

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

QUESTIONS	RATIONALE FOR QUESTIONS AND ADVICE ON ACTIONS REQUIRED
Please tell me your/ your child's full name and date of birth.	Check you have the correct patient records on the CIR. Confirm child's age verbally. Ensure you have correct vaccine for age: Comirnaty (3mcg) 6 months – 4 years, maroon cap . Those who turn 5 after the first dose should continue with Comirnaty (10mcg) 5-11yrs orange cap age appropriate dose.
Why does your child need this vaccine ?	Only those with severe primary or secondary immunosuppression or specific multiple or complex medical conditions are eligible for this vaccine (6 months to 4 years). Please check list on back page for more details. If in doubt contact 0800 IMMUNE (466 863).
Are you the parent or legal guardian ?	Consent from parent or legal guardian is required. It is acceptable to gain verbal consent from parent or guardian via phone if child attends with a different caregiver. Document parent or legal guardian's name in CIR if not using a written consent form.
Is your child feeling well today?	Postpone vaccine if: fever >38°C or significant acute systemic illness. For a very vulnerable child with a comorbid condition, ensure they are stable or as well as possible before vaccination and advise carer on need for post vaccination observation and hydration.
Does your child have a heart condition?	Children with a history of inflammatory heart disease, discuss with cardiologist/specialist paediatrician.
Has your child had COVID-19?	Anyone who has had SARS-CoV-2 infection, is advised to wait 3 months before any dose of COVID-19 vaccine, to ensure best response. Clinical discretion can be applied for those at risk of severe disease.
Has your child had a serious allergic reaction to anything including previous Comirnaty (Pfizer) vaccine?	Contraindications: A history of anaphylaxis to previous dose of the Comirnaty vaccine or to any component of the vaccine. Precaution: A definite history of anaphylaxis-type reaction to any other product. A slightly increased risk of anaphylaxis has been noted in individuals who have had a previous anaphylaxis-type reaction to any other product. These individuals can still receive Comirnaty. They should be well observed for at least 30 minutes and be given clear post vaccination advice. It is important that the observation staff are specifically alerted to this history by the vaccinator. All vaccination sites are set up with age-appropriate medical equipment to manage anaphylaxis.
Is this your child's first COVID-19 vaccination?	Check spacing between vaccines: A spacing of at least 3 weeks between first and second dose and 8 or more weeks between second and third dose is recommended (see comment on page 2). Day 0 is the vaccination day. No maximum spacing.
Has your child turned 5 since their last dose of COVID vaccine?	Children who start their primary course at 4yrs and then turn 5yrs still receive three doses at the same spacing as those under 5yrs but once they turn five they are given Comirnaty (10mcg) 5-11yrs orange cap vaccine. It is the same spacing of 3 weeks after first dose and 8 weeks after second dose. This remains a 3-dose schedule even if the child turns 5 years of age.
Did your child have any problems after their last COVID vaccine ?	Check for any adverse symptoms after the previous vaccine and refer to IMAC for further advice if there were any potential concerns not previously considered.
Does your child have a bleeding problem or blood disorders?	Vaccines can be administered to children on anticoagulants. For patients with haemophilia, vaccinations should be given as soon as possible after receiving clotting factor replacement or similar medicine. It is recommended that the platelet count is kept $\geq 30 \times 10^9/L$. Specialist advice is recommended. After vaccination, apply firm pressure over the injection site, without rubbing, for 10 minutes to reduce the risk of bruising.
Do you have any other questions?	If you need support to answer questions contact IMAC 0800 IMMUNE (466 863)

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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
- 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.

Gaining informed consent

- Confirm the caregiver/legal guardian has received adequate information about the vaccine, including the benefits, the common side effects and the rare but serious adverse events, including anaphylaxis. Offer them opportunity for questions and remind them of the need to wait 15 minutes.
- **Consent from parent or legal guardian is required for children under 12 years. It is acceptable to gain verbal consent from parent or guardian via phone if child attends with a different caregiver. Document parent or guardian's name in CIR if not using a written consent form.**
- For further information on informed consent, including information around those who do not have the capacity to consent, refer to the Immunisation Handbook (section 2.1.2).

Co- Administration / Opportunistic vaccination

Are they up to date with their vaccinations? 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.

Remember most will also be eligible for extra vaccine due to medical conditions. See IMAC factsheets for information of vaccine for specific conditions.

Preparation of vaccines

- Staff preparing and administering this vaccine are expected to have completed COVID-19 online training and have experience of using 12yr+ and 5-11yr Comirnaty vaccines. In addition to this they should be familiar with Comirnaty 3mcg maroon cap vaccine preparation resource and have watched the vaccine specific webinar.
- Locations where Comirnaty vaccine is being administered to a range of ages will need to be extra careful to ensure correct volumes of diluent are used, and that vaccine syringes are always labelled (ideally colour coded) and the age of the child and the dose of vaccine is reconfirmed prior to administration. A second checker is essential.
- Prepare Comirnaty 3mcg vaccines away from all other vaccines, in a separated dedicated space. It is essential that every dose of vaccine is clearly labelled, and that the vaccine preparation guidance is followed, including accurate documentation.
- It is recommended that all doses are prepared at once, to allow diluent volume to be cross checked. For more detailed instructions please see IMAC Comirnaty multi-dose vial preparation and administration guidance documents.

DO NOT interrupt the vaccine preparation process.

Post Vaccination advice to be given by Vaccinator

It is important that every caregiver/legal guardian is given clear post vaccination advice verbally and in writing, or encourage them to take a photo of the handout. This advice is needed for each dose of vaccine and 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, not feeding, not using an 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.
- Parents should seek medical advice if concerned about any side effects lasting more than two – three days.
- Awareness that anaphylaxis, although very unlikely, could occur within a few hours of vaccination and if they have any breathing difficulties they should dial 111.
- For those with insulin-dependent diabetes, discuss the need to closely monitor blood glucose for the next few days, as high or low glucose can occasionally be a side effect of the vaccine.
- Supply information on how and when to make a second and third appointment and encourage them to do this before leaving the clinic.

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