Important Safety Information on COMIRNATY Original & Omicron BA.4/BA.5 Bivalent Vaccine with English-only Vial and Carton Labels

2022/10/07

Audience
Healthcare professionals including infectious disease physicians, pharmacists, family physicians, public health officials, nurses and nurse practitioners, and other healthcare professionals at vaccination sites.

Key messages

- **On October 7, 2022, Health Canada authorized COMIRNATY Original & Omicron BA.4/BA.5 (COVID-19 mRNA Vaccine, Bivalent [Original and Omicron BA.4/BA.5]) [DIN 02531461].**
- **COMIRNATY Original & Omicron BA.4/BA.5 bivalent vaccine is indicated as a booster dose for active immunization against coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older.**
- **In order to provide rapid access to COMIRNATY Original & Omicron BA.4/BA.5 bivalent vaccine, Pfizer Canada ULC will distribute product vials and cartons with English-only labels with the name "Pfizer-BioNTech COVID-19 Vaccine, Bivalent Original and Omicron BA.4/BA.5" (see Appendix A), for a period of time.**
- **Existing supplies of COMIRNATY (COVID-19 Vaccine, mRNA, also referred to as Pfizer-BioNTech COVID-19 Vaccine) 30 mcg/0.3 mL monovalent vaccine for use in individuals 12 years of age and older continue to be available at this time:**
  - **GRAY CAP AND GRAY LABEL BORDER**
    - **30 mcg/0.3 mL – <u>Do NOT dilute</u>**
    - **For use in individuals 12 years of age and older**
    - **DIN: 02527863**
  - **PURPLE CAP AND PURPLE LABEL BORDER**
    - **30 mcg/0.3 mL <u>after dilution</u>**
    - **For use in individuals 12 years of age and older**
    - **DIN: 02509210**
- **Healthcare professionals are advised that:**
  - **COMIRNATY Original & Omicron BA.4/BA.5 (DIN 02531461) <u>bivalent</u> vaccine, which does NOT require dilution, has the**

same GRAY CAP AND GRAY LABEL BORDER as monovalent COMIRNATY (COVID-19 Vaccine, mRNA), 30 mcg/0.3 mL – Do NOT dilute (DIN: 02527863). To avoid medication errors, pay careful attention to the vial and carton label.

- **Important Canadian-specific information is absent from the vial and carton labels (see the "Information for healthcare professionals" section).**
- **Canadian-specific labelling information, including the COMIRNATY Original & Omicron BA.4/BA.5 Product Monograph and training materials, can be accessed at CVDvaccine.ca, or by scanning the QR code on the English-only carton labels. This information is also available on the federal government's covid-vaccine.canada.ca website. The Canadian COMIRNATY Original & Omicron BA.4/BA.5 Product Monograph in English and French is also available on Health Canada's Drug Product Database and at pfizer.ca.**

What is the issue?

On October 7, 2022, Health Canada authorized the bivalent vaccine, COMIRNATY Original & Omicron BA.4/BA.5, as a booster dose for active immunization against coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older.

In order to provide rapid access to COMIRNATY Original & Omicron BA.4/BA.5 bivalent vaccine, Pfizer Canada ULC will distribute product vials and cartons labelled in English only with the name "Pfizer-BioNTech COVID-19 Vaccine, Bivalent Original and Omicron BA.4/BA.5" for a period of time. Important Canadian-specific information is absent from these labels (see the "Information for healthcare professionals" section).

COMIRNATY Original & Omicron BA.4/BA.5 **bivalent** vaccine (DIN 02531461), which does NOT require dilution, has the same **GRAY CAP AND GRAY LABEL BORDER** as **monovalent** COMIRNATY (COVID-19 Vaccine, mRNA) 30 mcg/0.3 mL – Do NOT dilute (DIN: 02527863). To avoid medication errors, pay careful attention to the vial and carton label.

Products affected
COMIRNATY Original & Omicron BA.4/BA.5 (COVID-19 mRNA Vaccine, Bivalent [Original and Omicron BA.4/BA.5]) for individuals 12 years of age and older, suspension for intramuscular injection, multiple dose vials. Each vial with **GRAY cap and GRAY label border**, 30 mcg/0.3 mL (Do NOT dilute), contains 6 doses[1] (each dose is 0.3 mL).

DIN: 02531461

Manufacturer: BioNTech Manufacturing GmbH (Germany)
Canadian Importer and Distributor: Pfizer Canada ULC

[1] Low dead-volume syringes and/or needles can be used to extract 6 doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a 6th dose from a single vial.

Background information
COMIRNATY Original & Omicron BA.4/BA.5 (COVID-19 mRNA Vaccine, Bivalent [Original and Omicron BA.4/BA.5]) bivalent vaccine is indicated as a booster dose for active immunization against coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older.

Given the public health emergency resulting from the current pandemic, Health Canada has authorized the importation, sale, and advertising of COMIRNATY Original & Omicron BA.4/BA.5 with vial and carton labels that are in English only with the name "Pfizer-BioNTech COVID-19 Vaccine, Bivalent Original and Omicron BA.4/BA.5" for the initial global distribution of the vaccine.

The Canadian Product Monograph for COMIRNATY Original & Omicron BA.4/BA.5 bivalent vaccine, which is approved by Health Canada and available **in English and French**, should be used for complete product information.

Information for healthcare professionals

Healthcare professionals are advised that:

- On October 7, 2022, Health Canada authorized COMIRNATY Original & Omicron BA.4/BA.5 (COVID-19 mRNA Vaccine, Bivalent [Original and Omicron BA.4/BA.5]) [DIN 02531461] as a booster dose in individuals 12 years of age and older.
- In order to provide rapid access to COMIRNATY Original & Omicron BA.4/BA.5, Pfizer Canada ULC will distribute product vials and cartons labelled in English only with the name "Pfizer-BioNTech COVID-19 Vaccine, Bivalent Original and Omicron BA.4/BA.5" (see Appendix A), for a period of time.
- Existing supplies of COMIRNATY (COVID-19 Vaccine, mRNA, also referred to as Pfizer-BioNTech COVID-19 Vaccine) 30 mcg/0.3 mL monovalent vaccine

for use in individuals 12 years of age and older continue to be available at this time:

- GRAY CAP AND GRAY LABEL BORDER
  - 30 mcg/0.3 mL – Do NOT dilute
  - For use in individuals 12 years of age and older
  - DIN: 02527863
- PURPLE CAP AND PURPLE LABEL BORDER
  - 30 mcg/0.3 mL after dilution
  - For use in individuals 12 years of age and older
  - DIN: 02509210

- COMIRNATY Original & Omicron BA.4/BA.5 (DIN 02531461) bivalent vaccine, which does NOT require dilution, has the same **GRAY CAP AND GRAY LABEL BORDER** as monovalent COMIRNATY (COVID-19 Vaccine, mRNA), 30 mcg/0.3 mL – Do NOT dilute (DIN: 02527863). **To avoid medication errors, pay careful attention to the vial and carton label.**
- Canadian-specific labelling information, including the COMIRNATY Original & Omicron BA.4/BA.5 Product Monograph and training materials, can be accessed at **CVDvaccine.ca**, or by scanning the QR code on the English-only carton labels. This information is also available on the federal government's **covid-vaccine.canada.ca** website. The Canadian COMIRNATY Original & Omicron BA.4/BA.5 Product Monograph in English and French is also available on Health Canada's **Drug Product Database** or at **pfizer.ca**.
- The following important Canadian-specific information is absent from the vial and carton labels:
  - Drug Identification Number (DIN)
  - name and address of the Canadian DIN holder
  - name and address of the Canadian importer and distributor
  - all corresponding text in French
  - Canadian brand name "COMIRNATY Original & Omicron BA.4/BA.5"
- The vial and carton labels for the current supplies of vaccine include the statement "*For use under Emergency Use Authorization*." The US Food and Drug Administration (FDA) specific information (e.g., Rx only, NDC) should be disregarded as this is not relevant to the Canadian authorization.
- For any medical questions, contact Pfizer Canada ULC Medical Information at 1-800-463-6001.
- For any other general inquiries, contact Pfizer Canada ULC Customer Service at 1-833-VAX-COVI (1-833-829-2684) or email at CanadaCSVaccine@pfizer.com

Action taken by Health Canada

Health Canada is permitting the use of an English-only label for a limited period. Health Canada has imposed terms and conditions requiring Pfizer Canada ULC to provide vaccine supplies with Canadian-specific labels as soon as possible. Health Canada has made full labelling information available in English and French on the federal government's covid-vaccine.canada.ca website.

Health Canada is communicating this important safety information to healthcare professionals and Canadians via the Recalls and Safety Alerts Database on the Healthy Canadians website. This communication will be further distributed through the MedEffect™ e-Notice email notification system, as well as through social media channels, including LinkedIn and Twitter.

Report health or safety concerns

Managing marketed health product-related side effects depends on healthcare professionals and consumers reporting them. Any serious or unexpected side effects in patients receiving COMIRNATY Original & Omicron BA.4/BA.5 should be reported to your local Health Unit or Pfizer Canada ULC.

Pfizer Canada ULC
17300 Trans-Canada Highway
Kirkland, QC
H9J 2M5
www.pfizersafetyreporting.com
Telephone: 1-866-723-7111
Fax: 1-855-242-5652

To correct your mailing address or fax number, contact Pfizer Canada ULC Customer Service at 1-833-VAX-COVI (1-833-829-2684).

If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (https://www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization/form.html) and send it to your local Health Unit.

For other health product inquiries related to this communication, contact Health Canada at:

Biologic and Radiopharmaceutical Drugs Directorate
E-mail: brdd.dgo.enquiries@hc-sc.gc.ca

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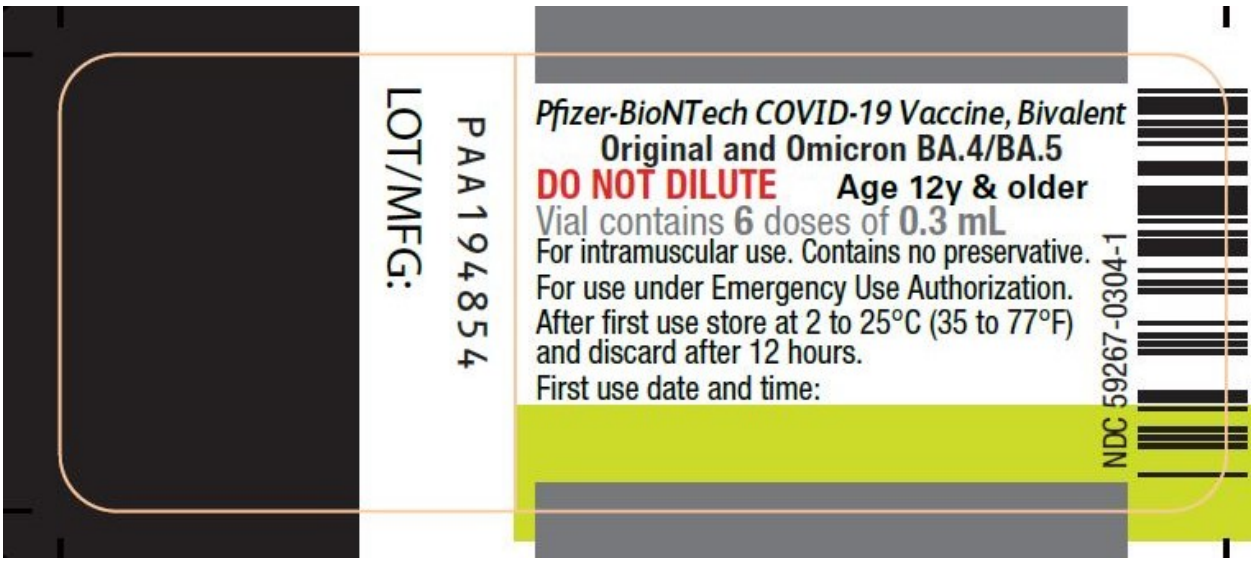
Vratislav Hadrava M.D., Ph.D.
Vice President & Medical Director
Pfizer Canada ULC

Appendix A – Vial and carton labels for COMIRNATY Original & Omicron BA.4/BA.5 (COVID-19 mRNA Vaccine, Bivalent [Original and Omicron BA.4/BA.5]) for individuals 12 years of age and older with English-only labelling

Vial Label



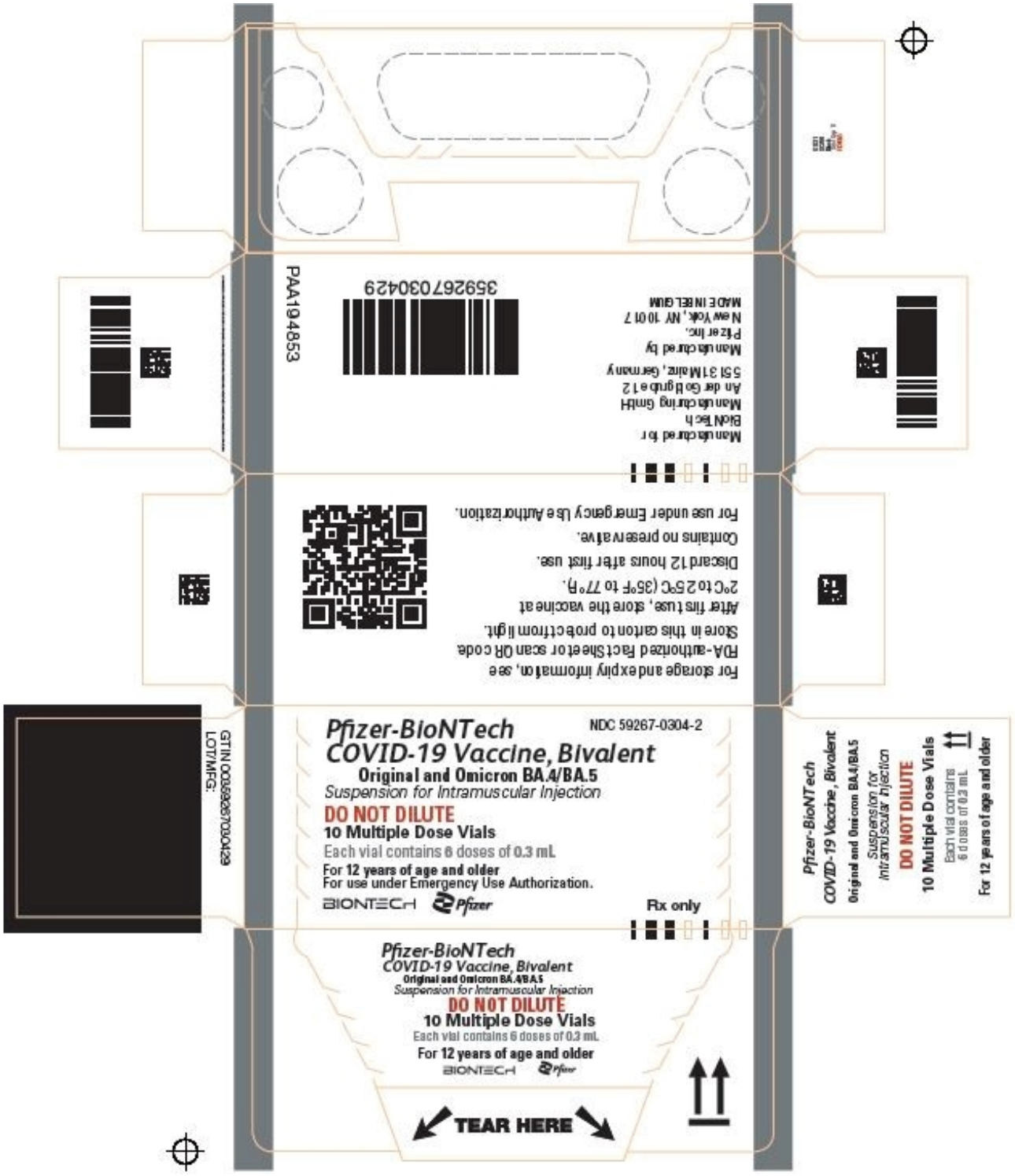
LOT/MFG: PAA194854*

Pfizer-BioNTech COVID-19 Vaccine, Bivalent
Original and Omicron BA.4/BA.5
DO NOT DILUTE **Age 12y & older**
Vial contains **6** doses of **0.3 mL**
For intramuscular use. Contains no preservative.
For use under Emergency Use Authorization.
After first use store at 2 to 25°C (35 to 77°F)
and discard after 12 hours.
First use date and time:

NDC 59267-0304-1

* Depending on product supply chain, the label component code number may be different.

Carton Label (10-vials)



FRONT PANEL:

Pfizer-BioNTech
COVID-19 Vaccine, Bivalent
Original and Omicron BA.4/BA.5
Suspension for Intramuscular Injection
DO NOT DILUTE
10 Multiple Dose Vials
Each vial contains **6** doses of **0.3 mL**
For **12 years of age and older**

BIONTECH Pfizer

↙ **TEAR HERE*** ↘

*

TOP PANEL:

Pfizer-BioNTech NDC 59267-0304-2
COVID-19 Vaccine, Bivalent
Original and Omicron BA.4/BA.5
Suspension for Intramuscular Injection
DO NOT DILUTE
10 Multiple Dose Vials
Each vial contains **6** doses of **0.3 mL**
For **12 years of age and older**
For use under Emergency Use Authorization.

BIONTECH Pfizer Rx only

BACK PANEL:

For storage and expiry information, see
FDA-authorized Fact Sheet or scan QR code.
Store in this carton to protect from light.

After first use, store the vaccine at
2°C to 25°C (35°F to 77°F).
Discard 12 hours after first use.
Contains no preservative.
For use under Emergency Use Authorization.

BOTTOM PANEL:

Manufactured for
BioNTech
Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

Manufactured by
Pfizer Inc.
New York, NY 10017

[Barcode]
359267030429*

MADE IN BELGIUM*

PAA194853*

SIDE PANEL
GTIN LOT/MFG:
SIDE PANEL
Pfizer-BioNTech ***COVID-19 Vaccine, Bivalent*** **Original and Omicron BA.4/BA.5** *Suspension for* *Intramuscular Injection* **DO NOT DILUTE** **10 Multiple Dose Vials** Each vial contains **6** doses of **0.3 mL** For **12 years of age and older**

* Depending on product supply chain and resulting differences in carton configuration, there may be the following slight differences in text and text location on the carton:

- The text “MADE IN BELGIUM” may not appear on all cartons.
- The label component code and bar code numbers may be different.
- The carton may not have a tearable flap; thus the text “ ↙ TEAR HERE ↘ ” may not be present.
- The upward arrows ( ) designating the carton storage orientation may appear on a different panel.