The Immunisation Advisory Centre

COVID-19 EDUCATION

VERSION 1

Comirnaty 30mcg grey cap and Comirnaty Original/Omicron 15/15mcg grey cap booster

Information for Healthcare Professionals

KEY INFORMATION

- From 1 March 2023, Aotearoa New Zealand will discontinue using the Comirnaty 30mcg purple cap vaccine.
- The Comirnaty 30mcg purple cap will be replaced by two different grey cap Comirnaty vaccines.
  - For primary course, Comirnaty 30mcg grey cap is to be used from 12 years of age.
  - Comirnaty 15/15mcg grey cap booster is the preferred option as a booster vaccine from age 16 years in those who have already received at least two primary doses and are eligible for a booster dose.
- Extra care must be taken when preparing grey cap Comirnaty vaccines as they are similar in appearance.
- **Grey cap Comirnaty vaccines DO NOT REQUIRE DILUTION**

Background

From 1 March 2023, Aotearoa New Zealand will replace the Comirnaty 30mcg COVID-19 vaccine purple cap with Comirnaty 30mcg grey cap and Comirnaty 15/15mcg grey cap booster vaccines.

During 2022 we had 3 significant waves of infection as new variants emerged. These were associated with increased hospitalisations and deaths. This pattern is likely to continue for the foreseeable future. Although Aotearoa has achieved high immunisation rates, resulting in uniquely high levels of hybrid immunity (wild disease and immunisation antibodies) against severe disease, the emerging immune-evasive Omicron variants and waning immunity have increased the need for additional doses.

The Comirnaty 15/15mcg grey cap booster contains 15mcg mRNA expressing the original SARS-CoV-2 variant spike protein (tozinameran) and 15mcg mRNA expressing the BA.4-5 Omicron variant (famtozinameran). This is the recommended COVID-19 booster vaccine for those aged 16 years or older.

The Comirnaty 30mcg grey cap vaccine contains 30mcg of mRNA expressing the original SARS-CoV-2 variant (tozinameran). This will replace the Comirnaty purple cap for primary course doses for those aged 12 years or over. This vaccine does not require dilution and has improved stability and storage.

Comirnaty 30mcg grey cap (multi-dose vial)

Each 0.3 ml dose of Comirnaty 30mcg grey cap contains:

- 30mcg tozinameran (mRNA encoding original SARS-CoV-2 spike protein)
- Lipid nanoparticle as used in other Comirnaty formulations
- Tris/sucrose buffer to improve the stability at +2˚C to +8˚C

This formulation DOES NOT require dilution. This vaccine is latex-free and the stopper is a synthetic bromobutyl rubber with grey plastic flip-off cap with aluminium seal.

Comirnaty 15/15mcg (multi-dose vial)

Each 0.3 ml dose of Comirnaty 15/15mcg grey cap contains:

- 15mcg tozinameran (mRNA expressing original SARS-CoV-2 spike protein)
- 15mcg famtozinameran (mRNA expressing Omicron BA.4-5 SARS-CoV-2 spike protein)
- Lipid nanoparticle as used in other Comirnaty formulations
- Tris/sucrose buffer to improve the stability at +2˚C to +8˚C

This formulation DOES NOT require dilution. This vaccine is latex-free and the stopper is a synthetic bromobutyl rubber with grey plastic flip-off cap with aluminium seal.

Recommended schedule

Comirnaty 30mcg grey cap is used as a primary course from 12 years of age. Two doses are given 8 weeks apart (minimum 21 days apart).

Comirnaty 15/15mcg grey cap booster is used as a booster dose from 16 years of age for those who have received a primary course of a COVID-19 vaccine and are eligible for a boosters.

Booster eligibility and spacing

Comirnaty 15/15mcg grey cap is only licensed for booster doses. It is the vaccine of choice for booster doses in NZ. Eligibility remains same as original booster doses. See the Immunisation Handbook for further details around recommended groups and spacing.

- All individuals aged from 16 years are recommended a booster dose after the primary course. This is given at least 6 months after previous dose if aged 16 – 17 years, or at least 3 months later from age 18 years.
- Second booster doses are available, to be given at least 6 months after the first booster, for people aged from 16 years who are increased risk from severe COVID-19, including people who are:
  - 65 Years and over
  - Of Māori or Pacific ethnicity aged over 40 years
  - Living with immunocompromise
  - With complex medical needs or disability
  - Living in residential care facilities, including aged care and disability care.
- Delay a booster dose for 3 months following COVID-19 infection.

Eligibility for booster doses is anticipated to be updated and amended in preparation for winter. Currently no additional booster doses have been recommended.

Precautions and contraindications

See screening guidelines *Grey and Orange cap Comirnaty Vaccination Screening Tool*. Note that the screening criteria is the same for the other Comirnaty vaccines (purple cap and orange cap).

Contraindications:

- History of anaphylaxis to previous dose of Comirnaty vaccine or to any component of the vaccine.
- Those with a past episode of myocarditis or pericarditis following a previous dose of vaccine should have a careful risk benefit discussion before having any further doses. Seek advice from IMAC.

Concomitant administration

All national immunisation schedule vaccines can be given at the same time as the Comirnaty 30mcg or 15/15mcg grey cap vaccines, preferably in a different limb. Influenza vaccination is also highly recommended for eligible groups and can be given at the same time as all COVID-19 vaccines.

Spacing of 28 days may be considered between JYNNEOS [mPOX vaccine] and subsequent mRNA COVID vaccine for individuals at increased risk of myocarditis and/or pericarditis following an mRNA vaccine (males aged 16 to 40) in an abundance of caution.

Comirnaty 15/15mcg grey cap efficacy data

Studies in the US have demonstrated an increase in effectiveness of booster doses against hospitalisation with COVID-19 and improved neutralising antibody activity when Comirnaty 15/15mcg grey cap COVID-19 vaccines are given, especially for those who received two to four previous mrna-cv doses several months prior.

Laboratory studies show the bivalent booster elicits moderately stronger antibody responses against omicron variants than the original booster. Real world experience shows that the bivalent booster doses reduce hospitalistaions and deaths with the greatest benefit in those at higher risk such as those over 65 years of age.

For further information on efficacy data for 15/15mcg and 30mcg formulations, refer to the Immunisation Handbook – section 5.4.3.

Vaccine safety

The responses to Comirnaty 30mcg grey cap vaccine are as seen with the original purple cap Comirnaty. These include injection site pain, fatigue, headache, myalgia, chills, arthralgia, pyrexia and injection site swelling. These reactions were mild to moderate and resolved within a few days of vaccination. Uncommon responses such as lymphadenopathy have been reported. It is important to inform consumers about the rarer reactions such as anaphylaxis, myocarditis and pericarditis.

The responses to the Comirnaty 15/15mcg grey cap booster given as a fourth dose are expected to be similar to those seen following 30mcg (purple cap) booster doses. No new adverse reactions have been identified in clinical trials.

Follow usual protocols and procedures for the management and reporting of adverse events.

Use in pregnancy and breastfeeding

Observational data for the original 30mcg Comirnaty 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 15/15mcg grey cap formulation, no clinically meaningful difference in reactogenicity has been reported. There is no theoretically plausible reason for there to be any increased risk in pregnancy because the differences between these vaccine formulations, and the original purple cap, are confined to mRNA spike protein sequences and the Tris buffer, which is used in the grey cap Comirnaty vaccines and is commonly used in other vaccines including the paediatric Comirnaty vaccines. Comirnaty 15/15mcg grey cap Comirnaty vaccine can be used in pregnancy and while breastfeeding.

Post-vaccine advice

Post vaccine advice remains the same as the purple cap Comirnaty vaccine. Every consumer must be given clear post-vaccination advice verbally and in writing during the consent process. 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 such as myocarditis and pericarditis. The advice should include expected side effects such as fever, swelling and pain at injection site, tiredness. 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.

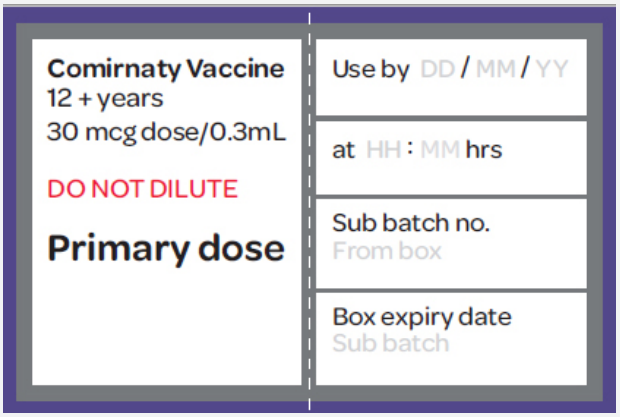
- An observation period following vaccination of at least 15 minutes is recommended or 30 minutes if there is a history of anaphylaxis. This is to ensure that any anaphylactic-type reactions can receive prompt treatment. Awareness that anaphylaxis, although very unlikely, could occur within a few hours of vaccination. If any breathing difficulties arise, call 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.
- Seek medical advice if concerned about any side effects.
- Supply information on how and when to make follow up appointments and encourage them to do this before leaving the clinic.

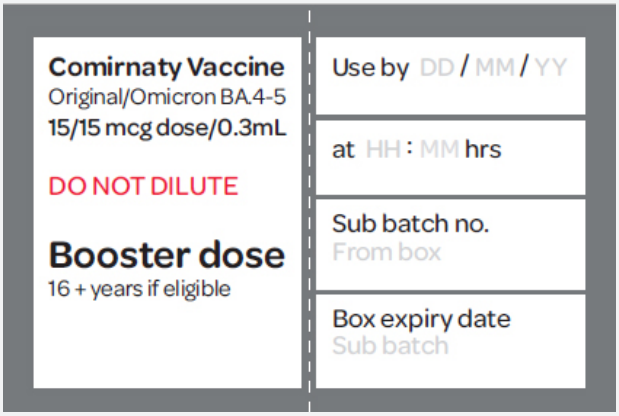
Written information such as the "After the COVID-19 vaccination" advice sheet are available at https://www.Health.Govt.NZ/COVID-19-novel-coronavirus/COVID-19-vaccines/COVID-19-vaccine-resources).

Error prevention

The packaging and vials for both the Comirnaty 30mcg grey cap and Comirnaty 15/15mcg grey cap vaccines are very similar.

- The 30mcg box has Comirnaty written in dark blue/purple and will have a similar colour expiry label attached.
- The 15/15mcg booster vaccine box is all in grey.
- The vials have either 30mcg or 15/15mcg written on them.
- 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 the Comirnaty 30mcg grey cap and Comirnaty 15/15mcg grey cap Comirnaty vaccines.





Strategies to minimise risk of error

Vaccine preparation

- Place STOP WHAT TOP poster on fridge
- Vaccine Preparation Guide and Vaccine Record must always be visible and followed.
- Where possible create a "Do not disturb" time/place when vaccines are being prepared.
- Store different Comirnaty Grey Cap vaccines in separate areas in the fridge. Consider coloured signage, labelling, open coloured baskets to differentiate between the grey cap vaccines used for Booster and Primary vaccinations.
- Create a physical barrier between the two grey cap preparation areas.
- Check you have the correct vaccine and that it is within expiry. A second checker must initial the vaccine record document to confirm they have independently checked this information.
- We recommend all doses are drawn up at the same time after first vial puncture. If not, ensure vial is labelled with 12-hour expiry and returned to fridge in a defined kidney dish away from unopened vials.
- Once prepared, label every syringe with a vaccine-specific grey cap syringe sticker (see above). A second checker must initial the vaccine record to show they have independently checked the 0.3ml volume.

Vaccine administration

- Where possible use a unique space for administering the different grey cap vaccines.
- Avoid having multiple syringes for different vaccine types, ages, and doses in the same space.
- Use CIR/AIR to reconfirm details of the vaccination event.
- Prior to administration verify consumer's name and date of birth and whether they are here for a primary or booster dose and check against the vaccine. Have another team member independently check the vaccine syringe and consumer's details before administering.

What to do if an error occurs

- Advise your clinical lead/senior vaccinator.
- Call IMAC for clinical advice as there may be some consumer specific risk (as per TWO documents).

Vaccinator resources

- Preparation of Comirnaty Grey Cap Vaccines Quick Reference Guide
- Vaccine record sheet
- https://www.immune.org.nz/ or 0800 IMMUNE (466 863)
- IMAC webinar will be recorded
- Medsafe Datasheets Comirnaty 30mcg grey cap (link)
- Medsafe Datasheet Comirnaty 15/15mcg grey cap (link)
- Vaccine safety poster
- Stop What Top poster
- Vaccine comparison chart

Patient resources

Patient resources (including easy read and translated resources):

- MOH (https://www.health.govt.nz/COVID-19-novel-coronavirus/COVID-19-vaccines/COVID-19-vaccine-resources)
- Unite against COVID (https://covid19.govt.nz)
- Summary of preparation and dosages for mRNA-CV (Comirnaty) formulations.

Summary of Comirnaty formulations

Also see vaccine comparison chart for more detailed information on vaccine in current use add link

Description	Maroon cap 3mcg	Orange cap 10mcg	Purple cap 30mcg REMOVED	Grey cap Monovalent 30mcg	Grey cap Original/Omicron 15/15mcg
Vial cap colour	**Maroon**	**Orange**	**Purple**	**Grey**	**Grey**
Age range	6 months – 4 years	5 to 11 years	12 years and over	12 years and over	16 years and over*
Used for	Primary	Primary	Primary and booster	Primary	Booster
Dose	3 mcg	10 mcg	30 mcg	30 mcg	Original/Omicron 15mcg + 15mcg
Buffer	Tris/sucrose	Tris/sucrose	PBS/sucrose	Tris/sucrose	Tris/sucrose
Dilution required	Yes	Yes	Yes	No	No
Volume per dose	0.2 mL	0.2 mL	0.3 mL	0.3 mL	0.3 mL
Doses per vial	10	10	6	6	6
Refrigerator (2°C to 8°C)	10 weeks	10 weeks	1 month	10 weeks	10 weeks
Travel time (2°C to 8°C)	Nil	Nil	48 hours	Nil	Nil

NOT IN USE from 1 March 2023

* Vaccine licenced from 12 years, but boosters are only available from 16 years and over (if eligible).

DON'T DELAY - IF IN DOUBT CALL 0800 IMMUNE (466 863)