



20 June 2022

Pfizer New Zealand

Level 10, 11 Britomart Place
Auckland CBD
Auckland 1010

Dear Healthcare Professional,

COMIRNATY® (COVID-19 Vaccine) Presentations available in New Zealand

Pfizer New Zealand Limited has commenced supply of a new formulation of COMIRNATY. There are two new products of COMIRNATY with the new formulation. COMIRNATY (orange cap, must dilute), new formulation, 0.1 mg/mL concentrate for suspension for injection, children 5 to 11 years of age (10 micrograms/0.2 mL dose) has provisional consent for the following indication:

*Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2, in **children aged 5 to 11 years**. The use of this vaccine should be in accordance with official recommendations.*

COMIRNATY (grey cap, do not dilute), new formulation, 0.1 mg/mL suspension for injection, 12 years of age and older (30 micrograms/0.3 mL dose), containing the new formulation for individuals 12 years of age and older, has also been granted provisional approval and will be available in the coming months.

Currently, COMIRNATY (purple cap, must dilute), 0.1 mg/mL suspension for injection, 12 years of age and older (30 micrograms/0.3 mL dose) is used in New Zealand. Supply of this product will eventually be transitioned to supply of COMIRNATY (grey cap, do not dilute).

As there will be two different COMIRNATY products in use (and potentially three during a future transition period) and the national COVID-19 immunisation plan is being implemented as quickly as possible, it is appropriate that important practical information regarding this vaccine is understood.

The key differences in the formulations are summarised in the table below:

	Purple cap, must dilute, 12 years of age and older	Grey cap, do not dilute, 12 years of age and older	Orange cap, must dilute, 5 to 11 years of age
Buffer	PBS/Sucrose	Tris/Sucrose	Tris/Sucrose
Vial cap colour	Purple	Grey	Orange
Age range	12 years of age and older	12 years of age and older	5 to 11 years of age
mRNA/dose	30 micrograms	30 micrograms	10 micrograms
Volume/dose	0.3 mL	0.3 mL	0.2 mL
Dilution required	Yes (1.8 mL saline)	No	Yes (1.3 mL saline)
Doses/vial	6	6	10 (after dilution)
Pharmaceutical form	Concentrated suspension for injection	Suspension for injection	Concentrate for suspension for injection
Fill Volume	0.45 mL	2.25 mL	1.3 mL
Pack size	195	10	10

Overview of new formulation: COMIRNATY (orange cap, must dilute)

COMIRNATY (orange cap, must dilute) formulation differs from the current “PBS/Sucrose” formulation of COMIRNATY (purple cap, must dilute) primarily by a change in the buffer from phosphate to Tris buffer. There are no changes in raw materials, lipids or lipid suppliers nor in the manufacturing processes for the drug substance and lipid nanoparticles (LNPs).



COMIRNATY (orange cap, must dilute)



COMIRNATY (purple cap, must dilute)

COMIRNATY (orange cap, must dilute) is supplied as a multidose vial and must be diluted before use.

One vial (1.3 mL) contains 10 doses of 0.2 mL after dilution with sodium chloride 9 mg/mL (0.9%) solution for injection.

One dose (0.2 mL) contains 10 micrograms of tozinameran, a COVID-19 mRNA Vaccine (embedded in lipid nanoparticles). Tozinameran is the International Nonproprietary Name (INN) for COMINARTY that has now been adopted. BNT162b2 [mRNA] was used previously until the INN was approved.

COMIRNATY (orange cap, must dilute) has provisional consent for active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2, in children **aged 5 to 11 years**.

The vaccine should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared diluted suspension and dose verification should occur before dilution and administration. It should be verified that the vial has an orange plastic cap before dilution. **Only the orange cap vial can be used for children aged 5 to 11 years.**

Further Information

Detailed instructions for dose verification, handling prior to use, and preparation of individual doses of COMIRNATY-are contained in the Medsafe approved Data Sheet, which is available from the Medsafe website www.medsafe.govt.nz , or from Pfizer by phone (0800 736 363) or www.comirnatyeducation.co.nz, which also allows access to the CMI and information regarding appropriate storage, shelf-life, dosing and other clinical and safety aspects of COMIRNATY.

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