The Immunisation Advisory Centre

COVID-19 EDUCATION

VERSION 1

Comirnaty (3mcg) 6 months-4 years, maroon cap

Information for Healthcare Professionals

KEY INFORMATION

- Comirnaty (3 mcg), maroon cap, 0.1 mg/mL concentrate for suspension for injection, infants and children 6 months to 4 years of age (3 micrograms / 0.2 mL dose)
- Only available for certain infants and children at increased risk of severe COVID-19 (see below and the Starship guidelines for children with complex or multiple health conditions at increased risk of severe COVID-19 for more information)
- Care must be taken when preparing vaccine to avoid vaccine errors especially in areas giving vaccines to a range of ages

Background

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. Around one in five children with symptomatic COVID-19 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 severe immunocompromise or with complex and/or multiple health conditions as described in the Starship Guidelines for COVID-19 in children. These are:

- Chronic or congenital airway/lung issues including bronchiectasis, cystic fibrosis, BiPAP for OSA (not mild, controlled asthma)
- Complex congenital heart disease, acquired heart disease or congestive heart failure
- Diabetes (insulin-dependent)
- Chronic kidney disease (GFR <15 ml/min/1.73m2)
- Severe neurodisability including severe neuromuscular conditions
- Complex genetic, metabolic disease or multiple congenital anomalies 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.

Severe obesity has been identified as a risk factor for older children and adolescents. A systematic review found children with comorbidities were 25 times more likely to have severe COVID-19 than those without (5.1 percent vs 0.2 percent) and have a 2.8 times higher relative risk of death. Children who develop pulmonary complications (eg, pneumonia) have a similar progression of disease as that seen in adults, requiring oxygen in hospital and in some cases corticosteroid and antiviral treatments.

Comirnaty, maroon cap

Each 0.2 mL dose contains:

- 3 mcg of tozinameran (mRNA encoding SARS-CoV-2 spike protein)
- The lipid nanoparticle is as used in the other Comirnaty formulations.
- The 3 mcg and 10 mcg paediatric formulations of mRNA-CV (with maroon and orange caps) use a Tris/sucrose buffer to improve the stability at +2° to +8°C.

This vaccine is latex-free. The vial stopper is made with synthetic rubber (bromobutyl), not natural rubber latex.

Efficacy in clinical trials

Combined for both 6-23 months and 2-4 years age groups, vaccine efficacy of 80.4 percent (95% CI: 14.1-96.7 percent) was reported during a period of omicron prevalence in the US. Due to a limited number of symptomatic COVID-19 cases in each group during the clinical trial, vaccine efficacy is difficult to predict due to wide confidence intervals. The antibody response after three doses was shown to be similar to that known to be effective in young adults.

Vaccine safety

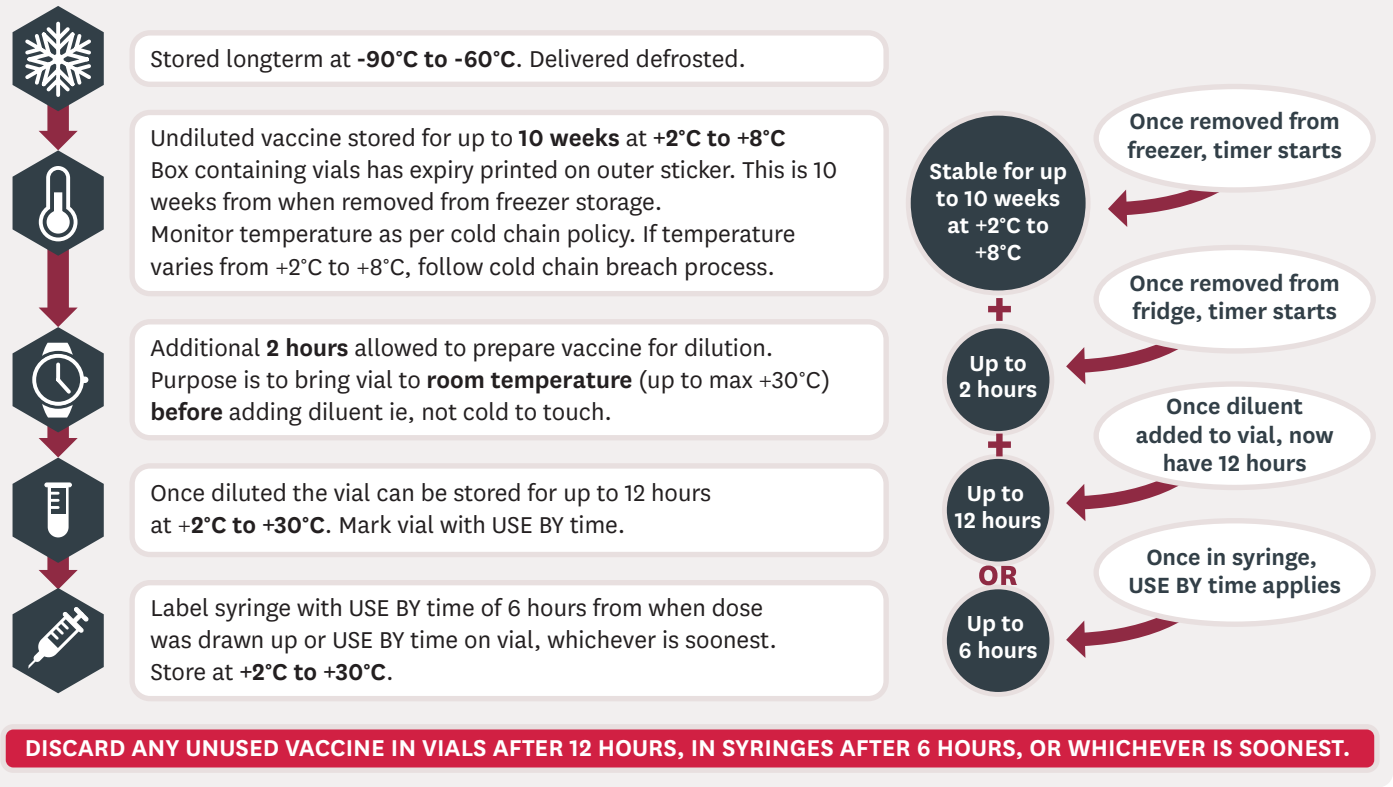
In clinical trials for Comirnaty maroon cap, the most frequent responses seen in infants aged 6–23 months were irritability, decreased appetite, injection-site tenderness and redness, and fever; and in children aged 2–4 years, injection-site pain and redness, fatigue and fever were most frequent. Less common responses included lymphadenopathy, diarrhoea, vomiting and nausea. Consistent with the clinical trial, systemic reactions were more frequently reported to v-safe for infants (ages 6 months – 2 years) than those aged 3–5 years.

The risk of myocarditis following vaccination is not thought to be greater in this age group 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 this vaccine in infants or young children, overall.

Storage and handling

This vaccine requires storage at ultra-low temperatures (-90°C to -60°C) and at this temperature has a shelf-life of 18 months. Defrosted vials have an expiry date of ten weeks. This new expiry date is written on the box at the time of defrosting. Always keep vials in their box and store at +2°C to +8°C. Do not refreeze. For details see figure below.

Comirnaty 3mcg vaccine (maroon top) storage summary



See also the IMAC COVID-19 Education factsheet 'Comirnaty (3 mcg) 6 mth-4 years maroon cap Vaccine Preparation' available from covid.immune.org.nz.

Eligibility for vaccination

The use of this vaccine is limited to young children 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 (not mild, controlled asthma)
- Complex congenital heart disease, acquired heart disease or congestive heart failure
- Diabetes (insulin-dependent)
- Chronic kidney disease (GFR <15 ml/min/1.73m2)
- Severe neurodisability including severe neuromuscular conditions
- Complex genetic, metabolic disease or multiple congenital anomalies including Trisomy 21
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- Haematologic malignancy and post-transplant (solid organ or HSCT in last 24 months)
- On immunosuppressive treatment including chemotherapy, high-dose corticosteroids, biologics or DMARDS.

Precautions and contraindications

See screening guidelines 'Comirnaty (3mcg) 6 months - 4 years, maroon cap screening guidance'.

A history of anaphylaxis to 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.

Schedule

Comirnaty maroon cap has been approved for use for certain young children aged under 5 years in New Zealand. Three doses are given to individuals who start their primary course aged 6 months to 4 years, inclusive. It is recommended to administer dose two at least 21 days after dose one followed by dose three at least eight weeks after dose two.

Children who start their course under five years need 3 doses even if they turn five part way through their course. For children who turn 5 years after their first dose, it is recommended to give an age-appropriate vaccine (ie, Comirnaty (10 mcg), age 5-11 years, orange cap) for subsequent doses. The schedule continues the same - dose two is given at least 21 days after first dose and dose three is given at least 8 weeks after previous dose.

Co-Administration

Other vaccines can be given at the same time as Comirnaty maroon cap, preferably in a different limb. If preferred, due to increased reactogenicity, 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. See attached table for clarity.

Vaccination following SARS-CoV-2 infection

Everyone who has had prior SARS-CoV-2 infection is recommended to complete the full vaccination course of Comirnaty, including eligible children from age 6 months to under 5 years. In these individuals, vaccination is recommended to be continued from three months after recovery from acute illness, or three months from the first confirmed positive test if asymptomatic. This applies to any dose of the primary course or booster doses, as age appropriate. Based upon clinical discretion, where the individual is at high risk of severe disease from reinfection and has not completed the full course, vaccination can be delivered sooner than three months after SARS-CoV-2 infection and completed with the recommended spacing between doses.

Vaccine preparation

Each multidose vial of Comirnaty maroon cap contains 0.4 ml of vaccine and should be diluted with 2.2 ml 0.9% NaCl. Once reconstituted, each reconstituted vial will supply ten doses of 0.2 mL. If the amount of vaccine remaining in the vial cannot provide a full 0.2 mL dose, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials.

Each 0.2 ml dose of Comirnaty maroon cap is to be administered intramuscularly.

For detailed instructions for Comirnaty maroon cap multi-dose vial preparation and administration see the most current IMAC COVID-19 education factsheet 'Comirnaty (3mcg) 6 mth-4 years maroon cap Vaccine Preparation' available from covid.immune.org.nz.

Error prevention

Overseas data warn that errors commonly occur **when preparing and administering maroon cap and orange cap Comirnaty vaccines at the same location**. Sites administering multiple COVID-19 vaccines must follow all steps for correct vaccine preparation and administration. Ensure all relevant **staff are trained to prepare and administer maroon cap vaccine**.

To minimise risk of error:

- Resources, such as vaccine preparation guide, vaccine preparation 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.
- Create a physical barrier between preparation areas. Set up resources and equipment to **create a maroon cap space**.
- Check the **box and vial label, dilution volume and dose volume** with an **independent second checker** to ensure you follow **maroon cap 6 months to 4 years instructions**.
- Decide on a unique coloured kidney dish to hold maroon cap vials and syringes and don't deviate.
- Always prepare vaccine for one patient at a time. Once prepared, **label every syringe** with supplied **maroon cap syringe sticker**.
- Where possible use a unique space for administering maroon cap vaccine.
- Avoid having multiple syringes in the same space.
- Prior to administration **verify name and birth date for the consumer** receiving the vaccine and check against the vaccine. Have another team member **independently check the vaccine syringe** and 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.
- 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 the need to closely monitor blood glucose for next few days, as high or low glucose can occasionally be a side effect of the vaccine.
- Parents should seek medical advice if concerned about any side effects lasting more than two – three days.
- Supply information on how and when to make a second and third appointment and encourage them to do this before leaving the clinic.

Summary of differences between Comirnaty vaccines

Description	Comirnaty (30 mcg)	Comirnaty (10 mcg)	Comirnaty (3 mcg)[a]
Vial cap colour	Purple	Orange	Maroon
Age range	12 years and over	5 to 11 years	6 months – 4 years
mRNA/per dose	30 mcg	10 mcg	3 mcg
Buffer	PBS/sucrose	Tris/sucrose	Tris/sucrose
Undiluted volume	0.45 mL	1.3 mL	0.4 mL
Dilution require (volume of NaCl to add)	Yes (1.8 mL)	Yes (1.3 mL)	Yes (2.2 mL)
Volume per dose	0.3 mL	0.2 mL	0.2 mL
Doses per vial	6	10	10
Primary course doses	2	2	3

Who can prepare and administer Comirnaty (3mcg) maroon cap?

Education: all vaccinators must complete both Comirnaty 12+ and 5-11 years online education, and watch the maroon cap webinar.

Preparation: Same rules apply as for other Comirnaty vaccines.

Administration: Vaccinators can only administer vaccines to the age ranges they have been assessed and authorised for. Reminder: Provisional vaccinators and provisional pharmacist vaccinators can only can only give vaccines to those aged 3 years and older due to the limited scope of the foundation course they completed.

References

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