Australian Government

COVID-19 VACCINATION

MODERNA BIVALENT (BA.4-5) 12 YEARS+ (PFS) VACCINE FACT SHEET

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 Moderna Bivalent (BA.4-5) 12 years+ (PFS) vaccine, which is **a single dose, pre-filled syringe** (PFS) and is approved for use as a booster dose in people aged **12 years and over**.

Eligible population

The Australian Technical Advisory Group on Immunisation (ATAGI) **recommends** the Moderna Bivalent (BA.4-5) 12 years+ (PFS) vaccine can be used for booster doses in people aged 12 years or older, in line with the current **ATAGI recommendation for booster doses.** All currently available COVID-19 vaccines are anticipated to provide benefit as a booster dose, however bivalent mRNA booster vaccines are preferred over other vaccines.

MODERNA BIVALENT (BA.4-5) 12 YEARS+ (PFS) VACCINE

The Moderna Bivalent (BA.4-5) 12 years+ (PFS) COVID-19 vaccine is **a single dose, pre-filled syringe** approved for use as a **booster dose only** in people aged **12 years and over**.

The Moderna Bivalent (BA.4-5) 12 years+ (PFS) vaccine is a new formulation of the COVID-19 vaccine targeting both the original COVID-19 strain and the Omicron BA.4-5 strains. Unlike other COVID-19 vaccines, the Moderna Bivalent (BA.4-5) 12 years+ (PFS) vaccine comes as a **single dose, (0.50mL) pre-filled syringe.** The vaccine contains two active ingredients for a total of 50 micrograms of active ingredient, comprising of 25 micrograms of elasomeran and 25 micrograms of davesomeran, a COVID-19 mRNA vaccine encoding Omicron BA.4 and BA.5.

The Moderna Bivalent (BA.4-5) 12 years+ (PFS) vaccine is distributed in **boxes of 10 single dose, pre-filled syringes**, with each dose being 0.50 mL.

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

This vaccine is currently only recommended as a **booster dose** for individuals aged 12 years and over who are eligible to receive a COVID-19 booster according to the **ATAGI 2023 booster advice**. This vaccine should not be used for primary course vaccination or in those aged less than 12 years.

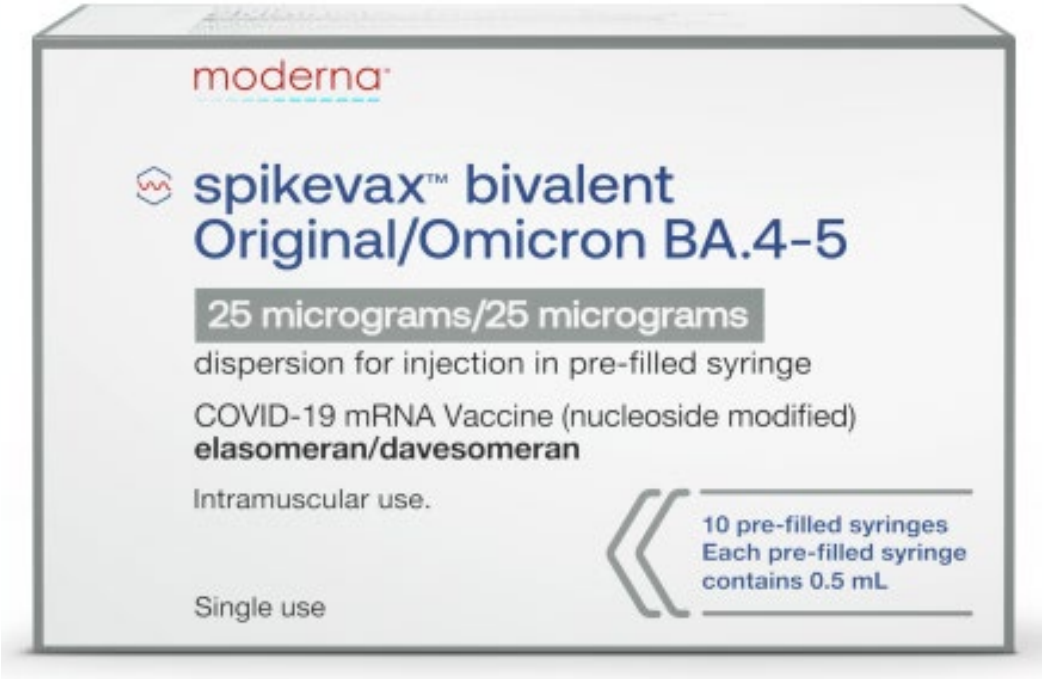
General practices and Pharmacists will receive the Moderna Bivalent (BA.4-5) 12 years+ (PFS) vaccine **thawed.** ACCHS will receive stock either **frozen** or **thawed**, dependent on how they currently receive **Moderna** vaccines**.**

The thaw use-by date is the allowable timeframe for vaccines to be in a thawed state (refrigerated at 2-8°C) and applies to all mRNA vaccines.

For the Moderna Bivalent (BA.4-5) 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.

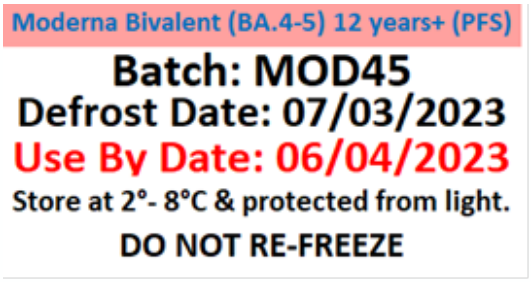
Moderna Bivalent (BA.4-5) 12 years+ (PFS) Pack Dimensions

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



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

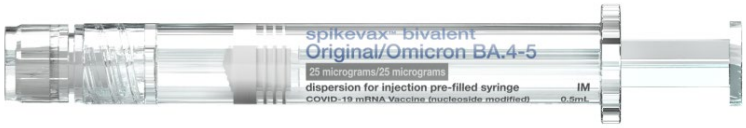
There will be a label applied to the front of the outer box that denotes the use-by date; the earliest of the thawed use-by date and batch expiry.



PLEASE NOTE: The packaging for this pre-filled single dose vaccine is **significantly larger** than the previous Moderna Spikevax Bivalent. The pack has blue writing with grey highlights on the end. You **will not be able to** store the same quantity of doses/vaccines in your Vaccine Fridge, as you can with other COVID-19 Vaccines. Please only order what you need.

Moderna Bivalent (BA.4-5) 12 years+ (PFS) Syringe

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



Please refer to the **TGA** or the **Product Information**

Moderna Bivalent (BA.4-5) 12 years+ (PFS) Consumables

The Moderna Bivalent (BA.4-5) 12 years+ (PFS) consumables that will be delivered separately to your vaccine include the below:

- Orange Needle 25 gauge 25 mm;
- Blue Needle 23 gauge 38 mm.

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 this roll-out, and who have already completed the **Moderna Site Readiness Declaration** previously, do not need to complete another declaration before being able to order Moderna Bivalent (BA.4-5) 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 Bivalent (BA.4-5) 12 years+ (PFS) vaccine.

Training

All clinical staff must complete the **COVID-19 Vaccination Training Program** (CVTP) before administering **Moderna Bivalent (BA.4-5) 12 years+ (PFS)** vaccine. The Module is called **Additional module 3d: Moderna Bivalent (BA.4-5) 12 years+ (PFS) Booster Vaccine**. The training will be available from **22 March 2023**.

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**.

Listing on the Vaccine Clinic Finder/Healthdirect Service Finder

Sites who place an order in their first ordering window will be added to the Healthdirect Service Finder (which replaces the COVID-19 Vaccine Clinic Finder) for the service.

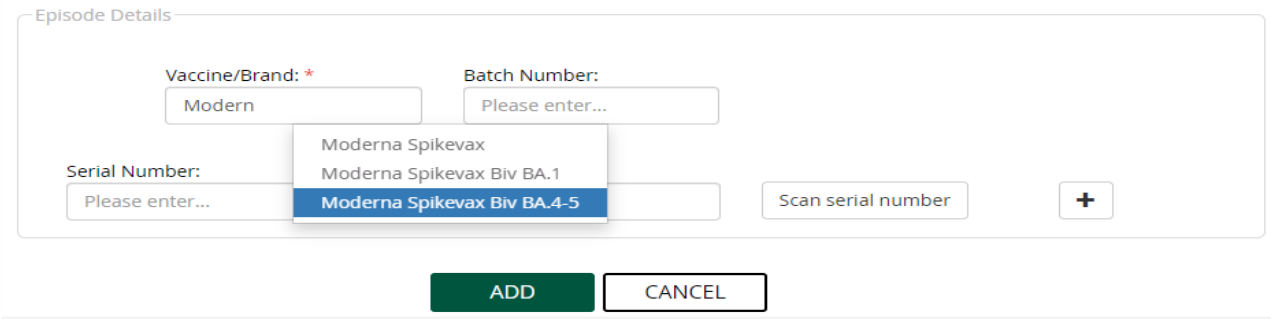
Please ensure you **log into** VCF Connect and update your service with your **opening times** and other information relevant to your site. This will ensure your new vaccine service displays correctly on the Service Finder.

It is a requirement of the program that all COVID-19 vaccines administered at your site are published on the Service Finder. If you have any questions about how to maintain your vaccine information in the Service Finder, please contact the VCF Connect helpline on 1800 316 375 or email **cv19.products@health.gov.au**

Reporting a Moderna Bivalent (BA.4-5) 12 years+ (PFS) vaccination to the Australian Immunisation Register

The **Moderna Spikevax Biv BA.4-5** vaccine will be added to the Australian Immunisation Register (AIR) on 26 March 2023. When reporting the administration of a **Moderna Bivalent (BA.4-5) 12 years+ (PFS)** vaccine to the AIR, vaccination providers should use the vaccine code **MODBBA**.

The **Moderna Spikevax Biv BA.4-5** vaccine will be 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 vaccinations administered in Australia to the AIR. Vaccination providers should use the latest version of their PMS to make sure they meet reporting requirements.

Please note:

- The existing Moderna Bivalent Spikevax vaccine will be updated to display as **Moderna Spikevax Biv BA.1**. Vaccination providers should use the existing vaccine code when reporting to the AIR (**MODBIV**).
- The original Moderna Spikevax vaccine (MODERN) will remain available for vaccination providers to report to the AIR where this is the vaccine administered.

It is important that vaccination providers enter the **correct vaccine and batch number** when reporting information to the AIR.

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 TIS National on 131 450 to assist in their consultations with patients and ensure informed consent is given for COVID-19 vaccines.

An example 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

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's recommendation for Moderna Bivalent (BA.4-5) 12 years+ (PFS) COVID-19 vaccine**
- **ATAGI 2023 booster advice**
- **ATAGI Clinical Guidance**

The **TGA** website contains the:

- **Information on the Moderna Bivalent (BA.4-5) 12 years+ (PFS)**
- **Moderna Bivalent (BA.4-5) 12 years+ (PFS) Product Information**
- **Moderna Bivalent (BA.4-5) 12 years+ (PFS) Consumer Medicine Information**

This information is current as at: March 2023