Australian Government

COVID-19 VACCINATION

MODERNA (XBB.1.5) 12 YEARS+ (PFS) 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 Moderna (XBB.1.5) 12 years+ (PFS) vaccine, which is **a single dose, pre-filled syringe** (PFS).

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

Moderna (XBB.1.5) 12 years+ (PFS) VACCINE

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

The vaccine comes in **0.50mL single dose, pre-filled syringes** with each dose containing 50 micrograms andusomeran, a COVID-19 mRNA vaccine.

Do not use the pre-filled syringe to deliver a partial 0.25mL volume. This vaccine **must not be diluted.**

General practices and community pharmacies will receive the vaccine **thawed.** ACCHS will receive stock either **frozen** or **thawed**, dependent on how they currently receive Moderna 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.

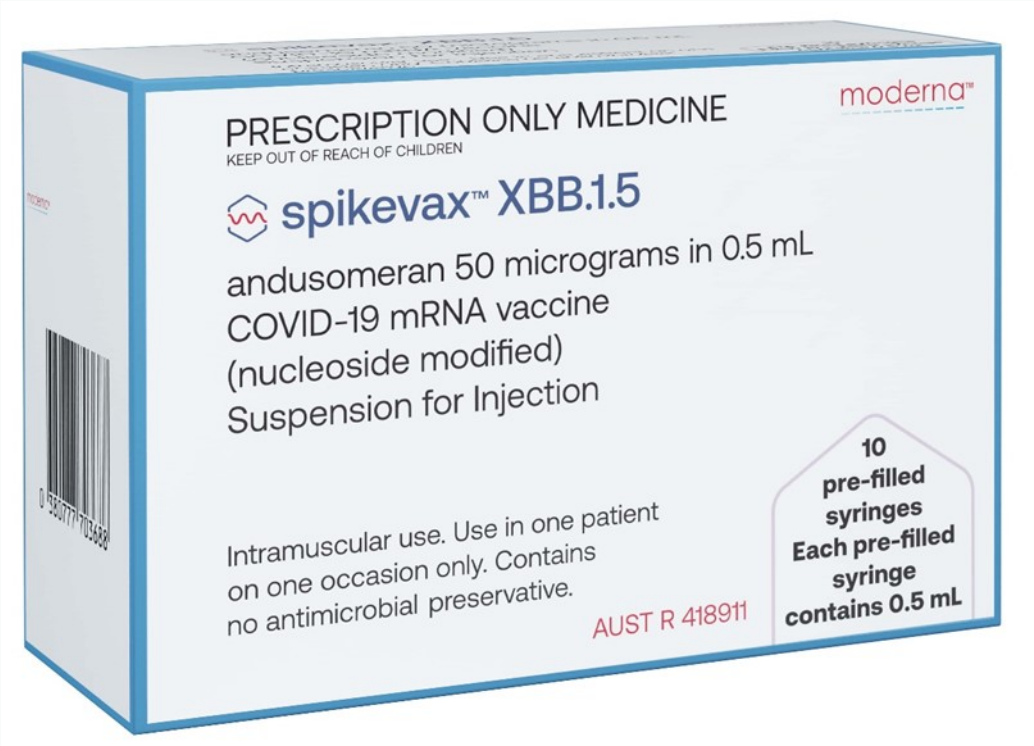
For the Moderna (XBB.1.5) 12 years+ (PFS) vaccine, **unopened** thawed syringes can be stored at **2°C to 8°C for a maximum of 30 days** within the **9-month shelf life,** provided that approved storage conditions have been maintained.

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

Moderna (XBB.1.5) 12 years+ (PFS) Pack Dimensions

Each box contains **10 x single dose (0.50mL) pre-filled syringes**.

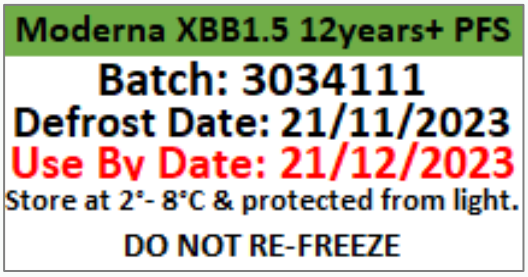
Box Dimensions (L x W x H) are: 133mm x 87mm x 55mm.



Please note this is the actual size of the packaging. This guide is to assist you in ensuring you will have enough storage space in your refrigerator to store this vaccine. Please only order what you need.

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** pre-filled syringes.

- 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. **30 days within the 9-month shelf life**.

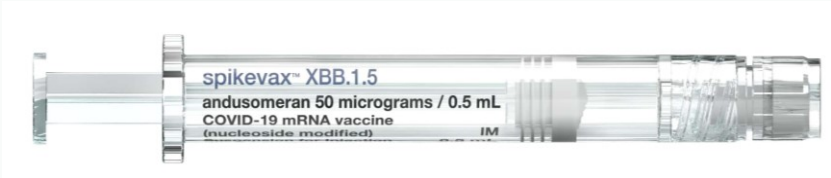


***Example sticker only**

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

Moderna (XBB.1.5) 12 years+ (PFS) Syringe

Each pre-filled syringe contains 0.5 mL of suspension, a plunger stopper and a tip cap (without a needle).



Moderna (XBB.1.5) 12 years+ (PFS) Consumables

The consumables that will be delivered separately to your vaccine include the below:

- 25 gauge 25 mm needle [1 inch] (pack of 100);
- 23 gauge 38 mm needle [1½ 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 **Moderna Site Readiness Declaration** previously, do not need to complete another declaration before being able to order the Moderna (XBB.1.5) 12 years+ (PFS) vaccine.

Any selected sites who have not yet completed a **Moderna** Site Readiness Declaration **will be required** to complete this in the COVID-19 Vaccine Administrative System (CVAS) before being able to order the Moderna (XBB.1.5) 12 years+ (PFS) vaccine.

Training

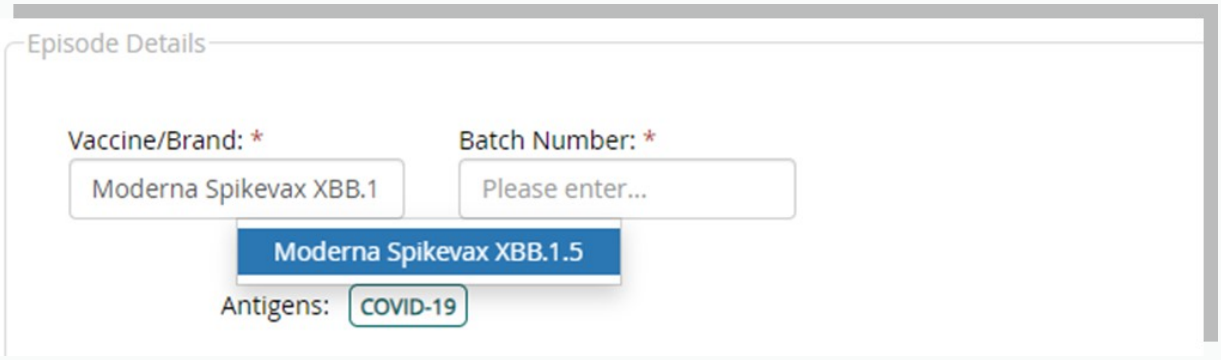
There is no longer mandatory COVID-19 training. Healthcare providers who are immunisers will need to ensure that their professional immunisation training, as required by jurisdictional and professional standards, is up to date.

Reporting a Moderna Spikevax XBB.1.5 vaccination to the Australian Immunisation Register

When reporting the administration of a **Moderna Spikevax XBB.1.5 vaccine** to the AIR, vaccination providers should use the vaccine code **MODXBB**.

The **Moderna Spikevax 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 Moderna Spikevax 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 100 or more single dose, pre-filled syringes (i.e. 10 or more boxes) 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 vaccine**

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**