



Australian Government

## COVID-19 VACCINATION

# COMIRNATY (PFIZER) 6 MONTHS – 4 YEARS (MAROON) FACT SHEET

Version 2 – July 2023

This fact sheet is for Primary Care sites who are participating in this roll-out as part of the COVID-19 Vaccination Program. It provides information and guidance about the administration and storage of the Pfizer (**Maroon**) Vaccine to the **eligible** cohort.

### Eligible population

The Australian Technical Advisory Group on Immunisation (ATAGI) **recommends** this vaccine can be used for **children aged 6 months to 4 years with severe immunocompromise, disability, and those who have complex and/or multiple health conditions** which increase the risk of severe COVID-19.

Children that have already turned 5 should continue to receive the vaccines that are currently approved and available: Pfizer (**Orange**) for 5 to 11 years.

### Vaccination Interval

The recommendation is for 3 primary doses for the Pfizer 6 months – 4 years (**Maroon**) vaccine. The recommended interval between each dose is 8 weeks. Children with severe immunocompromise are also recommended to receive 3 primary doses. This is different to other primary course COVID-19 vaccines, where an additional primary dose for individuals with severe immunocompromise is advised.

Completion of a primary course schedule with the same brand of vaccine is recommended.

### Booster Dose

**ATAGI does not** currently recommend a booster dose for children and adolescents aged under 18 years **who do not have** any risk factors for severe COVID-19.

### Vaccine Co-administration

**ATAGI recommends** that where possible a minimum interval of 7-14 days is recommended between a Pfizer paediatric COVID-19 vaccine and other vaccines in children aged 6 months to 4 years, to minimise the risk of adverse events such as fever.



## COMIRNATY (PFIZER) 6 MONTHS – 4 YEARS (MAROON)

The Pfizer 6 months – 4 years (**Maroon**) vaccine is a new formulation of the COVID-19 vaccine which ATAGI recommends for use as a COVID-19 vaccination for children aged 6 months - 4 years **with severe immunocompromise, disability, and those who have complex and/or multiple health conditions** which increase the risk of severe COVID-19.

The Pfizer 6 months – 4 years (**Maroon**) vaccine is approved for use as a primary course in individuals aged 6 months to 4 years. Please note the Pfizer (**Maroon**) vaccine is administered intramuscularly as a primary course of 3 doses (3 micrograms/0.20 mL each). \*Each of the 3 primary course doses should be administered 8 weeks apart.

The Pfizer 6 months – 4 years (**Maroon**) vaccine comes in multi-dose vials containing 10 doses, with each dose being 0.20 mL. **This vaccine requires dilution with 2.2mL of sodium chloride.**

General practices will receive the Pfizer 6 months – 4 years (**Maroon**) vaccine **thawed**. ACCHS will receive stock as either **frozen** or **thawed**, dependent on how they currently receive Pfizer vaccines. The thaw use-by date is the allowable timeframe for vaccines to be in a thawed state (refrigerated at 2-8°C). For the Pfizer 6 months – 4 years (**Maroon**) vaccine unopened thawed vials can be stored at 2°C to 8°C for a maximum of 70 days (10 weeks) within the 18-month shelf life.

After puncturing the vial for the first time, store the vial up to 30°C for up to 6 hours. Discard remaining solution after 6 hours. **Do not shake the vial.**

Please refer to the [TGA](#), or the [Product Information](#) for further information.

\*This is the ATAGI recommended dose interval for this vaccine type. As per the [Product Information](#), a minimum of 3 weeks between dose 1 and dose 2 may be acceptable in some scenarios.

### Pfizer (**Maroon**) Pack Dimensions

Each box contains 10 x 10 dose vials.  
The pack has maroon highlights to distinguish it from other Pfizer products.  
Box Dimensions (L x W x H) are:  
93mm x 38mm x 45mm Weight 76.1g



### Pfizer (**Maroon**) Vial

The Vial has a **maroon cap** with a **maroon label**.  
Vials are 35mm x 12mm Weight 5g.



### Pfizer (**Maroon**) Consumables

The Pfizer consumables that will be delivered separately to your vaccine will be the same as for Pfizer 5-11 vaccine (**Orange**) (or similar):

- Sodium Chloride 0.9% 10mL ampoules
- 1mL Syringe with fixed Needle 25 gauge 25mm [1 inch] (pack of 100)
- 3mL Luer lock syringe (pack of 100)
- Low Dead Space Needle 21 gauge 38 mm (pack of 100)
- 1 mL Luer lock syringe (pack of 100)
- Low Dead Space Needle 25 gauge 25 mm [1 inch]

## Disposal of Vials

Vaccines that are considered wastage (either due to expiry, damage, cold chain breach, or excess vaccine remaining in a used vial) must be disposed of in accordance with local requirements for disposal of Schedule 4 medication, the Product Information and Safety Data Sheets for the COVID-19 vaccine type being disposed of.

**Vaccines cannot be disposed of in the sink, toilet, or through the regular garbage disposal processes.**

## Site declaration

Sites who would like to participate in this roll-out, and who have already completed the **Pfizer Site Readiness Declaration** previously, do not need to complete another declaration before being able to order Pfizer (**Maroon**) vaccine. Any sites who have not yet completed a Pfizer Site Readiness Declaration **will be required** to complete this in COVID-19 Vaccine Administrative System (CVAS) before being able to order the Pfizer (**Maroon**) vaccine.

## Training

All clinical staff must complete the **COVID-19 Vaccination Training Program** (CVTP) before the roll-out of the Pfizer (**Maroon**) vaccine at their site. The Module is called **Additional Module 4a: Pfizer 6 month – 4 years (maroon) vaccine**.

Non-clinical staff, especially those who receive or handle vaccines, should also complete the CVTP. The training modules are updated regularly to reflect the latest advice on COVID-19 vaccines.

Read more on the COVID19 Training Page [COVID-19 vaccination training program | Australian Government Department of Health and Aged Care](#).

## Reporting a Pfizer Comirnaty vaccination to the Australian Immunisation Register for 6 months to 4 years

The minimum age for **Pfizer Comirnaty** vaccine changed to 6 months in the Australian Immunisation Register (AIR) in **January 2023**. When reporting the administration of a **Pfizer Comirnaty** vaccine to the AIR, vaccination providers should use the vaccine code **COMIRN**.

The **Pfizer Comirnaty** vaccine for children between 6 months to 4 years is available to report to the AIR using Practice Management Software (PMS), however if this vaccine is not displayed, we recommend vaccination providers contact their software provider in the first instance. Alternatively, vaccination providers can report the vaccine to the AIR using the [AIR site](#). Please see an example below:

The screenshot shows a software interface for recording a vaccination episode. The title is "Episode Details". There are three main input sections: "Vaccine/Brand:" with a dropdown menu showing "pfizer"; "Batch Number:" with a text input field containing "Please enter..."; and "Serial Number:" with a dropdown menu showing "Pfizer Comirnaty" (highlighted with a red box) and "Pfizer Comirnaty Biv BA.1", and a text input field containing "Pfizer Comirnaty Biv BA.4-5". To the right of the Serial Number dropdown is a "Scan serial number" button and a "+" button. At the bottom of the form are two buttons: "ADD" and "CANCEL".

It is mandatory under the *Australian Immunisation Register Act 2015* for vaccination providers to report all vaccinations administered in Australia to the AIR. Vaccination providers should use the latest version of their PMS to make sure they meet reporting requirements.

It is the responsibility of the vaccination provider to upload the COVID-19 vaccination into the patients AIR either within **24 hours** and no later than 10 working days after vaccination.

**Please note:** There are multiple Pfizer Comirnaty vaccines available in Australia and it is important that vaccination providers enter the correct vaccine and batch number when reporting information to the AIR. Healthcare providers **should check each patient's immunisation history and Medicare reference numbers before administering any COVID-19 vaccine.**

## Vaccine Administration Errors

It is mandatory under the *Australian Immunisation Register Act 2015*, for vaccination providers to report all vaccinations administered in Australia to the AIR. Vaccination providers should use the latest version of their PMS to make sure they meet reporting requirements.

**Please note:** The existing Pfizer Comirnaty vaccine (COMIRN) will remain available for vaccination providers to report to the AIR. **It is important** that vaccination providers enter the correct vaccine and batch number when reporting information to the AIR.

A vaccine administration error (VAE) occurs when a COVID-19 vaccine is given outside the current clinical guidelines. Including where guidance has recently changed.

**If a VAE occurs at your site, please contact the Vaccine Operations Centre (VOC) to inform them.** Once they have received all the relevant details relating to the incident, they will review and provide advice relating to the incident.

### Ways to prevent VAE's include checking:

- The Australian Immunisation Register (for previous vaccine doses, brands and age)
- The age of patient and eligibility for vaccination & vaccine type
- Vaccine manufacture expiry date (including any extensions that may apply)
- Vaccine thaw use-by date (for mRNA vaccines only)
- Keeping up to date with the latest ATAGI guidance

**VOC contact details:** 1800 318 208 or  
[COVID19VaccineOperationsCentre@health.gov.au](mailto:COVID19VaccineOperationsCentre@health.gov.au)

## Consent

Informed consent is required before administering any COVID-19 vaccine dose and providers are required to document consent in a patient's medical record. Verbal or written consent is acceptable. Doctors and support staff in private medical practices can access interpreters from Translating and Interpreting Service (TIS National) on 131 450 to assist in their consultations with patients and ensure informed consent is given for COVID-19 vaccines.

The Pfizer 6 months to 4 years [information and consent form](#) has been developed for parents and guardians of children within this cohort. This is available at the link above and on the Department of Health and Aged Care website.

## Reporting in COVID-19 Vaccine Administrative System (CVAS)

A reminder that it is **mandatory** to complete a **CVAS Delivery Acceptance Report** on the day of vaccine delivery and the **Vaccine Stock Management Report** for all vaccine stock held in the clinic is due by 9pm on Friday local time each week.

You will need to complete a Stock Management report for each vaccine your site is approved to administer, **even if you do not receive any deliveries or administer any doses in that week**. Any wastage involving 10 or more vials in one incident should be reported immediately after the wastage event via the Wastage reporting tab in CVAS.

## Childhood Immunisation Community Kit

The childhood immunisation community kit offers a range of activities to help children learn how to stay safe from viral infections like COVID-19, with helpful information for parents and guardians about the importance of all childhood vaccinations: [Childhood immunisation community kit | Australian Government Department of Health and Aged Care](#)

## The Teeny Tiny Stevies song 'I got you'

This catchy song from Teeny Tiny Stevies explains how kids and parents can protect themselves from COVID-19 and other viruses: [The Teeny Tiny Stevies song 'I got you' | Australian Government Department of Health and Aged Care](#)

## Useful Links

The **ATAGI** website contains:

- [ATAGI recommendation for Pfizer 6 months to 4 years](#)
- [ATAGI Clinical Guidance](#)

The **TGA** website contains the:

- [Information on the Pfizer vaccine](#)
- [Pfizer Maroon Cap Product Information](#)
- [Consumer Medicine Information](#)

The **Department of Health and Aged Care** website contains the:

- [COVID-19 Vaccines in Australia – A3 poster](#)
- [ATAGI recommended COVID-19 doses and vaccines Poster](#)