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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



Dear Customer,

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.

A Health Product Risk Communication (HPRC) was issued by Pfizer Canada, in collaboration with Health Canada, on December 9, 2022, providing important information regarding the new bivalent vaccine formulation.

- **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. Please refer to Appendix A for copies of the current vial and carton labels.**
- **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.**

For more information on this new formulation and to review the Health Product Risk Communication visit www.CVDvaccine.ca

Sincerely,

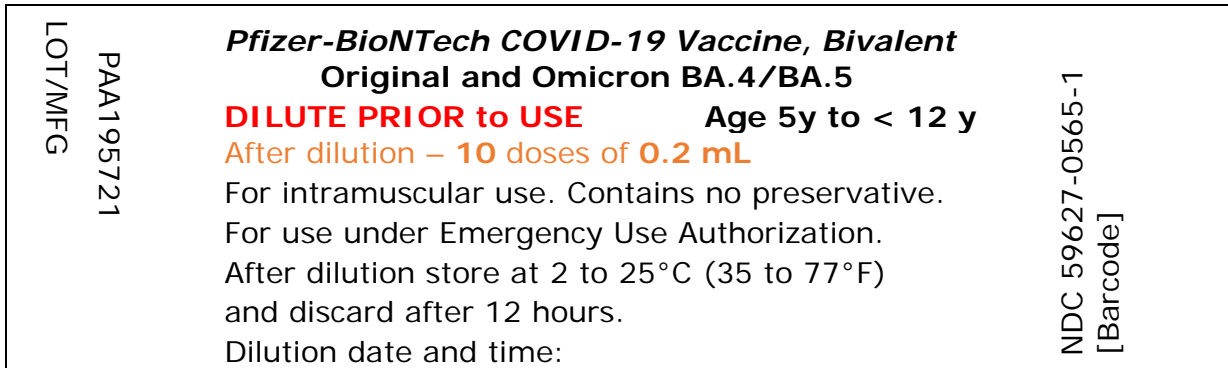
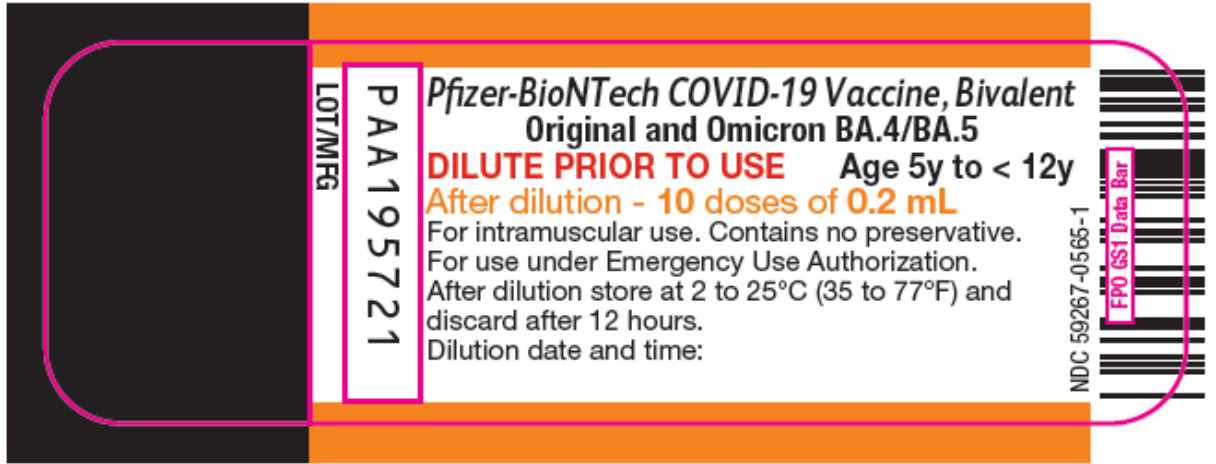
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Appendix A – Vial and carton labels for COMIRNATY Original & Omicron BA.4/BA.5 (COVID-19 mRNA Vaccine, Bivalent [Original and Omicron BA.4/BA.5]) for children 5 to less than 12 years of age with English-only labelling

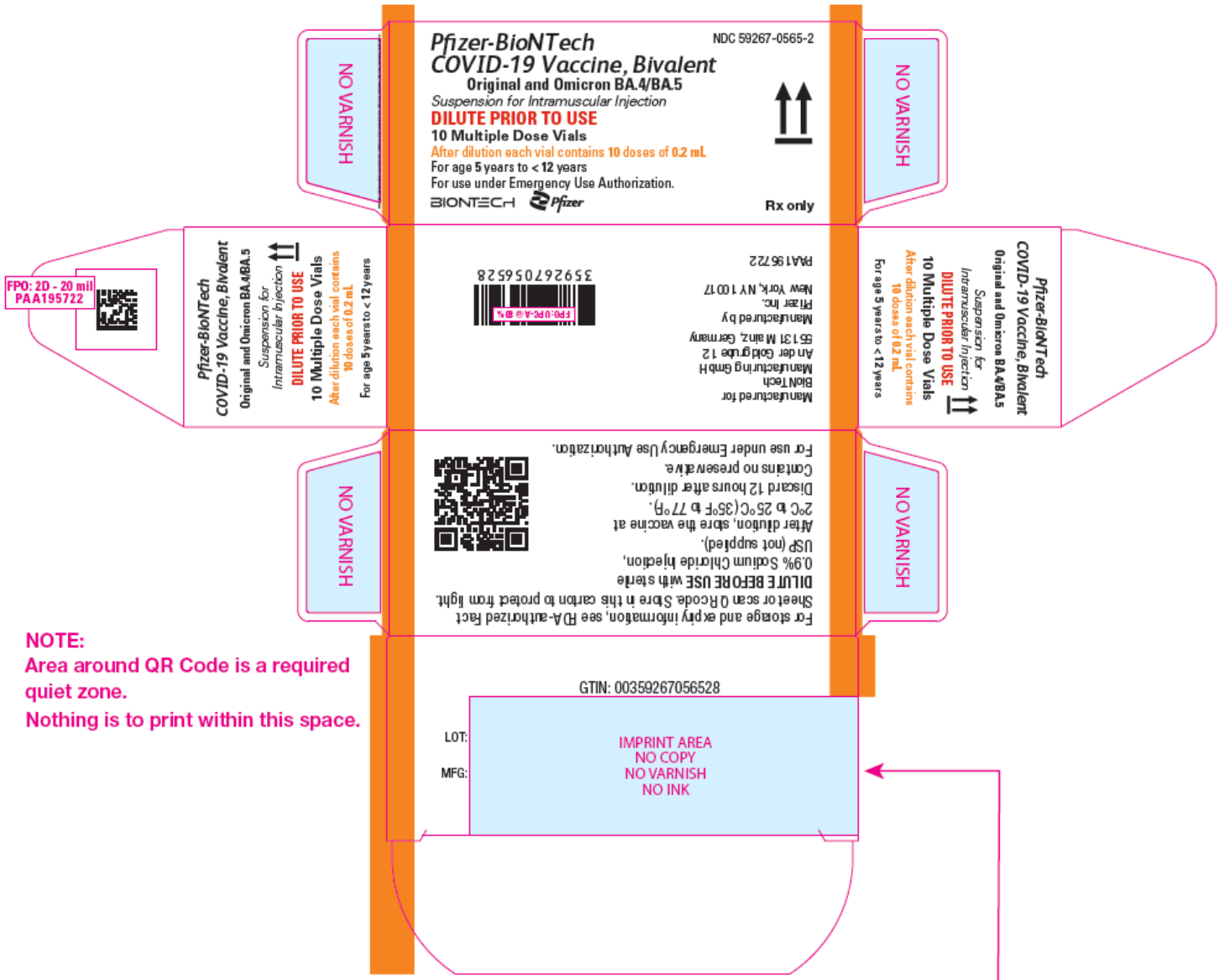
Vial label *




* 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.

Carton Label† (10-vials)



† 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.