



PFIZER (XBB.1.5) CHILDREN 5-11 YEARS (LIGHT BLUE) SINGLE DOSE VIAL FACT SHEET

Version 4 – March 2024

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 children aged 5-11 years. This vaccine **must not be given** to people aged **12+ years**.

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

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





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 and is for for children aged 5-11 years. This vaccine must not be given to people aged 12+ years.

The vaccine comes in a **single-dose vial**, with each does 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. **Please only order what you need. You do not have to order all your allocation at once.**

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. Do not shake the vial

Once the single-dose vaccine has been drawn-up into the syringe, the syringe must be kept at **2°C to 30°C and used within 6 hours**. Discard syringe after 6 hours.

Please refer to the <u>TGA</u> or the <u>Product Information</u> 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: $37 \times 47 \times 89 \text{ mm}$

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

This vaccine comes in a **<u>single-dose vial</u>** 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.
- **DO NOT** use vaccine beyond the **Use-by date**.

Defrost Date: 21/11/2023 Use By Date: 31/12/2023 Store at 2°- 8°C & protected from light.

Batch: Test2

DO NOT RE-FREEZE

* Example Sticker only

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 [1¹/₂ 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, must ensure they have completed the **Pfizer Site Readiness Declaration** in CVAS.

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**.

Please see an example below:

sode Details		
Vaccine/Brand: *	Batch Number: *	
Pfizer Comirnaty XBB.1.5	Please enter	
Pfizer Comin Antigens: COVID		

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 <u>correct vaccine and batch/lot number</u> when reporting information to the AIR. Healthcare providers **should check each patient's** immunisation history and <u>Medicare reference numbers</u> 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.

The Australian Immunisation Handbook can assist vaccination providers with 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 TGA website contains the:

- Pfizer (XBB.1.5) Product Information
- Consumer Medicine Information

The Department of Health and Aged Care website contains the:

- Recommendations on use of Pfizer monovalent Omicron XBB.1.5 COVID-19 vaccines
- COVID-19 Vaccines in Australia A3 poster
- Recommended COVID-19 vaccine doses
- Australian Immunisation Handbook Covid-19 Chapter
- COVID-19 Vaccine Reference Guide
- Childhood immunisation community kit | Australian Government Department of Health
 and Aged Care
- The Teeny Tiny Stevies song 'I got you' | Australian Government Department of Health and Aged Care

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