Australian Government

COVID-19 VACCINATION

COMIRNATY (PFIZER) BIVALENT (BA.4-5) 12 YEARS+ (GREY) FACT SHEET

Version 3 – 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 Bivalent (BA.4-5) 12 years+ (Grey) vaccine.

Eligible population

The Australian Technical Advisory Group on Immunisation (ATAGI) has reviewed the available evidence and **advises** that for people aged 12 years and older, a bivalent COVID-19 vaccine is now preferred over original (ancestral) vaccines for both **primary course** vaccination and **booster doses**. There is currently no bivalent vaccine available for children aged 6 months – 11 years, and existing original vaccines should continue to be used for eligible patients in this age group.

ATAGI continues to **recommend** primary course vaccination in all people from 5 years of age. For most people, a primary course consists of two doses, or three doses in those who are severely immunocompromised.

Please refer to the Department of Health and Aged Care website for up-to-date advice on Booster Doses

COMIRNATY (PFIZER) BIVALENT BA.4-5 VACCINE (PFIZER BIVALENT (BA.4-5) 12 YEARS+ (GREY)

The Pfizer Bivalent (BA.4-5) 12 years+ (Grey) vaccine is a new formulation of the COVID-19 vaccine targeting both the original COVID-19 strain and the Omicron BA.4-5 strains.

The vaccine contains two active ingredients for a total of 30 micrograms of active ingredient, comprising of 15 micrograms of tozinameran and 15 micrograms of famtozinameran mRNA encoding Omicron BA.4 and BA.5.

The Pfizer Bivalent (BA.4-5) 12 years+ (Grey) comes in multi-dose vials containing 6 doses, with each dose being 0.30 mL. This vaccine **must not be diluted.**

General practices and community pharmacies will receive the Pfizer Bivalent (BA.4-5) 12 years+ (Grey) 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) and applies to all mRNA vaccines.

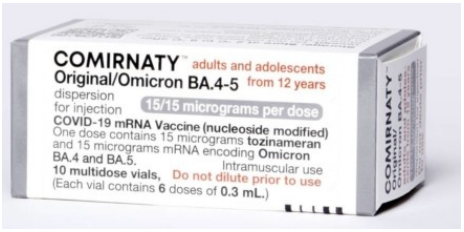
For the Pfizer Bivalent (BA.4-5) 12 years+ (Grey), unopened thawed vial can be stored at 2°C to 8°C for a maximum of 70 days (10 weeks) within the 18-month shelf life.

Stability has been shown with storage of Pfizer Bivalent (BA.4-5) 12 years+ (Grey) vaccine for 12 hours at 8°C to 30°C after initial puncture.

However, because this vaccine contains no antimicrobial preservatives, ATAGI recommends that after puncture, vials must be kept at 2°C to 30°C and used within 6 hours after initial puncture. Discard remaining solution after 6 hours. **Do not shake the vial.**

Please refer to the TGA or the Product Information for further information.

Pfizer Bivalent (BA.4-5) 12 years+ (Grey) Pack Dimensions



Each box contains 10 x 6 dose vials. The pack has grey highlights on the ends.

Box Dimensions (L x W x H) are:
93mm x 38mm x 45 mm
Weight 76.1g

There is a label on the front of the pack that denotes the use-by date; the earliest of the thawed use by date and batch expiry. This label also identifies that this vaccine is to be used for people **aged 12 years+.**

Pfizer Bivalent (BA.4-5) 12 years+ (Grey) Vial

The vial has a grey **cap** with a grey **label**.

Vials are 35mm x 12mm Weight 5g

Pfizer Bivalent (BA.4-5) 12 years+ (Grey) Consumables

The Pfizer Bivalent (BA.4-5) 12 years+ (Grey) consumables that will be delivered separately to your vaccine include the below, (or similar):

- 1 mL Luer lock syringe (pack of 100);
- Low Dead Space Needle Orange 25 gauge 25 mm [1 inch];
- Low Dead Space Needle Blue 23 gauge 38 mm (pack of 100).

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 Bivalent (BA.4-5) 12 years+ (**Grey**) vaccine.

Any selected sites who **have not yet completed a Pfizer Site Readiness Declaration will be required** to complete this in the COVID-19 Vaccine Administrative System (CVAS) before being able to order the Pfizer Bivalent (BA.4-5) 12 years+ (**Grey**) vaccine.

Training

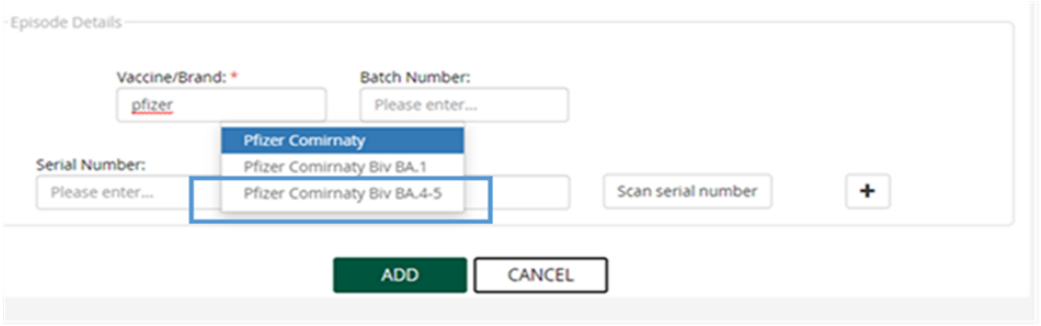
All clinical staff must complete the **COVID-19 Vaccination Training Program** (CVTP) before administering Pfizer Bivalent (BA.4-5) 12 years+ (**Grey**) vaccine. The Module is called **Additional module 1b: Pfizer Bivalent BA.4-5 COVID-19 vaccine.**

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 vaccination training page **COVID-19 vaccination training program | Australian Government Department of Health and Aged Care.**

Reporting a Pfizer Bivalent BA. 4-5 Comirnaty vaccination to the Australian Immunisation Register

When reporting the administration of a **Pfizer Comirnaty Biv BA.4-5** vaccine to the AIR, vaccination providers should use the vaccine code **COMBBA.**

The **Pfizer Comirnaty Biv BA.4-5** vaccine 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:



It is mandatory under the *Australian Immunisation Register Act 2015*, for vaccination providers to report all COVID-19 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:

- The existing Pfizer Bivalent Comirnaty vaccine will be updated to display as **Pfizer Comirnaty Biv BA.1**, vaccination providers should use the existing vaccine code when reporting to the AIR (COMBIV).
- The original Pfizer Comirnaty vaccine (COMIRN) will remain available for vaccination providers to report to the AIR where this is the vaccine administered.

Please note: 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.**

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. Vaccination providers 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.

An example form for vaccination providers to obtain patient consent prior to COVID-19 vaccination can be found **here**. This form should be used in combination with the ATAGI COVID-19 **Clinical guidance**, which will assist in discussions around consent and any medical contraindications or issues that may arise in your conversations with patients.

Reporting in COVID-19 Vaccination 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.

Useful Links

The **ATAGI** website contains the:

- **ATAGI's recommendation for Pfizer Bivalent Primary Course**
- **ATAGI recommendation for booster doses**
- **ATAGI Clinical Guidance**

The **TGA** website contains the:

- **Information on the Pfizer vaccine**
- **Pfizer Bivalent BA.4-5 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**