weeks (70 days) within the use-by date and up to 24 hours at temperatures 8-30 °C, prior to use. • Discard any unused vaccine 12 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 **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;

<table>
<tr><td></td><td>

A program of study specific for their profession approved by the Chief Health Officer for administration of vaccinations 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>
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>
Australian Product Information – COMIRNATY ® Tozinameran [mRNA]) COVID-19 VACCINE
Comirnaty-Tozinameran-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 recommendations on the use of the paediatric Pfizer COVID-19 vaccine in children aged 5 to 11 years in Australia
ATAGI recommendations for a booster in children aged 5-11 years
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>Chief Health Officer</td><td>
<table>
<tr><th>Signature</th><th>Name</th><th>Date</th></tr>
<tr><td>EDOC 2023/386213</td><td>Adjunct Professor Christine Connors</td><td>22/12/2023</td></tr>
</table>
</td></tr>
<tr><td>Period of effect</td><td>This SSTP remains in force until 22/12/2025 unless revoked earlier.</td></tr>
<tr><td colspan="2">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</td></tr>
</table>