Immunisation Advisory Centre

VERSION 3

Comirnaty 3mcg and 10mcg paediatric vaccines

Information for healthcare professionals

Comirnaty Omicron 3mcg (yellow cap)

MUST DILUTE

6 months - 4 years at risk children

Dose volume 0.3mL

Multi-dose (3 doses)

Comirnaty Omicron 10mcg (blue cap)

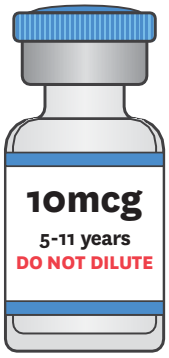
DO NOT DILUTE

All children aged 5-11 years

Dose volume 0.3mL

Single dose vial (1 dose)

Check dose; vial can have excess volume



Measure each dose carefully	Draw up with the administration needle	Follow IMAC vaccine preparation guidance sheets	These vaccines are latex-free. The vial stopper is made with synthetic rubber (bromobutyl), not natural rubber

NOTE: From December 2025, Comirnaty 10mcg LP.8.1 vaccine (0.3mL dose, blue cap) will be available for children aged 5 to 11 years. This replaces Comirnaty 10mcg JN.1 vaccine.
For children aged 6 months to 4 years, Comirnaty 3mcg JN.1 vaccine will continue to be used until Comirnaty 3mcg LP.8.1 vaccine becomes available.

Background: COVID-19 disease and vaccination for pēpi and tamariki

Commonly, children have mild or no symptoms of COVID-19 with a short duration of illness; symptoms typically include headache, fever, cough, and may include sore throat, nasal congestion, sneezing, croup, muscle aches and fatigue. Children with symptomatic COVID-19 may present with gastrointestinal symptoms, such as nausea, vomiting, abdominal pain and diarrhoea.

The incidence of severe or fatal disease in children is significantly lower than in adults. Children at increased risk of more severe disease are predominantly those living with pre-existing health conditions, including severe immunocompromise or with complex and/or multiple health conditions as described in the Starship Guidelines for COVID-19 in children (see starship.org.nz/guidelines/ covid-19-disease-in-children/). These children are likely to benefit most from paediatric Omicron LP.8.1-matched vaccines.

Due to high levels of SARS-CoV-2 immunity in children, from widespread previous infection with lower virulent Omicron variants as well as vaccination, the risk for very rare COVID-19 complications is extremely low in children. This includes paediatric multisystem inflammatory syndrome temporally associated with SARS-CoV-2 (PIM-TS) observed early in the pandemic in children and adolescents.

As is seen with most RNA viruses, mutations occur, and variant strains of SARS-CoV-2 continually emerge. This has given SARS-CoV-2 a changing survival advantage through increased transmissibility. To help overcome this, COVID-19 vaccines are adjusted to be better matched to the circulating variants, such variants related to LP.8.1.

Emergence of new variants is monitored in New Zealand by the New Zealand Institute for Public Health and Forensic Science (PHF Science; formerly ESR) through whole genome sequencing of specimens taken from hospitalised cases and wastewater sampling. For more information on current COVID-19 variants see the PHF Science wastewater surveillance at esr.cri.nz/digital-library/ wastewater-dashboard/.

Vaccine effectiveness

Earlier in the pandemic, Comirnaty vaccines were highly effective against both symptomatic and severe COVID-19 infection. Clinical trial data showed efficacy against confirmed symptomatic COVID-19 of 68–98% after two doses of Comirnaty 10mcg in children aged 5–11 years. In those age 6 months to 4 years, Comirnaty 3mcg also demonstrated good efficacy in clinical trials although with wide confidence intervals due to the low number of covid infections amongst the infants in the trials (VE: 80% 14-98%).

Since the Omicron variants emerged, effectiveness of these vaccines has been maintained against severe disease in all age groups internationally, but wanes for mild disease over a period of weeks after each dose. Effectiveness is better maintained with recommended additional doses.

Studies in adults have shown that JN.1-matched vaccines provide protection against moderate to severe disease caused by a range of Omicron variants. Across all age groups, at least three exposures to SARS-COV-2 spike protein through vaccination and infection provide significant protection against Omicron-associated hospitalisation and death.

Further additional doses help to maintain a high level of immunity, particularly in those who are immunocompromised. There is limited data on LP.8.1 vaccine effectiveness at this stage, but the vaccine boosts pre-existing immunity in people who received earlier Comirnaty vaccines and stimulates better matched antibodies to the LP.8.1 sublineages.

Vaccine safety

Experience of LP.8.1 Comirnaty vaccines in adults and children is limited. Since there is no change in the formulation of the vaccine, except for the spike protein expressed by the mRNA, the responses to paediatric LP.8.1 Comirnaty vaccines are expected to be similar to the original formulations.

Generally, fewer adverse events were reported in children than adults who received the original Comirnaty vaccine. Common responses were mostly mild to moderate. These included local injection-site pain and fewer reported fatigue, headache, muscle or joint pain, gastrointestinal symptoms and fever.

In infants aged 6–23 months the most frequent side effects were irritability, decreased appetite, injection-site tenderness and redness, and fever; and in children aged 2-4 years, the most frequently reported side effects are injection-site pain and redness, fatigue and fever. Post-surveillance reporting identifies systemic reactions are more frequent for infants (ages 6 months – 2 years).

The risk of myocarditis following vaccination is not thought to be greater in younger age groups than any other group, acknowledging that the background rate of myocarditis in infants (aged under 1 year) is higher than in older children – unrelated to COVID-19 vaccination.

There is no current evidence of a safety concern for these vaccines in children.

Co-administration

Other vaccines can be given at the same time as either Comirnaty 3mcg JN.1 or 10mcg LP.8.1 vaccines, preferably in a different limb.

If preferred, due to increased reactogenicity, temporal spacing between Comirnaty and Bexsero may be considered. This is not essential, especially when antipyretic prophylaxis (eg paracetamol) is given prior to and following Bexsero vaccination as recommended for those aged under 2 years.

If the timing of mpox or COVID-19 vaccination is not urgent, consider allowing a gap of 4 weeks between Jynneos and Comirnaty.

Precautions and contraindications

Refer to IMAC's Comirnaty 3mcg and Comirnaty 10mcg Screening Guides, and the relevant datasheets for more detail. A history of anaphylaxis to a previous dose of the Comirnaty vaccine or to any component of the vaccine is a contraindication. Postpone vaccine if child has a fever >38°C or significant acute systemic illness. For very vulnerable children with comorbid conditions, ensure they are stable or as well as possible before vaccination and advise carer on need for post-vaccination observation and hydration.

For children with a history of inflammatory heart disease, discuss vaccination with cardiologist/specialist paediatrician/IMAC Medical Advisor.

Eligibility and vaccine schedules

Comirnaty 3mcg (6 months to 4 years)

Eligibility

The use of Comirnaty 3mcg vaccine is limited to young children aged 6 months to 4 years with severe immunocompromise or with complex and/or multiple health conditions who are at highest risk of severe disease if they were to catch COVID-19, as described in the Starship guidelines for COVID-19 in children (see starship.org.nz/guidelines/covid-19-disease-in-children/).

These are:

- Chronic or congenital airway/lung issues including bronchiectasis, cystic fibrosis, BiPAP for OSA
- Complex congenital heart disease, acquired heart disease or congestive heart failure
- Diabetes (insulin-dependent)
- Chronic kidney disease (GFR <15 ml/min/1.73m^2)
- Severe neurodisability including severe neuromuscular conditions
- Complex genetic, metabolic and/or liver disease or multiple congenital abnormalities, including Trisomy 21
- Primary or acquired immunodeficiency
- Haematologic malignancy and post-transplant (solid organ or HSCT in last 24 months)
- On immunosuppressive treatment including chemotherapy, high-dose corticosteroids, biologics or DMARDS.

Schedule

PRIMARY COURSE

- 3 doses of Comirnaty 3mcg – the first two doses are given 3 weeks apart, followed by a third dose administered at least 8 weeks after the second dose.
- Those part way through a primary course with a previous Comirnaty 3mcg vaccine, should complete the 3-dose series with the current Comirnaty 3mcg vaccine.
- Those turning 5 years part way through a primary course, should complete the course using the current Comirnaty 3mcg vaccine.

ADDITIONAL DOSES

A further single Comirnaty 3mcg dose with a different variant vaccine can be given from 6 months (minimum of 3 months with clinical discretion) after a completed vaccine course.

Comirnaty 10mcg vaccine (5 to 11 years)

Eligibility

All children aged 5 to 11 years who have not completed a primary course of COVID-19 vaccination are eligible for a single dose of Comirnaty 10mcg vaccine.

Schedule

PRIMARY COURSE

Single dose for all children aged 5 to 11 years who have not completed a primary course.

SEVERELY IMMUNOCOMPROMISED

3-dose primary course, with 8 weeks between doses.

- Those part way through a primary course with a previous Comirnaty 10mcg vaccine, should complete the 3-dose series with the available Comirnaty 10mcg vaccine.
- **Those turning 12 years during 3-dose course, should complete the course using the current Comirnaty 10mcg vaccine**. The exception is, that if more than 3 months have elapsed between doses, they should complete the course with the Comirnaty 30mcg vaccine.

ADDITIONAL DOSES

- An additional dose is only available and recommended for **severely immunocompromised children and those with medical conditions that increase their risk of severe COVID-19 infection including severe asthma**. See list above and link to Starship guidance.
- Vaccine can be administered at least 6 months (but minimum of 3 months with clinical discretion) after their previous COVID-19 vaccine.

Call 0800 IMMUNE (0800 466 863) for clinical advice

Summary of differences between Comirnaty vaccines

Description	Comirnaty Omicron 30mcg JN.1 12 years and older Ready to use (SDV)	Comirnaty Omicron 10mcg LP.8.1 5 to 11 years Ready to use (SDV)	Comirnaty Omicron 3mcg JN.1 6 months to <5 years Dilute to use (MDV)
Vial cap colour	Light grey	Light blue	Yellow
Dose	30mcg	10mcg	3mcg
Dose volume	0.3mL	0.3mL	**0.3mL**
Dilution	No dilution required	No dilution required	Dilute to use
Amount of diluent	No dilution required	No dilution required	1.1mL
Doses per vial	1 dose per vial	1 dose per vial	3 doses per vial
Vials per pack	10 vials	10 vials	2 vials

Storage conditions: Delivered defrosted. Store at (2°C to 8°C) for 10 weeks. Refer to box expiry.
30mcg and 10mcg - prepare each dose as required.
Once 3mcg vial is punctured max of 12 hours storage (2°C to 30°C). Max 6 hours in syringe.

Vaccination following SARS-CoV-2 infection

A child who has had SARS-CoV-2 infection is advised to wait 6 months before any dose of COVID-19 vaccine. However, clinical discretion can be applied and there are no safety concerns with doses given earlier or if uncertain infection history.

To minimise risk of errors

Resources, such as vaccine preparation guide, 3mcg vaccine record and vaccine screening guide, have been designed and colour-coded to match the vial cap. These documents must always be displayed and followed.

- Where possible create a “Do not disturb” time/place when vaccines are being prepared.
- Store different Comirnaty vaccines in separate areas in the refrigerator.
- Check you have selected the correct vaccines, check the expiry date from the box, and record this and the sub batch number.
- For Comirnaty 3mcg vaccine, double check dilution volume and dose volume for each syringe with an independent second checker and complete a vaccine record sheet. Preparing all three doses at same time allows an additional check for correct dilution and dose volume.
- Decide on unique coloured kidney dishes to hold different mcg strengths of Comirnaty vials and syringes if preparing more than one type or strength of vaccine.
- Prior to administration, verify name and birth date for consumer receiving vaccine and check against vaccine. Have another team member independently check vaccine syringe & consumer’s age before administering.

Post-vaccine advice

It is important that every caregiver/legal guardian is given clear post-vaccination advice verbally and in writing.

This advice is needed for each dose of vaccine, for all ages and must include the following information:

- Discussion of potential minor side effects as well as the rare but serious ones. The advice should include expected side effects such as fever, off feeding, not using arm or complaining of a sore arm. Give advice on how to manage side effects, including the use of paracetamol or other analgesia for fever, pain or discomfort, and if unwell they should rest, drink fluids and avoid vigorous activities.
- Cardiac problems are extremely rare but can be serious, so ensure the parent/guardian understands the importance of seeking medical advice early for symptoms. Children may not be able to describe cardiac symptoms - parents/guardians should be advised to look for signs such as child being pale, lethargic, and having shortness of breath, or odd feelings in their chest or stomach.
- For infants, other symptoms could include being sweaty, off feeds and coughing. These symptoms should not be ignored. It is important consumers seek advice from a doctor or Healthline.
- The risk of myocarditis following vaccination is not thought to be greater in children aged 6 months to 4 years nor 5-11 years than any other group.
- An observation period following vaccination of at least 15 minutes is recommended. This is to ensure that any anaphylactic-type reactions can receive prompt treatment. Awareness that anaphylaxis, although very unlikely, could occur within a few hours of vaccination. If the child has any breathing difficulties, caregivers should dial 111.
- For those with insulin-dependent diabetes, discuss need to closely monitor blood glucose for next few days, as high/low glucose can occasionally be a side effect of vaccine.
- Parents should seek medical advice if they have any serious concerns about the child’s health or about any side effects lasting more than two to three days.
- Supply information on how and when to make a second and third appointment (if required) and encourage them to do this before leaving the clinic.

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