

**Important Safety Information on COMIRNATY Original & Omicron BA.4/BA.5 Bivalent Vaccine with English-only Vial and Carton Labels: New Formulation for Use in Children 5 to Less Than 12 Years of Age**



2022/12/09

**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 December 9, 2022, Health Canada authorized a new formulation of COMIRNATY Original & Omicron BA.4/BA.5 (COVID-19 mRNA Vaccine, Bivalent [Original and Omicron BA.4/BA.5]) [DIN 02533197] for use in children 5 to less than 12 years of age.**
- **The new formulation 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 children 5 to less than 12 years of age.**
- **In order to provide rapid access to the new formulation, 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) 10 mcg/0.2 mL monovalent vaccine for use in children 5 to less than 12 years of age continue to be available at this time.**
- **Healthcare professionals are advised that:**
  - **COMIRNATY Original & Omicron BA.4/BA.5 (DIN 02533197) bivalent vaccine has the same **ORANGE CAP and ORANGE LABEL BORDER** as monovalent COMIRNATY (COVID-19 Vaccine, mRNA), 10 mcg/0.2 mL (DIN 02522454). 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](https://www.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](https://www.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](https://www.drugproductdatabase.ca) and at [pfizer.ca](https://www.pfizer.ca).**

### What is the issue?

On December 9, 2022, Health Canada authorized a new formulation of 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), for use in children 5 to less than 12 years of age.

In order to provide rapid access to the new formulation, 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 02533197) has the same **ORANGE CAP and ORANGE LABEL BORDER** as monovalent COMIRNATY (COVID-19 Vaccine, mRNA) 10 mcg/0.2 mL (DIN 02522454). **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 use in children 5 to less than 12 years of age, suspension for intramuscular injection, multiple dose vials. Each vial with **ORANGE CAP and ORANGE LABEL BORDER**, 10 mcg/0.2 mL - DILUTE PRIOR TO USE, contains 10 doses<sup>1</sup> (each dose is 0.2 mL after dilution).

DIN: 02533197

Manufacturer: BioNTech Manufacturing GmbH (Germany)

Canadian Importer and Distributor: Pfizer Canada ULC

### Background information

The new formulation of COMIRNATY Original & Omicron BA.4/BA.5 (COVID-19

<sup>1</sup> Low dead-volume syringes and/or needles can be used to extract 10 doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract 10 doses from a single vial.

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 children 5 to less than 12 years of age.

Given the public health emergency resulting from the current pandemic, Health Canada has authorized the importation, sale, and advertising of the new formulation 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 December 9, 2022, Health Canada authorized a new formulation of COMIRNATY Original & Omicron BA.4/BA.5 (COVID-19 mRNA Vaccine, Bivalent [Original and Omicron BA.4/BA.5]) [DIN 02533197] as a booster dose for use in children 5 to less than 12 years of age.
- In order to provide rapid access to the new formulation, 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) 10 mcg/0.2 mL monovalent vaccine for use in children 5 to less than 12 years of age continue to be available at this time.
- COMIRNATY Original & Omicron BA.4/BA.5 (DIN 02533197) bivalent vaccine has the same **ORANGE CAP and ORANGE LABEL BORDER** as monovalent COMIRNATY (COVID-19 Vaccine, mRNA), 10 mcg/0.2 mL (DIN 02522454). **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](https://covidvaccine.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](https://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](https://drugsafe.ca) or at [pfizer.ca](https://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](mailto: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](https://www.canada.ca/en/health-canada/services/covid-vaccine/canada-specific-labels.html) website.

Health Canada is communicating this important safety information to healthcare professionals and Canadians via the [Recalls and Safety Alerts Database](https://www.canada.ca/en/health-canada/services/recalls-and-safety-alerts.html) 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](http://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](mailto:brdd.dgo.enquiries@hc-sc.gc.ca)

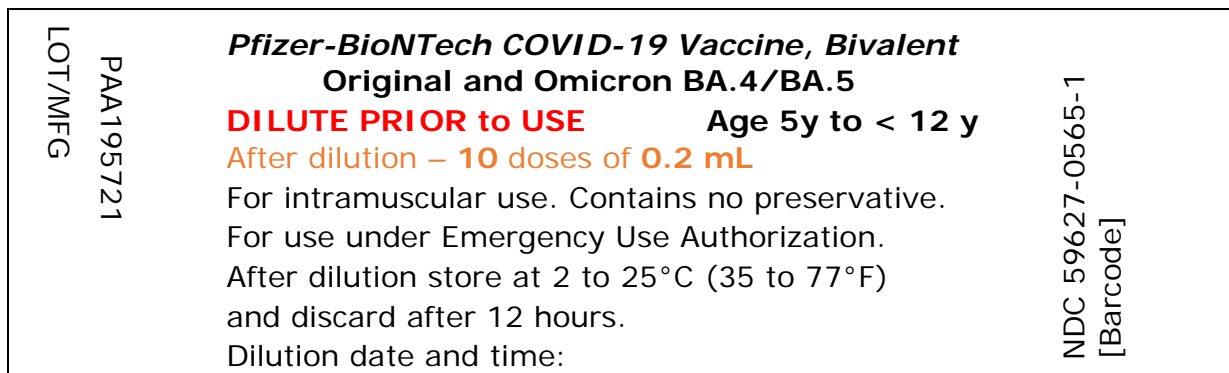
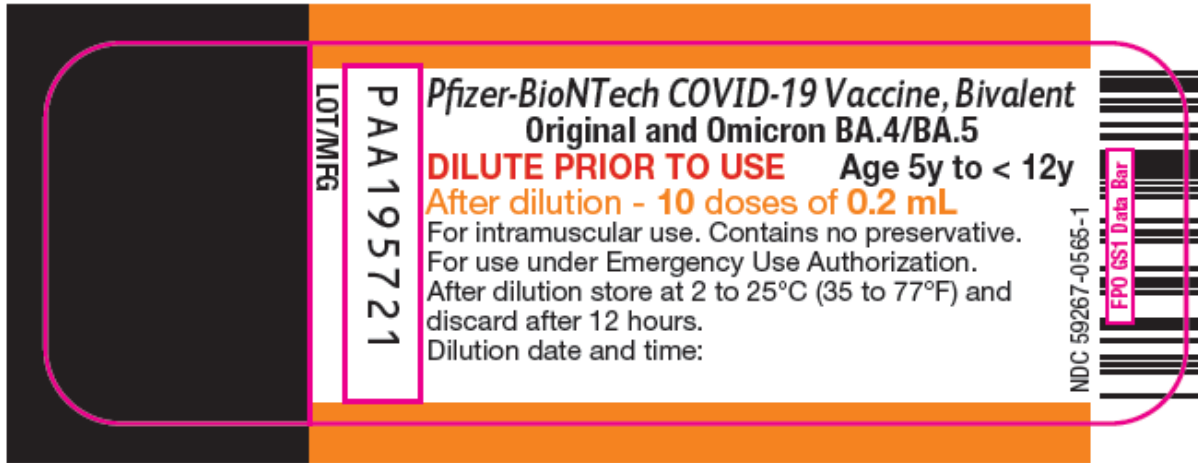
### Original signed by

DocuSigned by:  
  
D62C6DFD49824FC...

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 children 5 to less than 12 years of age with English-only labelling**

**Vial Label \***



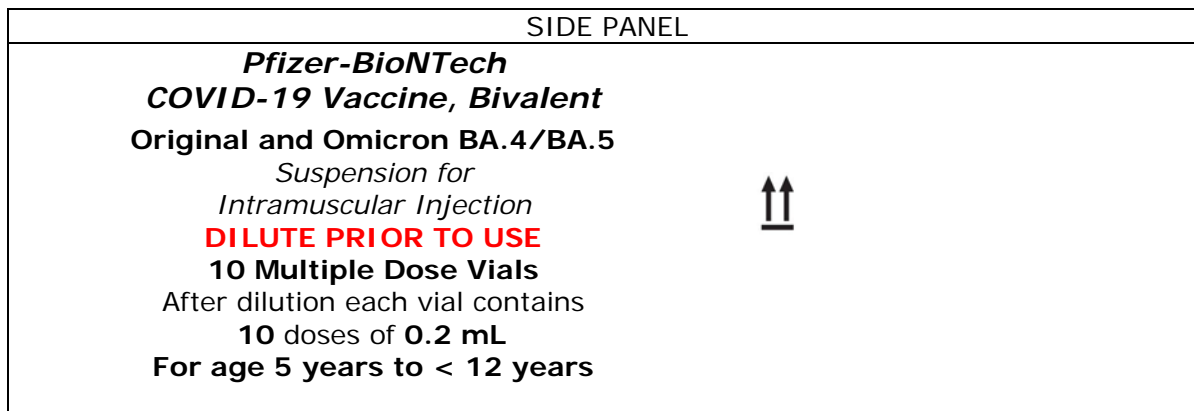
\* Depending on product supply chain and resulting differences in label, there may be the following slight differences:

- The label component code may be different.
- The label may include a green band near the lower orange border.












† 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.