Immunisation Advisory Centre

VERSION 2

Comirnaty 30mcg (12+ years)

Guidance for health care professionals

Key information

- Comirnaty 30mcg vaccine is available from 12 years, for those eligible for funded healthcare. There is currently no private- purchase option.
- Comirnaty 30mcg JN.1 supersedes the previous 12+ Comirnaty vaccines. As of January 2025, Comirnaty 30mcg JN.1 is the only COVID-19 vaccine available for those aged 12 years and older.
- A single dose of Comirnaty 30mcg JN.1 (12+ years) is used as a primary course or as an additional dose for those who are eligible.
- The vaccine is available as single dose, ready-to-use vials.

Background

SARS-CoV-2 continues to circulate globally and to evolve rapidly with continuous changes to the spike protein. By using variant-matched vaccines, like we do for influenza vaccines, we can maximise vaccine effectiveness.

Numerous sub-lineages of Omicron have caused, and continue to cause, global waves of infection. Previous variants, such as Delta and the original strain, have largely disappeared.

In Aotearoa New Zealand, COVID-19 admissions and deaths continue year-round, with cases peaking in the summer and winter months. Although the hospital admissions and deaths are lower than in previous years, the elderly remain at particular risk. Of all the COVID-19 hospitalisations in NZ, six out of 10 individuals were aged over 60 years, and people aged over 70 years with COVID-19 are five times more likely to be hospitalised than all other age groups.

The WHO Technical Advisory Group on COVID-19 Vaccine Composition (TAG-CO-VAC) monitors the evolution of SARS-CoV-2 variants and assesses the performance of COVID-19 vaccines against the circulating variants. 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 have been available internationally since October 2024.

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 healthy people, 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 protect against COVID-19-related hospitalisation and death for several months.

Comirnaty 30mcg JN.1 (light grey cap)
One single dose vial contains 1 dose of 0.3mL
Each dose (0.3mL) contains: · 30mcg of bretovameran, a COVID-19 mRNA vaccine (embedded in lipid nanoparticles). Bretovameran is a single-stranded, 5'-capped messenger RNA (mRNA) encoding the vial spike protein of SARS-CoV-2 JN.1. · Lipid nanoparticle · Tris/sucrose buffer to improve stability at +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 and aluminium seal.

Recommended schedule

Comirnaty 30mcg JN.1 is administered intramuscularly as a single dose of 0.3mL to individuals 12 years of age and older for eligible individuals as a primary or additional dose.

Anyone swapping to Comirnaty 30mcg JN.1 after only one dose of original Comirnaty 30mcg, Nuvaxovid, or other overseas vaccines can have a single Comirnaty 30mcg JN.1 from three months after that previous dose.

Three-dose primary course for immunocompromise

Three primary doses of Comirnaty 30mcg JN.1 are recommended for those who are severely immunocompromised, given at 8-week intervals. A prescription is required for any Comirnaty 30mcg JN.1 dose given with less than three months spacing between a previous one.

Additional dose eligibility and spacing

A **single dose** of Comirnaty 30mcg vaccine is recommend for those aged 16 to 29 (minimum 6 months from previous dose.)

Additional doses of Comirnaty 30mcg JN.1 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 and for anyone aged ≥75 years and older. They continue to be **available** for healthy people aged 30 and over.

For more details on recommended groups, spacing and eligibility, see Table 5.2 and Table 5.3 of the Immunisation Handbook.

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

Clinical discretion can be applied when considering vaccination given less than six months after a 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 JN.1 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 JN.1, see the Comirnaty 30mcg JN.1 screening tool.

Co-administration

All National Immunisation Schedule vaccines can be given at the same time as the Comirnaty 30mcg JN.1 vaccine, preferably in a different limb.

Influenza vaccination is also highly recommended for eligible groups and can be given at the same time as any COVID-19 vaccine.

If the timing of mpox or COVID-19 vaccination is not urgent, consider allowing a gap of 4 weeks between Jynneos and Comirnaty. This is particularly relevant for young males and those who have a history of cardiac inflammation.

Vaccine effectiveness

The monovalent Comirnaty 30mcg JN.1 vaccine stimulates antibody responses against JN.1-derived variants, including JN.1 subvariants, KP3 and XEC.

The updated vaccines continue to provide protection against hospitalisation and death. For example, in Scandinavia, a dose of the XBB.1.5 vaccine given to adults aged ≥65 years remained 58% and 75% effective at reducing hospital admissions and deaths, respectively, for at least 24 weeks during 1 October 2023 and 21 April 2024. The level of protection was the same regardless of number of doses of previous COVID-19 vaccines or for those aged 65–74 and 75 years and over.

It is anticipated that Comirnaty 30mcg JN.1 will provide similar protection.

Vaccine safety

The adverse event profile of Comirnaty 30mcg JN.1 is expected to be like that of earlier formulations as the only change is in the mRNA spike protein sequence.

In a clinical trial of Comirnaty XBB.1.5, the most common local reaction was injection site pain, which started from one to two days and lasted one to three days. Fatigue and headache were the most common systemic adverse events. These reactions were reported less frequently by over 55-year-old participants than among 12–17-year-olds.

Responses to AusVaxSafety post-vaccination surveys sent on day three after vaccination with Comirnaty 30mcg XBB.1.5 showed that around one quarter of 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 occur very rarely following a COVID-19 vaccination but have been reported following receipt of any of the COVID-19 vaccines currently available. The highest incidence was seen in adolescent males after a second dose of an mRNA vaccine. Cases have been reported at any age in male and female adults and after any dose of a COVID-19 vaccine. Australian reports show that myocarditis occurs after fewer than one in every 100,000 additional doses given.

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

Vaccine safety data from the US showed a small cluster of ischaemic stroke cases following co-administration of bivalent Comirnaty vaccine with high-dose or adjuvanted influenza vaccine in people aged 65 and over. Further analysis suggested the rate of stroke was actually reduced in vaccinated individuals. COVID-19 and influenza infections increase the risk of a stroke. Data for XBB.1.5 vaccines have not provided evidence of a confirmed safety concern.

Recent US data has identified a potential sign for Guillain- Barré syndrome (GBS) after Comirnaty XBB.1.5 in adults aged over 65 years. No signal for GBS was seen with previous formulations. The true risk is unknown and further analysis is ongoing.

Monitoring elsewhere has been reassuring. For example, in Denmark no increase was observed for any of the adverse events investigated, including strokes, GBS and myocarditis after receipt of the XBB.1.5 vaccine.

Use in pregnancy and breastfeeding

Comirnaty 30mcg JN.1 vaccine can be used in pregnancy and while breastfeeding. Observational data for the original Comirnaty 30mcg 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 JN.1 formulation, there is no plausible theoretical reason for any increased risk in pregnancy. The differences between these vaccine formulations are confined to mRNA spike protein sequences.

Additional doses in pregnancy

People who are pregnant 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 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 the Comirnaty 30mcg JN.1 screening tool.

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.

Comirnaty 30mcg JN.1 (12+ years) vaccine storage summary

- Vaccine is stored long-term at -90°C to -60°C. Delivered to sites defrosted.
- Box containing vials has an updated expiry printed on outer sticker. This is 10 weeks from when removed from freezer storage. Follow this box expiry date, not the one on the vial.
- On arrival, store vaccine in box at +2°C to +8°C.
- Monitor temperature as per cold chain policy. If temperature varies from +2°C to +8°C, follow cold chain breach process.
- We recommend administering a Comirnaty 30mcg dose immediately following drawing up the exact 0.3mL dose.
- Discard vial with any remaining contents.

Strategies to minimise risk of error

- Have Vaccine Preparation Guide visible to follow. Where possible create a "Do not disturb" time/place when vaccines are being prepared.
- Store different Comirnaty vaccines in separate areas in the fridge. Consider coloured signage, labelling, coloured baskets to differentiate between the different vaccines.
- Create a physical barrier between different vaccine preparation areas.
- Use a second checker for key checks such as correct vaccine strength, expiry and drawn up dose volume
- Select needle length appropriate for consumer 25mm or 38mm. Ensure needle is firmly attached to the syringe.