



12 July 2021

Dear Healthcare Professional,

**Pfizer New Zealand**

Generator  
Level 10, 11 Britomart Place  
Auckland CBD  
Auckland 1010

**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 12 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**

Pfizer's COVID-19 vaccine, COMIRNATY™, 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.

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

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

**Product name:**

Pfizer-BioNTech COVID-19 Vaccine  
COVID-19 Vaccine  
COVID-19 mRNA Vaccine  
COMIRNATY (final tradename)

Active ingredient (generic) name:

BNT162b2 [mRNA]

Stock supplied during the initial period in New Zealand may vary with respect to the labelling of the product. As such, the product supplied may be either:

1. Labelled '**Pfizer-BioNTech COVID-19 Vaccine**' (see Attachment 1), or
2. Labelled '**COMIRNATY**' (see Attachment 2).

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.

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 that is available on the Medsafe website.

**Product Labelling**

1. '**Pfizer-BioNTech COVID-19 Vaccine**':

See Attachment 1, however, please be aware of the following:

- 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**':

The labels to be supplied with this stock are provided in Attachment 2, however, please be aware of the following:

- 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.

### **Storage Requirements**

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.

### **Storage**

Refer to tables below for storage conditions and shelf life details.

Store in the original package in order to protect from light.

During storage, minimise exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Thawed vials can be handled in room light conditions.

#### *Storage Options for Unopened Vials of Comirnaty:*

Storage	Ultra Low Temperature (ULT) Freezer	Freezer	Refrigerator
Temperature	<b>-90 °C to -60 °C</b>	<b>-25 °C to -15 °C</b>	<b>2 °C to 8 °C</b>
Storage Time	Can be stored up to <b>6 months</b> at this temperature after manufacture – until expiry date printed on label	Can be stored up to <b>2 weeks</b> at this temperature	Can be stored up to <b>1 month</b> at this temperature

Prior to use, the unopened vial can be stored for up to 2 hours at temperatures up to 30 °C.

Once thawed, COMIRNATY should not be re-frozen.

*Transferring Vial Trays Between Storage Environments:*

Originating Temperature Environment	Max. Time at Room Temp. (up to 25 °C) during Storage or Transfer*		Time Required to Stay in Frozen Environment after Room Temp. Exposure during Transfer
	Closed-lid, Full Trays (195 vials)	Open-lid (< 195 vials)	
<b>From ULT Freezer</b> -90 °C to -60 °C OR <b>From Thermal Shipping Container**</b> -90 °C to -60 °C	Up to 5 minutes	Up to 3 minutes	At least 2 hours before they can be removed again
<b>From Freezer</b> -25 °C to -15 °C	Up to 3 minutes	Up to 1 minute***	No specified time before they can be taken out again

\*When removing vials from a vial tray, to protect the vials that will remain in the freezer, when possible, keep the vial tray in the frozen environment while transferring the vials to a secondary container.

\*\*The Thermal Shipping Container should not be opened for more than 3 minutes at a time.

\*\*\*If possible, open-lid trays should be left in the -25 °C to -15 °C environment when removing vials for use. If the tray must be removed from the freezer, return to freezer in less than 1 minute.

For **diluted medicinal product**, chemical and physical in-use stability, including during transportation, 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, unless the method of dilution precludes 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.

For additional information regarding Pfizer's COVID-19 vaccine, refer to the COMIRNATY Data Sheet on the Medsafe website, or contact Pfizer by phone (0800 736 363) or e-mail [medicalaffairs.anz@pfizer.com](mailto:medicalaffairs.anz@pfizer.com).



**Scott Williams**

Vaccines Medical Director New Zealand, Australia and Korea


**Pfizer Vaccines**

# **Attachment 1**

## **Pfizer-BioNTech COVID-19 Vaccine Labelling**

NO COPY

**Pfizer-BioNTech COVID-19 Vaccine**  
Suspension for Intramuscular Injection  
**195 Multiple Dose Vials**  
(after dilution each vial contains 5 doses of 0.3 mL)



**STORAGE:**  
Prior to dilution, store at -80°C to -60°C (-112°F to -76°F).  
Store in this carton to protect from light.

**DOSAGE AND ADMINISTRATION:**  
After dilution, each vial contains 5 doses of 0.3 mL.  
See FDA-authorized Fact Sheet for dosage, preparation and administration information.

**MUST BE DILUTED BEFORE USE.**  
Dilute with sterile 0.9% Sodium Chloride Injection, USP (not supplied).  
After dilution, store the vaccine at 2°C to 30°C (35°F to 86°F).  
Use within 6 hours of dilution.  
Discard any unused vaccine or any vaccine frozen after dilution.  
Contains no preservatives. **Rx only**


NDC 59267-1000-2

Manufactured by  
Pfizer Inc  
New York, NY 10017

Manufactured for  
BioNTech  
Manufacturing GmbH  
Ander Goldgrube 12  
55131 Mainz, Germany

For Use under Emergency  
Use Authorization.

359267100023  
FPO UPC @ 100%



PAA156052

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**Pfizer-BioNTech COVID-19 Vaccine**  
Suspension for Intramuscular Injection  
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NDC 59267-1000-2

Manufactured by  
Pfizer Inc  
New York, NY 10017

Manufactured for  
BioNTech  
Manufacturing GmbH  
Ander Goldgrube 12  
55131 Mainz, Germany







For Use under Emergency  
Use Authorization.

PAA156052

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GS	J. Wood		4			CHANGES		
GA	T. Nowak					OK	CHANGES	OK



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Time/Date:

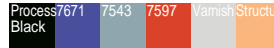
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GS	J. Wood	4			CHANGES	CHANGES	CHANGES
GA	T. Nowak				OK	OK	OK



**Attachment 2**  
**COMIRNATY Labelling**

date:14-Dec-20 17:09:17

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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 |   
 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.

PC: 04260703260002  
 Lot/EXP/SN

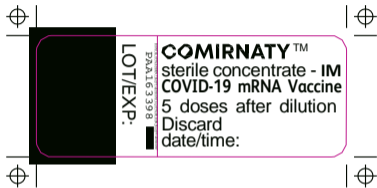
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date/initials: 09-Dec-20/SPEN	P7543C		
country: EU	P7597C		



itemnr.: PAA163398

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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 6 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.

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 BioNTech Manufacturing GmbH  
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Scan  
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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.

PC: 04260703260002  
 Lot/EXP/SN

PAA165993

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 DM  
 AREA**



itemnr.: PAA165993

formatcode: L565

dimensions: 105mm x 130mm

date/initials: 08 Jan 21/SPEN

country: EU

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P7671C

P7543C

P7597C

Item description

BL-COMIRNATY VAC 195X GVL EU

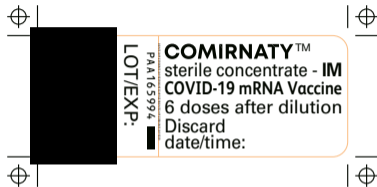
Issue reason

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itemnr.: PAA165994

formatcode: L560

dimensions: 41mm x 16mm

date/initials: 08-jan-21/SPEN

country: EU

sourcecode:

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Item description

L-COMIRNATY VAC GVL EU

Issue reason

2P2100050 CHANGE FROM 5 TO 6 DOSES