



Australian Government

## COVID-19 VACCINATION

# PFIZER (XBB.1.5) 5-11 YEARS (LIGHT BLUE) 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) 5-11 years (**Light Blue**) vaccine.

For patient eligibility for this vaccine, please refer to the [Australian Immunisation Handbook COVID-19 Chapter](#)



### PFIZER (XBB.1.5) 5-11 YEARS (LIGHT BLUE)

The Pfizer (XBB.1.5) 5-11 years (**Light Blue**) vaccine is a new formulation of the COVID-19 vaccine targeting the Omicron XBB.1.5 subvariant.

The vaccine comes in a **single-dose vial**, with each dose being 0.30mL and containing 10 micrograms of raxtozinameran, a COVID-19 mRNA vaccine.

#### **This vaccine does not require dilution.**

General practices and 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) 5-11 years (**Light Blue**) 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.

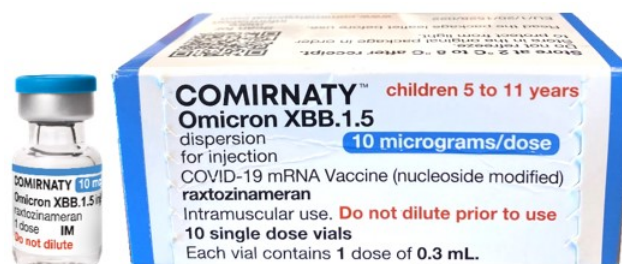
## Pfizer (XBB.1.5) 5-11 years (Light Blue) Pack Dimensions

Pack dimensions are larger than the previous Pfizer vaccine for this cohort.

Each box contains **10 single dose vials**.

Box Dimensions (L x W x H) are:

37 x 47 x 89 mm



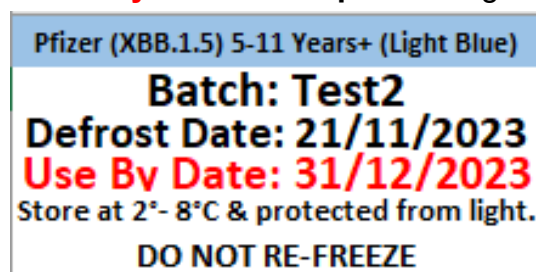
## Pfizer (XBB.1.5) 5-11 years (Light Blue) Vial

This vaccine comes in a **single-dose vial** and has a **Light Blue** cap with a **Light Blue** label.

Vials are 35mm x 12mm Weight 5g.

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** single-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) 5-11 years (Light Blue) 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 38mm low dead space needle [1½ inch] (pack of 100);
- 1 mL syringe with fixed 25 gauge 25mm needle [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 administer this vaccine, and who have already completed the **Pfizer Site Readiness Declaration** previously, do not need to complete another declaration before being able to order the Pfizer (XBB.1.5) 5-11 years (**Light Blue**) 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 the Pfizer (XBB.1.5) 5-11 years (**Light Blue**) 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:

Episode Details

Vaccine/Brand: \* Pfizer Comirnaty XBB.1.5

Batch Number: \* Please enter...

Pfizer Comirnaty XBB.1.5

Antigens: COVID-19

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 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.

## USEFUL LINKS

The **ATAGI** website contains:

- [ATAGI recommendations on use of the Moderna and Pfizer monovalent Omicron XBB.1.5 COVID-19 vaccines](#)

The **TGA** website contains the:

- [Pfizer \(XBB.1.5\) 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](#)
- [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](mailto:COVID19VaccineOperationsCentre@Health.gov.au)