Immunisation Advisory Centre

VERSION 5

Comirnaty 3mcg paediatric vaccine

Information for healthcare professionals

6 months – 4 years at risk children

MUST BE DILUTED

- ***Multi-dose vial (3 doses)***
- ***Dose volume 0.3mL***
- ***Draw up with the administration needle***
- ***Vaccines are latex-free. The vial stopper is made with synthetic rubber***

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 Starship Guidelines for COVID-19 in children (starship.org.nz/guidelines/ covid-19-disease-in-children/). These children are likely to benefit most from paediatric Comirnaty 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, children are at extremely low risk of COVID-19 complications. 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, variant strains of SARS-CoV-2 continually emerge as it mutates. 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 as LP.8.1.

Emergence of new variants is monitored by the New Zealand Institute for Public Health and Forensic Science through whole genome sequencing of specimens taken from hospitalised cases and wastewater sampling. For more information on current COVID-19 variants, see PHF Science wastewater surveillance at phfscience.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 aged 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-19 infections amongst the infants in the trials (VE:80% (CI 14-98%)).

Since the Omicron variants, 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. Across all age groups, hybrid immunity from at least three exposures to SARS-COV-2 spike protein through vaccination and infection provides significant protection against COVID-19 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 in young children at this stage, but the vaccine boosts pre-existing immunity in people who received earlier Comirnaty vaccines and stimulates better-matched antibodies to the current sublineages.

Vaccine safety

Experience of LP.8.1 Comirnaty vaccines in adults and children is limited. Since there is no change in the vaccine formulation, except for the spike protein expressed by the mRNA, the responses to paediatric LP.8.1 Comirnaty vaccines are expected to be similar to previous 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 age group, acknowledging that the background rate of myocarditis in infants (aged under 1`2 months) 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 Comirnaty 10mcg vaccine, 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 (e.g. paracetamol) is given prior to and following Bexsero vaccination as recommended for those aged under 2 years.

Precautions and contraindications

Refer to IMAC's Comirnaty 3mcg Screening Guide, and the relevant datasheet 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 or paediatrician/IMAC Medical Advisor.

Eligibility and vaccine schedule

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 high-dose corticosteroids, chemotherapy, biologics or DMARDS.

Schedule

PRIMARY COURSE FOR IMMUNOCOMPROMISE

- 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

Additional doses of Comirnaty 3mcg can be given every 6 months (from 6 months after last COVID-19 vaccination) for individuals with severe immunocompromise, or annually for those at higher risk of severe COVID-19 burden.

Summary of differences between Comirnaty vaccines

Description	Comirnaty 30mcg 12 years+ Prefilled syringe	Comirnaty 10mcg 5 to 11 years Ready to use (SDV)	Comirnaty 3mcg 6 months to 4 years Dilute to use (MDV)
Cap colour	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
Dose per unit	1 dose per syringe	1 dose per vial	3 doses per vial
Items per pack	10 syringes	10 vials	2 vials

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

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 the vaccine preparation guide 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.
- 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. Given 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 very low in children younger than 12 years. Background rates of myocarditis from any cause are higher in infants under 12 months than in other children, so parents need to be particularly vigilant for any symptoms in infants.
- 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.