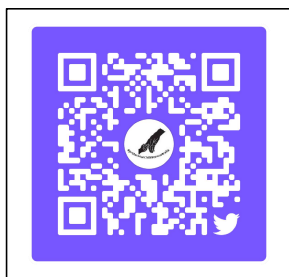


AUSTRALIAN PRODUCT INFORMATION – COMIRNATY™ PFIZER (tozinameran) COVID-19 VACCINE [Tris/Sucrose Presentation]

- The decision has been made on the basis of **SHORT TERM EFFICACY AND SAFETY DATA**. Continued approval depends on the evidence of **LONGER TERM EFFICACY** and **SAFETY** from **ONGOING CLINICAL TRIALS**.
- **MYOCARDITIS** (INFLAMMATION OF THE HEART MUSCLE) and **PERICARDITIS** (SWELLING AND IRRITATION OF THE THIN, SACLIKE TISSUE SURROUNDING YOUR HEART) - Very rare cases of **MYOCARDITIS** and **PERICARDITIS** have been observed **following vaccination with COMIRNATY**. These cases have primarily occurred within 14 days following vaccination, more often after the second vaccination, and **MORE OFTEN IN YOUNGER MALES**.
- **IMMUNOCOMPROMISED INDIVIDUALS** - The **EFFICACY, SAFETY** and **IMMUNOGENICITY** of **COMIRNATY** has **NOT BEEN ASSESSED** in **IMMUNOCOMPROMISED INDIVIDUALS**, including those receiving **IMMUNOSUPPRESSANT THERAPY**.
- **DURATION OF PROTECTION** - The **DURATION OF PROTECTION** afforded by **COMIRNATY** is **UNKNOWN** as it is **still being determined** by **ONGOING CLINICAL TRIALS** and observational studies.
- **PAEDIATRIC USE** - The **SAFETY** and **EFFICACY** of **COMIRNATY IN CHILDREN** aged less than 5 years of age have **NOT YET** been established.
- **EFFECTS ON LABORATORY TESTS** - NO DATA AVAILABLE.
- **PAEDIATRIC USE** - Effects on laboratory tests NO DATA AVAILABLE.
- **INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS** - NO interaction studies have been performed.
- **ADMINISTRATION OF COMIRNATY with other vaccines HAS NOT been studied**.
- **FERTILITY, PREGNANCY AND LACTATION** - There is **LIMITED EXPERIENCE** with use of **COMIRNATY** in **PREGNANT WOMAN**. Administration of **COMIRNATY** in pregnancy should **ONLY BE CONSIDERED** when the **potential benefits** outweigh **any potential risks** for the **MOTHER** and **FETUS**.
- **GENOTOXICITY (THE ABILITY OF HARMFUL SUBSTANCES TO DAMAGE CELLS)/CARCINOGENICITY (THE ABILITY OR TENDENCY TO CAUSE CANCER)** - **NEITHER GENOTOXICITY** nor **CARCINOGENICITY** studies **WERE PERFORMED**. The components of **COMIRNATY (lipids and mRNA)** are **NOT EXPECTED** to have genotoxic potential.



ATAGI recommendations on the use of the paediatric Pfizer COVID-19 vaccine in children aged 5 to 11 years in Australia 8 December 2021.12.27.

- Children aged 5 to 11 years accounted for **0.7% of COVID-19 related hospitalisations in Australia** and for **0.04% of COVID-19 related ICU admissions** over this period.
- This reported proportion of hospitalised cases is likely to be an **OVERESTIMATE OF SEVERE DISEASE**, since children are often hospitalised for **social indications** (e.g., **if their carers are hospitalised with COVID-19**).
- **ONE DEATH** in an **UNVACCINATED** child aged between 5-11 years with COVID-19 has been reported in Australia; it is noted that this child had **SIGNIFICANT UNDERLYING HEALTH CONDITIONS**.
- Vaccine effectiveness data from real world experience are **NOT YET AVAILABLE** for children aged 5-11 years.
- Clinical trials were conducted prior to the emergence of the Omicron variant, and the results reflect vaccine efficacy against older strains of SARS-CoV-2. **Vaccine efficacy or effectiveness against the Omicron strain is NOT YET KNOWN IN CHILDREN AGED 5-11 YEARS.**
- A longer dosing interval **MAY** also reduce the risk of **MYOCARDITIS** and **PERICARDITIS** after vaccination in adults. **However, it should be noted that this study DID NOT include children aged 5-11 years.**
- The Pfizer clinical trial and safety expansion population included a total of approximately 3000 children who received the trial vaccine. **The trial was therefore NOT POWERED to detect any rare UNANTICIPATED ADVERSE EVENTS OR TO ASSESS rates of MYOCARDITIS and PERICARDITIS following immunisation in the 5-11 age group.**
- The risk of **MYOCARDITIS** or **PERICARDITIS** after mRNA COVID-19 vaccination in children **AGED 5-11 years IS NOT YET KNOWN.**
- ATAGI supports the right of children and their guardians to make an **INFORMED DECISION** about vaccination (**THE “PAPERWORK” or “PRODUCT INFORMATION”** that comes with the vials of Pfizer is **LITERALLY A BLANK PIECE OF PAPER**, how can one make an informed decision when the company supplying the product can not provide **ANY INFORMATION WHEN ONE GOES TO GET VACCINATED?**
- **CHILDREN IN THIS AGE GROUP ARE TOO YOUNG TO INDIVIDUALLY CONSENT FOR A COVID-19 VACCINE AND RELY ON THEIR PARENTS/CARERS DECISION-MAKING.**

