22 December 2021

Pfizer New Zealand
Level 10, 11 Britomart Place
Auckland CBD
Auckland 1010

Dear Healthcare Professional,

Supply of new formulation of COMIRNATY® (COVID-19 Vaccine) 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 be 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:

Description	**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)	No	Yes (1.3 mL)
Doses/vial	6 (after dilution)	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.

1 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 age 5 to 11 years**.

Detailed instructions for dose verification, handling prior to use, mixing prior to dilution, dilution, and preparation of individual 0.2 mL doses of COMIRNATY (orange cap, must dilute) are contained in the Medsafe approved Data Sheet.

Shelf life and storage summary for COMIRNATY (orange cap, must dilute)

Unopened vial

Frozen vial

Vials have a shelf life of 6 months when stored at -90°C to -60°C.

Thawed vial

Once removed from frozen storage, the unopened vial may be stored refrigerated at 2°C to 8°C for a single period of up to 10 weeks within the 6-month shelf life.

Prior to use, the unopened vials can be stored for up to 12 hours at temperatures between 8ºC to 30ºC.

Once thawed COMIRNATY (orange cap, must dilute) should not be re-frozen.

Diluted medicinal product

Chemical and physical in-use stability has been demonstrated for 12 hours at 2ºC to 30°C, after dilution with sodium chloride 9 mg/mL (0.9%) solution for injection. From a microbiological point of view, unless the method of dilution precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

Detailed information for shelf life and storage for COMIRNATY (orange cap, must dilute) are contained in the Medsafe approved Data Sheet.

Product Labelling (orange cap, must dilute)

Due to the nature of the pandemic, production and supply of the vaccine is being managed in a just-in-time model, which means that it is possible to receive the vaccine packaged in several different artworks. Irrespective of the artwork, all are equivalent, in that they refer to the same product with the identical formulation.

Emergency Use Authorisation (EUA) internationally labelled product will be initially supplied to New Zealand (Pfizer-BioNTech COVID-19 vaccine). The EUA labels do not include the brand name “COMIRNATY” nor the name of the active ingredient, BNT162b (mRNA)/tozinameran. In addition, the EUA labels refer to the dose form as a suspension, whereas other labels refer to it as a dispersion. These differences reflect their intended use in different markets, however they are physically identical. Examples of the various carton and vial labels that may be supplied are provided in the attachments.

The EUA labelled product will have the following differences to the Data Sheet:

	EUA labelled product	Data Sheet
Product Name	Pfizer-BioNTech COVID-19 vaccine	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)
Dose form description	Suspension for Intramuscular Injection	Concentrate for suspension for injection (sterile concentrate)
Age Indication	For age 5 years to < 12 years	children 5 to 11 years of age
Diluent	sterile 0.9% Sodium Chloride Injection, USP	sodium chloride 9 mg/mL (0.9%) solution for injection
Storage temperature after dilution	After dilution, store the vaccine at 2°C to 25°C (35°F to 77°F).	2ºC to 30°C, after dilution
Shelf life after dilution	Discard 6 hours* after dilution.	Discard any unused vaccine within 12 hours after dilution.
Regulatory status	For use under Emergency Use Authorization	This medicine has been given a provisional consent under Section 23 of the Act.

* The difference in shelf-life after dilution only reflects the available data at the time of label artwork production.

EUA labelled product does not state the expiry date of the vaccine. The date printed on the vials and cartons for EUA labelled product instead, reflects the date of manufacture. Regardless of storage condition, the vaccine should be used within 6 months from the date of manufacture printed on the vials and cartons, as shown below. This information is also available on www.comirnatyeducation.co.nz.

This is applicable only for EUA labelled product.

MANUFACTURE DATE	EXPIRY DATE (6 MONTHS)
08/2021	31-Jan-2022
09/2021	28-Feb-2022
10/2021	31-Mar-2022
11/2021	30-Apr-2022
12/2021	31-May-2022

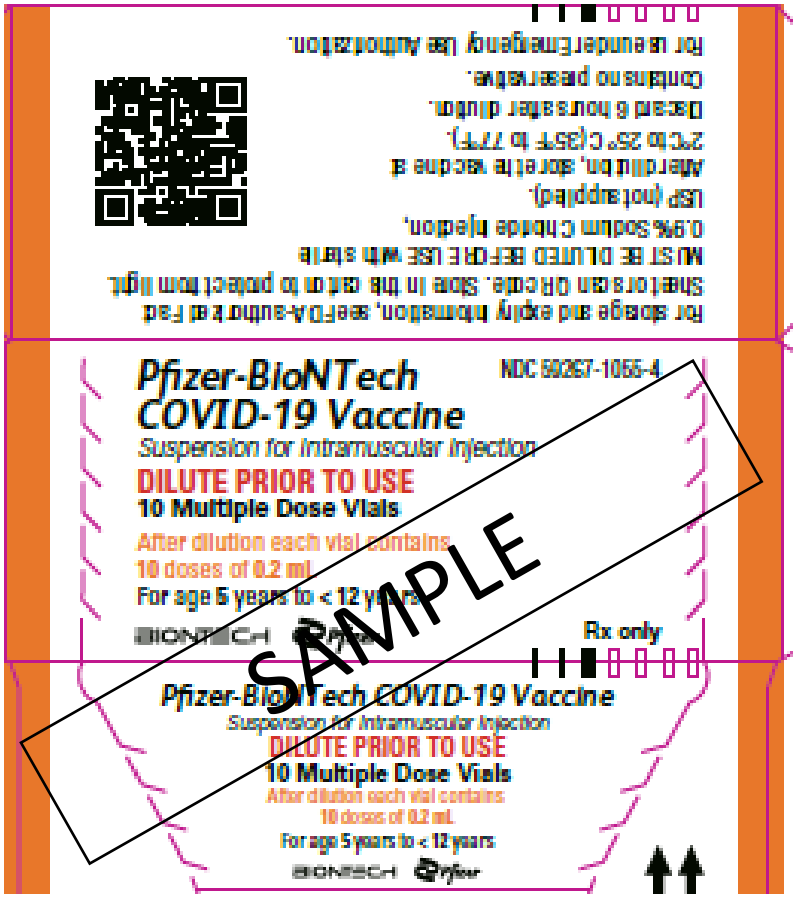
For additional information regarding COMIRNATY, refer to the COMIRNATY Data Sheet on the Medsafe website, or contact Pfizer by phone (0800 736 363) or www.pfizermedinfo.co.nz.

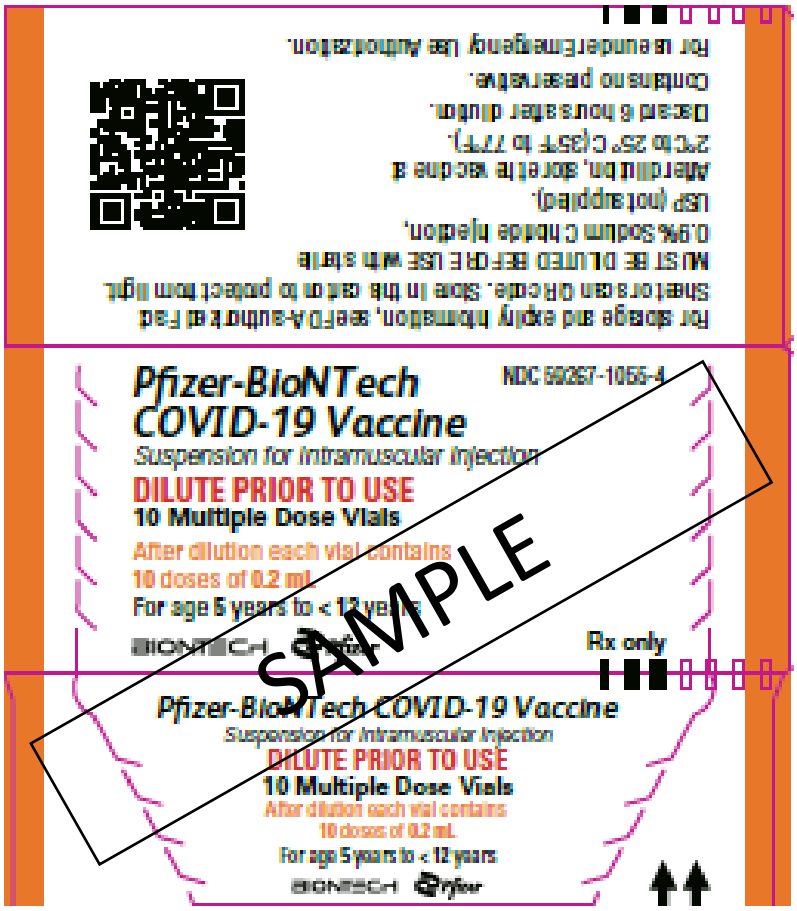
Scott Williams

Vaccines Medical Director New Zealand, Australia and Korea

Pfizer Vaccines

Attachment: Examples of carton and vial labels




Pfizer-BioNTech
COVID-19 Vaccine
Suspension for Intramuscular Injection
DILUTE PRIOR TO USE
10 Multiple Dose Vials
After dilution each vial contains
10 doses of 0.2 mL
For age 5 years to < 12 years
NDC 59267-1055-4
Rx only
SAMPLE
Pfizer-BioNTech COVID-19 Vaccine
Suspension for Intramuscular Injection
DILUTE PRIOR TO USE
10 Multiple Dose Vials
After dilution each vial contains
10 doses of 0.2 mL
For age 5 years to < 12 years
For storage and expiry information, see FDA-authorized Fact Sheet or scan QR code. Store in the carton to protect from light.
MUST BE DILUTED BEFORE USE with sterile
0.9% Sodium Chloride Injection,
USP (not supplied).
After dilution, store the vaccine at
2°C to 25°C (35°F to 77°F).
Discard 6 hours after dilution.
Contains no preservative.
For use under Emergency Use Authorization.

COMIRNATY™
Children 5 to 11 years
concentrate for dispersion for injection
10 micrograms/dose
COVID-19 mRNA Vaccine (nucleoside modified)
tozinameran
Intramuscular use after dilution
10 multidose vials (After dilution, each vial contains 10 doses of 0.2 mL.)
Expiry date at 2 °C to 8 °C:
(Maximum as stated in the package leaflet.
Cross out former expiry date.)
Excipients ALC-0315, ALC-0159, DSPC, cholesterol, trometamol, trometamol hydrochloride, sucrose, water for injections
BioNTech | Pfizer
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany
EU/1/20/1528/XXX
Scan QR code for more information
Storage: Store at 2 °C to 8 °C after receipt.
Do not refreeze once thawed. Keep in the original package in order to protect from light.
Read the package leaflet before use and for additional storage information.
After dilution, store the vaccine at 2 °C to 30 °C and use within 6 hours.
Dilute before use: Dilute each vial with 1.3 mL sodium chloride 9 mg/mL (0.9 %) solution for injection.
PAA181044
SAMPLE

COMIRNATY™
Children 5 to 11 years
concentrate for
10 micrograms/dose
dispersion for injection
COVID-19 mRNA Vaccine (nucleoside modified)
tozinameran
Intramuscular use after dilution
10 multidose vials (After dilution, each vial contains 10 doses of 0.2 mL.)
Expiry date at 2 °C to 8 °C: .....
(Maximum as stated in the package leaflet.
Cross out former expiry date.)
Excipients: ALC-0315, ALC-0159, DSPC, cholesterol, trometamol, trometamol hydrochloride, sucrose, water for injections
BioNTech
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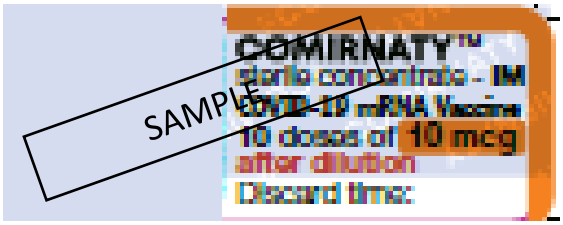
An der Goldgrube 12
55131 Mainz, Germany
EU/1/20/1528/XXX
Scan QR code for more information
Storage: Store at 2 °C to 8 °C after receipt.
Do not refreeze once thawed. Keep in the original package in order to protect from light.
Read the package leaflet before use and for additional storage information.
After dilution, store the vaccine at 2 °C to 30 °C and use within 6 hours.
Dilute before use: Dilute each vial with 1.3 mL sodium chloride 9 mg/mL (0.9%) solution for injection.
PAA181045
SAMPLE


SAMPLE
COMIRNATY
sterile concentrate - IM
10 doses of 10 mcg
after dilution
Discard time:


LOT/MFG:
PAA177913
Pfizer-BioNTech COVID-19 Vaccine
DILUTE PRIOR TO USE
SAMPLE