Australian Government

COVID-19 VACCINATION

PFIZER (XBB.1.5) 12 YEARS+ (Grey) FACT SHEET

Version 1 – November 2023

This fact sheet is for Primary Care sites who are participating in the COVID-19 Vaccination Program. It provides information and guidance about the administration and storage of the Pfizer (XBB.1.5) 12 years+ (**Grey**) vaccine.

For patient eligibility for this vaccine, please refer to the **Australian Immunisation Handbook COVID-19 Chapter**

PFIZER (XBB.1.5) 12 YEARS+ (GREY)

The Pfizer (XBB.1.5) 12 years+ (**Grey**) vaccine is a new formulation of the COVID-19 vaccine targeting the new Omicron XBB.1.5 subvariant.

The vaccine comes in multi-dose vials containing 6 doses, with each dose being 0.30 mL and containing 30 micrograms of raxtozinameran, a COVID-19 mRNA vaccine.

This vaccine **does not require dilution.**

General practices and community pharmacies will receive this 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°C to 8°C) and applies to all mRNA vaccines.

For the Pfizer (XBB.1.5) 12 years+ (**Grey**) vaccine, an **unopened** thawed vial can be stored at **2°C to 8°C for a maximum of 70 days (10 weeks)** within the **24-month shelf life,** provided that approved storage conditions have been maintained.

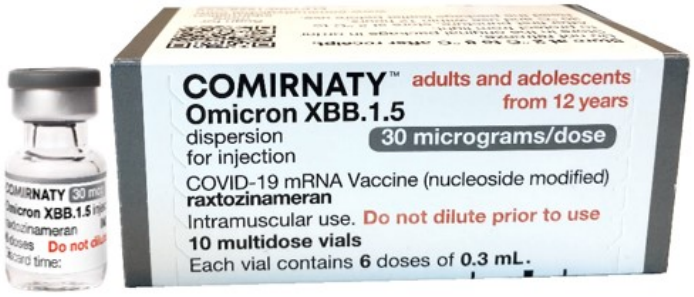
ATAGI recommends that after puncture, vials must be kept at **2°C to 30°C and used within 6 hours after initial puncture**. Discard remaining solution after 6 hours. **Do not shake the vial.**

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

Pfizer (XBB.1.5) 12 years+ (Grey) Pack Dimensions

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

Box Dimensions (L x W x H) are:
89mm x 37mm x 47 mm
Weight 95.0g



Pfizer (XBB.1.5) 12 years+ (Grey) Vial

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

Vials are 35mm x 12mm Weight 7.8g.

For all thawed (2°C to 8°C) vaccine deliveries, there will be a sticker applied to the external packaging specifying the accurate vaccine **Use-by date** for **unopened** multi-dose vials.

- The **Defrost date** is the date that the frozen vaccines were thawed and stored at 2°C to 8°C by the logistics provider.
- The **Use-by date** considers both the defrost date and shelf-life (batch expiry) i.e. 70 days within the 24-month shelf life.

Example sticker only

DO NOT use vaccine beyond the **Use-by date**.

Pfizer (XBB.1.5) 12 years+ (Grey) Consumables

The consumables that will be delivered separately to your vaccine include the below, (or similar):

- 1 mL Luer lock syringe (pack of 100);
- 25 gauge 25 mm low dead space needle [1 inch] (pack of 100);
- 23 gauge 38 mm low dead space needle [1½ inch] (pack of 100);
- 1mL syringe with fixed needle 25 gauge 25mm [1 inch] (pack of 100).

Disposal of Vaccines

Vaccines that are considered wastage (either due to expiry, damage, cold chain breach) 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 the Program, and who have already completed the **Pfizer Site Readiness Declaration** previously, **do not need to complete another declaration** before being able to order Pfizer (XBB.1.5) 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 (XBB.1.5) 12 years+ (**Grey**) vaccine.

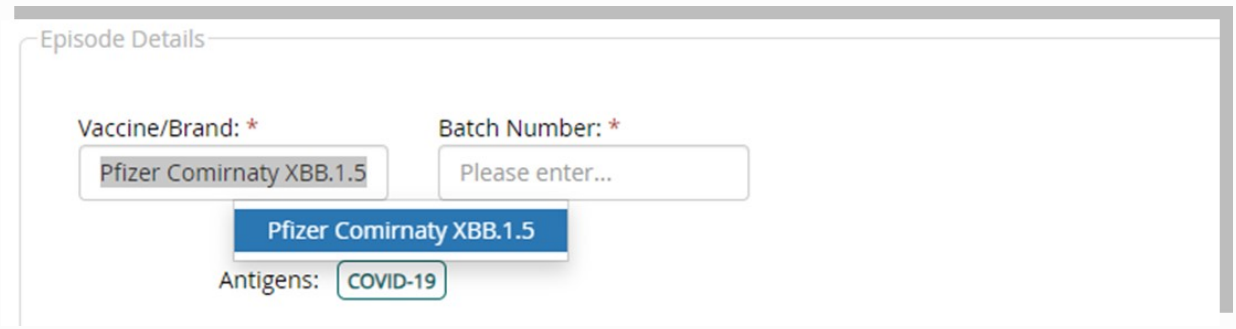
Training

There is no longer mandatory COVID-19 training. Healthcare providers who are immunisers will need to ensure that their professional immunisation training, as required by jurisdictional and professional standards, is up to date.

Reporting a Pfizer Comirnaty XBB.1.5 vaccination to the Australian Immunisation Register

When reporting the administration of a Pfizer Comirnaty XBB.1.5 vaccine to the AIR, vaccination providers should use the vaccine code **COMXBB.**

The Pfizer Comirnaty XBB.1.5 vaccine will be available to report to the AIR from **4 December 2023**, 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 report the COVID-19 vaccination to the 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/lot 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 **Australian Immunisation Handbook COVID-19 Chapter**, 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 recommendations on use of the Moderna and Pfizer monovalent Omicron XBB.1.5 COVID-19 vaccines**

The **TGA** website contains the:

- **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**
- **Australian Immunisation Handbook Covid-19 Chapter**
- **COVID-19 Vaccine Reference Guide**

If you have any questions, please contact the Vaccine Operations Centre (VOC) on 1800 318 208 or COVID19VaccineOperationsCentre@Health.gov.au