Immunisation Advisory Centre

VERSION 3

# Comirnaty Omicron 30mcg XBB.1.5 (12+ years)

## Guidance for healthcare professionals

### Key information

Comirnaty Omicron 30mcg XBB.1.5 supersedes the previous 12+ Comirnaty vaccines.

As of August 2024, Comirnaty 30mcg XBB.1.5 is the only COVID-19 vaccine available for those aged 12 years and older. A single dose of Comirnaty 30mcg XBB.1.5 is used as a primary course from 12 years of age.

There are single and multi-dose vials available.

Eligibility criteria remain the same for primary course and additional doses.

### Background

SARS-CoV-2 continues to circulate widely internationally and to evolve rapidly with continuous changes to the spike protein. Because of this we need to maximise vaccine effectiveness by using variant-matched vaccines, similar to the way we do for influenza vaccines. Omicron is the only variant currently circulating globally and previous variants such as Delta and the original strain have largely disappeared. Numerous sub-lineages of Omicron have caused global waves of infection.

The WHO Technical Advisory Group on COVID-19 Vaccine Composition (TAG-CO-VAC) recommended the use of a monovalent XBB.1.5 descendant lineage for the vaccine antigen in May 2023. XBB.1.5-matched vaccines continued to be recommended following review of their performance in December 2023. After reviewing the predominant lineages in April 2024, the TAG-CO-VAC advised the use of a monovalent JN.1 lineage as the antigen in future formulations of COVID-19 vaccines, and these are now being developed internationally.

One dose (0.3mL) of Comirnaty XBB.1.5 contains 30mcg of raxtozinameran (mRNA expressing the spike protein of Omicron XBB.1.5) embedded in lipid nanoparticles. In contrast, each 0.3mL dose of Comirnaty 15/15mcg grey cap (bivalent) contained 15mcg tozinameran (nucleoside-modified mRNA expressing original SARS-CoV-2 spike protein) and 15mcg famtozinameran (mRNA expressing Omicron BA.4-5 SARS-CoV-2 spike protein). The other components are unchanged.

Although protection against reinfection with Omicron variants wanes within months of additional doses, protection remains sustained against severe disease. It is not yet certain how long the protection from COVID-19 vaccines and infection lasts. For most, it appears that protection against severe disease extends beyond six months as immune memory develops. The immune function of some people, particularly older age groups, is not as robust as it is in younger healthy people. This means that any protection they gain from the vaccine is shorter-lived, increasing the risk of severe COVID-19 as their immunity wanes.

Additional doses help to bolster this immunity and have been shown to be highly protective, at least for several months, against COVID-19-related hospitalisation and death.

| **Comirnaty 30mcg XBB.1.5** Multi-dose vial – dark grey cap | **Comirnaty 30mcg XBB.1.5** Single dose vial – light grey cap |
|---|---|
| One multi-dose vial (2.25mL) contains 6 doses of 0.3mL | One single dose vial contains 1 dose of 0.3mL |

**Each dose (0.3mL) contains:**

- 30mcg of raxtozinameran, a COVID-19 mRNA vaccine (embedded in lipid nanoparticles). Raxtozinameran is a single-stranded, 5'-capped messenger RNA (mRNA) encoding the vial spike protein of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Omicron XBB.1.5)
- Lipid nanoparticle
- Tris/sucrose buffer to improve the stability +2˚C to +8˚C

**DOES NOT require dilution**

This vaccine is latex-free, and the stopper is a synthetic bromobutyl rubber with grey plastic flip-off cap with aluminium seal.

## Recommended schedule

Comirnaty 30mcg XBB.1.5 is administered intramuscularly as a single dose of 0.3mL for individuals 12 years of age and older for eligible individuals as a primary or additional dose.

## Primary course

A single dose of Comirnaty 30mcg XBB.1.5 is used as a primary course from 12 years of age.

Anyone swapping to Comirnaty 30mcg XBB.1.5 after only one dose of original Comirnaty 30mcg, Nuvaxovid or other overseas vaccines can have a single Comirnaty 30mcg XBB.1.5 from three months post that previous dose.

## Three dose primary course for immunocompromise

Three primary doses of Comirnaty 30mcg XBB.1.5 are recommended for those who are severely immunocompromised, at eight-week intervals. A prescription is required for any Comirnaty 30mcg XBB.1.5 dose given with less than three months spacing between a previous one.

## Additional dose eligibility and spacing

A **single dose** is recommended for individuals aged 16 years and over, after completing the primary course. This is given at least six months after previous COVID-19 vaccination or COVID-19 infection.

Additional doses of Comirnaty 30mcg XBB.1.5 continue to be **recommended** from six months after last COVID-19 vaccination for those aged 12 and over who are eligible because of a higher risk of severe infection. They continue to be **available** for healthy people aged 30 and over.

For more details on recommended groups, spacing and eligibility, see the Immunisation Handbook or the COVID vaccine eligibility table_V3 in the NIP dropbox (tinyurl.com/54hpue2w).

The interval recommended from prior COVID-19 infection or vaccination is six months as we know that protection against severe disease persists for up to at least six months. Having a dose earlier has limited benefit.

Clinical discretion can be applied when considering vaccination given less than six months after infection or previous dose. A shorter spacing of at least three months may be appropriate for those considered at high risk of severe disease from COVID-19 re-infection. Spacing of at least six months is preferred.

## Contraindications and precautions

This guidance remains the same as for the previous Comirnaty vaccine. Comirnaty 30mg XBB.1.5 is only contraindicated for those who have history of anaphylaxis to a previous dose of any Comirnaty vaccine or to any component of the vaccine. For details on precautions when administering Comirnaty 30mcg XBB.1.5 see v21 of the Comirnaty XBB.1.5 Screening Tool (tinyurl.com/mry9vpu3).

## Co-administration

All National Immunisation Schedule vaccines can be given at the same time as the Comirnaty 30mcg XBB.1.5 vaccine, preferably in a different limb. Influenza vaccination is also highly recommended for eligible groups and can be given at the same time as all COVID-19 vaccines.

Spacing of 28 days may be considered between JYNNEOS (mpox vaccine) and Comirnaty 30mcg XBB.1.5 vaccine for individuals at increased risk of myocarditis and/or pericarditis following an mRNA vaccine (males aged 16 to 40) in an abundance of caution.

## Vaccine effectiveness

The monovalent Comirnaty 30mcg XBB.1.5 vaccine stimulates antibody responses against variants of the Omicron XBB lineage and JN.1 derived variants in people who have previously received earlier vaccines.

Monovalent XBB.1.5 vaccines provide some enhanced protection compared to bivalent variant-containing vaccines and monovalent index virus (original) vaccines. The effectiveness is greater against hospitalisation and death than against infection.

An American study found Comirnaty 30mcg XBB.1.5 vaccine provided 54% increased protection against symptomatic SARS-CoV-2 infection (including JN.1 variants) compared with no receipt of updated vaccine in adults over 18 years of age. In a study from Denmark, it was associated with a 76·1% reduced risk of COVID-19 hospitalisation in the short term in a population vaccinated with a booster dose during the previous season.

## Vaccine safety

The adverse event profile of Comirnaty 30mcg XBB.1.5 is similar to earlier formulations.

In a clinical trial, the most common local reaction was injection site pain which started from one to two days and lasted one to three days. It was reported less frequently by >55-year-old participants than those aged 12-17 years. Fatigue and headache were the most common systemic adverse events. They were also reported less frequently by >55-year-old participants than among 12–17-year-olds.

Responses to AusVaxSafety surveys sent on day three after Comirnaty 30mcg XBB.1.5 showed that 26% of over 62,000 respondents reported at least one adverse event (local reaction, fatigue, muscle or joint pain, headache and fever). Four percent missed usual activities and fewer than 0.5% visited a doctor or ED following vaccination.

Myocarditis and/or pericarditis following vaccination with a COVID-19 vaccine are very rare but have been reported following receipt of all currently available COVID-19 vaccines. The highest incidence has been reported in adolescent males after a second dose of an mRNA vaccine, although cases have been reported in male and female adults of all ages and

after any dose of a COVID-19 vaccine. Australian data shows reports of myocarditis after an additional dose are very rare, occurring in less than 1 in every 100,000 doses given.

Having a longer interval between doses reduces the incidence of adverse events, including the rate of myocarditis and pericarditis following mRNA vaccines.

Early vaccine safety data from the US showed a small cluster of ischaemic stroke cases following coadministration of bivalent Comirnaty vaccine with high dose or adjuvanted influenza vaccine in people aged 65 years and over. Further analysis suggested that rate of stroke was actually reduced in vaccinated individuals and that COVID-19 and influenza infection increased the risk of stroke. Reassuringly, ongoing US and global monitoring do not indicate a safety signal.

## Use in pregnancy and breastfeeding

Observational data for the original 30mcg Comirnaty vaccine shows no increased risk of adverse pregnancy outcomes or increased risk of miscarriage in the first trimester. Although there is no current data available for the Comirnaty 30mcg XBB.1.5 formulation, there is no theoretically plausible reason for there to be any increased risk in pregnancy. This is because the differences between these vaccine formulations and the original purple cap are confined to mRNA spike protein sequences and the Tris buffer, which is used in the previous grey cap Comirnaty vaccines and is commonly used in other vaccines including the paediatric Comirnaty vaccines. Comirnaty 30mcg XBB.1.5 grey cap vaccine can be used in pregnancy and while breastfeeding.

## Additional doses in pregnancy

Pregnant people are at higher risk of complications from COVID-19 infection compared to those who are not pregnant.

Comirnaty vaccines can be given at all stages of pregnancy. An additional dose is particularly recommended for those who are pregnant with medical conditions, those who have never received a COVID-19 vaccine or who have no history of a COVID-19 infection or who meet other eligibility criteria.

## Post-vaccine advice

Continue to follow post- vaccine advice as listed in v21 of the Screening Tool (tinyurl.com/mry9vpu3).

It is essential that every consumer is given thorough and clear post-vaccination advice verbally and in writing. This advice is needed for each dose of vaccine and for all ages.

## Vaccine storage and preparation

Follow Comirnaty_Vaccine preparation guide 30mcg XBB.1.5 (12+ years) (tinyurl.com/2erm9cmr).

### Comirnaty Omicron 30mcg XBB.1.5 (12+ years) vaccine storage summary

Stored long-term at **-90°C to -60°C**. Delivered defrosted.

Defrosted vaccine stored for up to **10 weeks** at **+2°C to +8°C**
Box containing vials has expiry printed on outer sticker.
This is 10 weeks from when removed from freezer storage.
Monitor temperature as per cold chain policy. If temperature varies from +2°C to +8°C, follow cold chain breach process.

Once cap removed vial can be stored for 12 hours between **+2°C to+30°C**. Always store in separate container with a completed label.

Vaccine dose should be administered as soon as possible after drawing up into a syringe. The maximum storage time in a syringe is 6 hours from draw up or 12 hours from cap removal, whichever is soonest. Store at **+2°C to+30°C**.

Stable for up to 10 weeks at +2°C to +8°C ← Once removed from freezer, timer starts

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Up to 12 hours ← Use opened vial within 12 hours

OR

Up to 6 hours, but within vial USE BY time ← Once in syringe, use as soon as possible

**DISCARD ANY UNUSED VACCINE IN VIALS AFTER 12 HOURS, IN SYRINGES AFTER 6 HOURS, OR WHICHEVER IS SOONEST**

**Call 0800 IMMUNE (0800 466 863) for clinical advice**