Pfizer New Zealand Limited
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Pfizer New Zealand Limited

14 February 2021

Dear Healthcare Professional,

Supply of COMIRNATY COVID-19 Vaccine in New Zealand

Pfizer New Zealand Limited has commenced supply of COMIRNATY COVID-19 VACCINE 0.5 mg/mL concentrated suspension for injection. COMIRNATY is indicated for active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2, in individuals 16 years of age and older. The use of this vaccine should be in accordance with official recommendations.

As 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.

Identification and labelling

Pfizer's COVID-19 vaccine is supplied as a concentrated suspension in a 2 mL, multi-dose glass vial with a purple, flip-off cap. The vaccine will be supplied in trays containing 195 vials, or other packaging configurations depending upon the agreement with the New Zealand government.

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 a number of different artworks. Given the name of the vaccine and the name of the active ingredient have changed over time, it is possible that the following names may appear on labels, inserts and other associated packaging components:

Product name:
Pfizer-BioNTech COVID-19 Vaccine
COVID-19 Vaccine
COVID-19 mRNA Vaccine
COMIRNATY

Active ingredient (generic) name:
BNT162b2 [mRNA]

Irrespective of the pack livery, all are equivalent, in that they refer to the same product with the same formulation.

Example product labelling is attached to this letter. Please be aware of the following:

1. ***'Pfizer-BioNTech COVID-19 Vaccine'*** (see Attachment 1):

- The labels will also state that they are for use under Emergency Use Authorization. This statement has been included to meet the requirements of the US Food and Drug Administration (FDA) but is not relevant or applicable to the vaccine's use in New Zealand.

- The labels will state that the vaccine MUST BE DILUTED BEFORE USE with sterile 0.9% Sodium Chloride Injection, USP. However, any pharmacopeial grade of sterile 0.9% sodium chloride can be used for dilution of this vaccine.

- The use of the name 'BNT 162b2 (SARS-COV-2-mRNA vaccine) 5-dose vial' in the fact sheet is not applicable to NZ. Vaccine supplied in NZ will be referred to differently, as explained above).

- The vials instruct to record the Date and Time of **dilution**, this is aligned with the instructions in the Medsafe-approved Data Sheet.

2. *Product supplied with the tradename **'COMIRNATY'*** (see Attachment 2)***:***

- Instructions on the vials require the Date and Time that the vial contents should be **discarded** to be recorded on the vial. This is different to the instructions in the Medsafe approved Data Sheet, which instruct to record the Date and Time of dilution.

Number of doses per vial

This is a multidose vial and must be diluted with 1.8 mL 0.9% saline solution before use. Instructions for dilution are contained in the Medsafe approved Data Sheet available at www.medsafe.govt.nz/profs/Datasheet/c/comirnatyinj.pdf. One vial (0.45 mL) contains 6 doses of 0.3 mL after dilution. 1 dose (0.3 mL) contains 30 micrograms of BNT162b2 [mRNA] (embedded in lipid nanoparticles).

Whilst some stock is labelled as containing 5 doses when diluted, 6 doses may be withdrawn from each vial, **if the appropriate combination of low dead-volume needles and/or syringes is used**. This information is reflected in the Medsafe-approved Data Sheet. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose. If the amount of vaccine remaining in the vial cannot provide a full 0.3 mL dose, discard the vial and any excess volume. DO NOT pool excess vaccine from multiple vials.

Each box of the vaccine may contain either the US fact sheet or the EU fact sheet as a package insert. For the purpose of use in New Zealand, please refer to the Medsafe-approved Data Sheet for COMIRNATY that is available on the Medsafe website.

Storage requirements for the frozen, thawed and diluted vaccine

Adherence to the storage and handling guidance relating to the vaccine is critical to ensuring its quality and efficacy. As all of the storage guidance may not be present on the labels supplied, please ensure that the following guidance is followed when storing the vaccine. This guidance is also provided in the Medsafe-approved Data Sheet and the resources provided by Pfizer.

Frozen vaccine

The vaccine is shipped frozen to New Zealand, and must be stored in a freezer at -90°C to -60°C. The vaccine should be kept it in the original package in order to protect it from light. During storage, minimise exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Refer to sections 6.3 and 6.4 of the Data Sheet for additional information on handling the frozen vial trays.

Thawed vaccine

The vaccine must be thawed prior to dilution. Frozen vials should be transferred to an environment of 2°C to 8°C to thaw; a 195 vial pack may take 3 hours to thaw. Alternatively, frozen vials may also be thawed for 30 minutes at temperatures up to 30°C for immediate use.

Once removed from the freezer, the unopened vaccine can be stored for up to 5 days at 2°C to 8°C, and up to 2 hours at temperatures up to 30 °C, prior to use. Thawed vials can be handled in room light conditions. Once thawed, COMIRNATY should not be re-frozen.

Depending upon your location, you could receive the vials pre-thawed at 2°C to 8°C. Vials that have been pre-thawed at a site approved by the New Zealand Ministry of Health will be repackaged in new cartons containing 5 or 15 vials per carton, and will be labelled with the thawed expiry date (5 days from the date of thawing). **If you receive the vaccine pre-thawed, please note the expiry date that is marked on the carton label, as this represents the date that the vaccine must be diluted and administered by.**

Diluted vaccine

For diluted medicinal product, chemical and physical in-use stability has been demonstrated for 6 hours at 2°C to 30°C after dilution in sodium chloride 9 mg/mL (0.9%) solution for injection. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

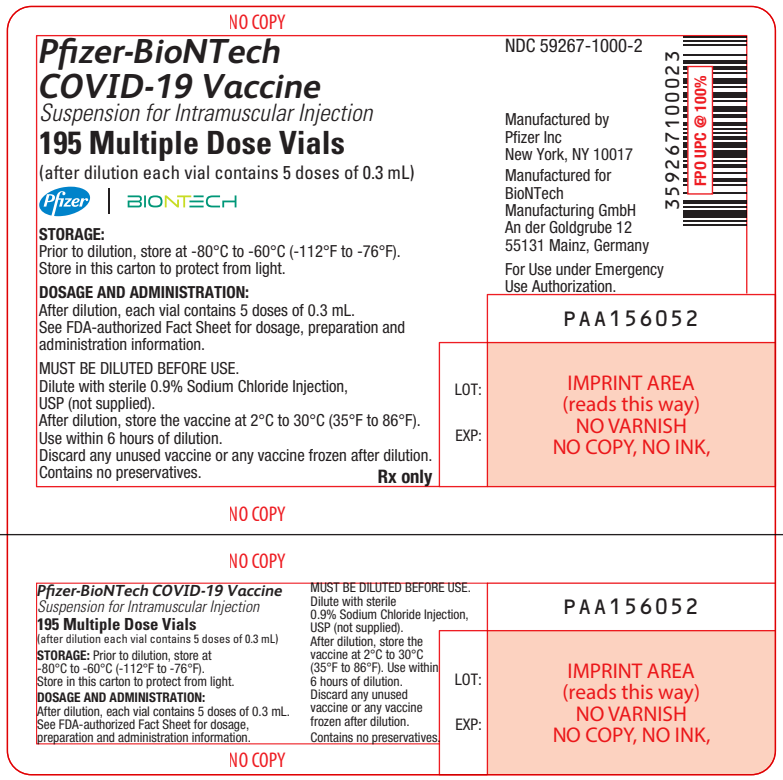
For additional information regarding Pfizer's COVID-19 vaccine, refer to the COMIRNATY Data Sheet on the Medsafe website www.medsafe.govt.nz/profs/Datasheet/c/comirnatyinj.pdf, or contact Pfizer by phone (0800 736 363) or e-mail medicalaffairs.anz@pfizer.com

Scott Williams
Vaccines Medical Director New Zealand, Australia and Korea

Attachment 1

BNT 162b2 (SARS-COV-2-mRNA) vaccine

‘5-dose/vial’ labelling



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rev. 08JUN11

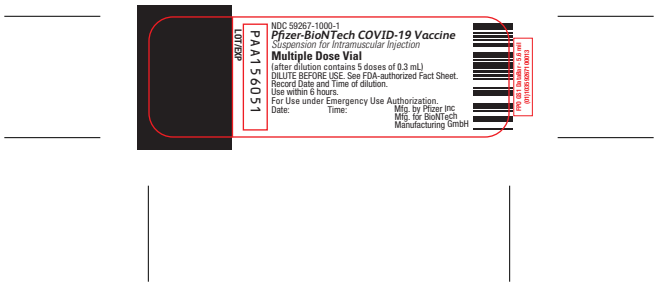
Additional Info:

Colors: Black, Process Blue, PMS 3278, PMS 2297, Dieline, No Varnish

☐ EDITOR'S COPY
GS: DATE:

Mgr	D. M. Guerin
GS	J. Wood
GA	T. Nowak

Rev	GA	PR	GS / ART REV (LCA)	GS / ART REV (FA)
4		CHANGES OK	CHANGES OK	CHANGES OK



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Time/Date:

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rev. 08JUN11

Additional Info:
Minimum point size - 3.5pt.

Colors: Black, Dieline

☐ **EDITOR'S COPY**
GS: **DATE:**

		Rev	GA	PR	GS / ART REV (LCA)	GS / ART REV (FA)
Mgr	D. M. Guerin	4		CHANGES OK	CHANGES OK	CHANGES OK
GS	J. Wood					
GA	T. Nowak					

Attachment 2

Comirnaty

‘5-dose/vial’ labelling

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COMIRNATY™

Concentrate for dispersion for injection

COVID-19 mRNA Vaccine

Intramuscular use after dilution

195 multidose vials

(After dilution, each vial contains 5 doses of 0.3 mL.)

Storage: Prior to dilution, store at -90°C to -60°C in the original package in order to protect from light. After dilution, store the vaccine at 2°C to 30°C and use within 6 hours. Discard any unused vaccine.

Dilute before use: Dilute each vial with 1.8 mL sodium chloride 9 mg/mL (0.9%) solution for injection.

Read the package leaflet before use.

Excipients: ALC-0315, ALC-0159, DSPC, cholesterol, potassium chloride, potassium dihydrogen phosphate, sodium chloride, disodium phosphate dihydrate, sucrose, water for injections.

BIONTECH | Pfizer

BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

Scan QR code for more information

EU/1/20/1528

COMIRNATY™

Concentrate for dispersion for injection

COVID-19 mRNA Vaccine

Intramuscular use after dilution

195 multidose vials

Prior to dilution, store at -90°C to -60°C.

PAA164513

PC: 04260703260002
Lot/EXP/SN

OVERPRINT AREA

INLINE DM AREA

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date:26-Nov-20 16:24:39

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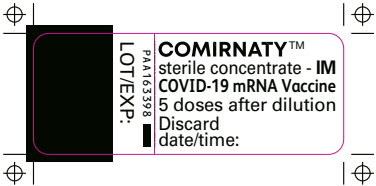

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