Important Safety Information on COMIRNATY (COVID-19 Vaccine, mRNA, also referred to as Pfizer-BioNTech COVID-19 Vaccine): New Presentation for Use in Children Aged 6 Months to Less Than 5 Years with English-only Vial and Carton Labels

2022/09/09

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

Key messages

- **On September 9, 2022, Health Canada authorized a NEW PRESENTATION of COMIRNATY (COVID-19 Vaccine, mRNA) 3 mcg/0.2 mL (DIN 02530325) for use in children aged 6 months to less than 5 years.**
- **This new presentation has a MAROON vial cap and MAROON label border. It requires dilution with 2.2 mL of sterile 0.9% Sodium Chloride Injection, USP prior to use.**
- **Vials of COMIRNATY intended for children aged 6 months to less than 5 years (MAROON cap/ MAROON label border) cannot be used to prepare doses for individuals 5 years of age and older.**
- **COMIRNATY is now authorized as four different presentations, which are clearly differentiated by their vial cap and label border colours. Each presentation has specific age authorizations, storage, handling, and preparation requirements. The differences are noted in Table 1 in the "Information for healthcare professionals" section.**
- **Additionally, although the vaccine's brand name is now COMIRNATY, Canada will continue to receive vials of the vaccine labelled as Pfizer-BioNTech COVID-19 Vaccine. Pfizer Canada ULC is providing vaccine supplies with US Emergency Use Authorization English-only labels on the vials and cartons to expedite the global distribution of COMIRNATY.**
- **Healthcare professionals are advised that:**
  - **It is important that information on the different presentations is carefully reviewed prior to use. The presentation and lot number should be documented on patient vaccine records and for the purposes of adverse reaction reporting.**
  - **Important Canadian-specific information is absent from the vial and carton labels (see the "Information for healthcare**

professionals" section).

- **The Canadian-specific labelling information, including the COMIRNATY Product Monograph and training materials can be accessed at CVDvaccine.ca or COMIRNATY.ca, or by scanning the QR code on the English-only carton label. This information is also available on the federal government's covid-vaccine.canada.ca website. The COMIRNATY Canadian Product Monograph in English and French is also available in Health Canada's Drug Product Database or at pfizer.ca.**

What is the issue?

On September 9, 2022, Health Canada authorized a new presentation of COMIRNATY (COVID-19 Vaccine, mRNA) 3 mcg/0.2 mL dose (DIN 02530325) for use in children aged 6 months to less than 5 years. This new presentation has a **MAROON** vial cap and **MAROON** label border.

In addition, as an extraordinary measure to provide access to vaccine supplies in the context of the global pandemic, Pfizer and BioNTech are continuing to provide vaccine supplies with vials and cartons labelled with the name Pfizer-BioNTech COVID-19 Vaccine (see Appendix A). This label is presented in English only and is missing some important Canadian-specific information normally found on Health Canada approved labels (see the "Information for healthcare professionals" section).

Products affected

COMIRNATY (COVID-19 Vaccine, mRNA, also referred to as Pfizer-BioNTech COVID-19 Vaccine) for children aged 6 months to less than 5 years, suspension for intramuscular injection, multiple dose vials. Each vial with **MAROON** cap and **MAROON** label border, 3 mcg / 0.2 mL **after dilution**, contains 10† doses (each dose is 0.2 mL).
DIN: 02530325

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

Background information

COMIRNATY is now indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 6 months of age and older.

Vaccine vials intended for use in children 6 months to less than 5 years of age have a **MAROON** cap, and the vial labels also have a **MAROON** border. This new presentation **requires** dilution with 2.2 mL of sterile 0.9% Sodium Chloride Injection, USP prior to use.

† 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.

Given the public health emergency resulting from the current pandemic, Health Canada has authorized the importation, sale, and advertising of this presentation with vial and carton labels that are in English only for the current global distribution of the vaccine.

The Canadian Product Monograph for COMIRNATY, which is approved by Health Canada and available in **English and French**, should be used for complete product information.

Information for healthcare professionals
COMIRNATY is now authorized as four different presentations (see Table 1):

- **MAROON CAP AND MAROON LABEL BORDER**
  - **3 mcg/0.2 mL after dilution**
  - **For use in children 6 months to less than 5 years of age**
  - **DIN: 02530325**

- **ORANGE CAP AND ORANGE LABEL BORDER**
  - **10 mcg/0.2 mL after dilution**
  - **For use in children 5 to less than 12 years of age**
  - **DIN: 02522454**

- **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**

IMPORTANT: Each presentation has specific age authorizations, storage, handling, and preparation requirements. The differences are noted in Table 1.

Only vials of COMIRNATY with **MAROON** caps and label borders are authorized to be used to prepare doses for children 6 months to less than 5 years of age.

Table 1: Important Differences between the Four COMIRNATY Presentations (adapted from the COMIRNATY Product Monograph)

	The Pfizer-BioNTech COVID-19 vaccine Multiple Dose Vial	The Pfizer-BioNTech COVID-19 vaccine Multiple Dose Vial	The Pfizer-BioNTech COVID-19 vaccine Multiple Dose Vial	The Pfizer-BioNTech COVID-19 vaccine Multiple Dose Vial
Vial colour	**Vials with Purple Cap/ Label Border** 	**Vials with Gray Cap/ Label Border** 	**Vials with Orange Cap/ Label Border** 	**Vials with Maroon Cap/ Label Border** 
Age range	**12 years and older**	**12 years and older**	**5 to <12 years**	**6 months to <5 years**
Dilution required	Yes	No	Yes	Yes
Amount of diluent required per vial (0.9% Sodium Chloride Injection, USP)	**1.8 mL** per vial	DO NOT DILUTE before use	**1.3 mL** per vial	**2.2 mL** per vial
Number of doses per vial[1]	6 doses per vial (after dilution)	6 doses per vial	10 doses per vial (after dilution)	10 doses per vial (after dilution)
Dose amount	30 micrograms per dose	30 micrograms per dose	10 micrograms per dose	3 micrograms per dose
Dose volume	0.3 mL per dose	0.3 mL per dose	0.2 mL per dose	0.2 mL per dose
Storage conditions				
ULT freezer storage time (-90 to -60°C)	Until expiry date printed on vial label[2]	12 months after manufacturing date printed on vial label	12 months after manufacturing date printed on vial label	12 months after manufacturing date printed on vial label
Freezer storage time (-25 to -15°C)	2 weeks	Do not store at -25 to -15°C	Do not store at -25 to -15°C	Do not store at -25 to -15°C
Refrigerated storage time (2 to 8°C)	1 month	10 weeks	10 weeks	10 weeks
Room temperature storage time (8 to 25°C)	2 hours prior to dilution (including any thaw time)	12 hours prior to first puncture (including any thaw time)	12 hours prior to dilution (including any thaw time)	12 hours prior to dilution (including any thaw time)
After first puncture (2 to 25°C)	Discard after 6 hours	Discard after 12 hours[3]	Discard after 12 hours[3]	Discard after 12 hours[3]
Expiry date	Date printed on vial label[2]	12 months after manufacturing date printed on vial label	12 months after manufacturing date printed on vial label	12 months after manufacturing date printed on vial label

ULT: ultra-low temperature.

1. Low dead-volume syringes and/or needles can be used to extract 6 or 10 doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract 6 or 10 doses from a single vial.
2. As long as all approved storage conditions have been maintained, expiry dates have been extended for the following **purple vials**:
   - Vials and cartons with an expiry date of August 2021 to March 2022 may remain in use for **6 months beyond** the printed date.
   - Vials and cartons with an expiry date of June 2022 to August 2022 may remain in use for **3 months beyond** the printed date.
3. Vial labels and cartons may state that a vial should be discarded 6 hours after first use (**gray vials**) or dilution (**orange vials** and **maroon vials**). The information in the Product Monograph and here supersedes the number of hours printed on vial labels and cartons.

Healthcare professionals are advised that:

- It is important that information on the different COMIRNATY presentations is carefully reviewed prior to use. The presentation and lot number should be documented on patient vaccine records and for the purposes of adverse reaction reporting.
- Canadian-specific information can be accessed on CVDvaccine.ca **or** COMIRNATY.ca, or by scanning the QR code on the carton label. This information is also available on the federal government's covid-vaccine.canada.ca website. The COMIRNATY Canadian Product Monograph, which is available in English and French on Health Canada's Drug Product Database, the federal government's covid-vaccine.canada.ca website or at pfizer.ca, should be used for complete product information.
- 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
    - The "COMIRNATY" brand name
- The vial and/or carton labels for the current supplies of vaccine include the statements "*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 feasible. 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 Web Site. This communication update 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 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

Original signed by

DocuSigned by:
D62C6DFD49824FC...

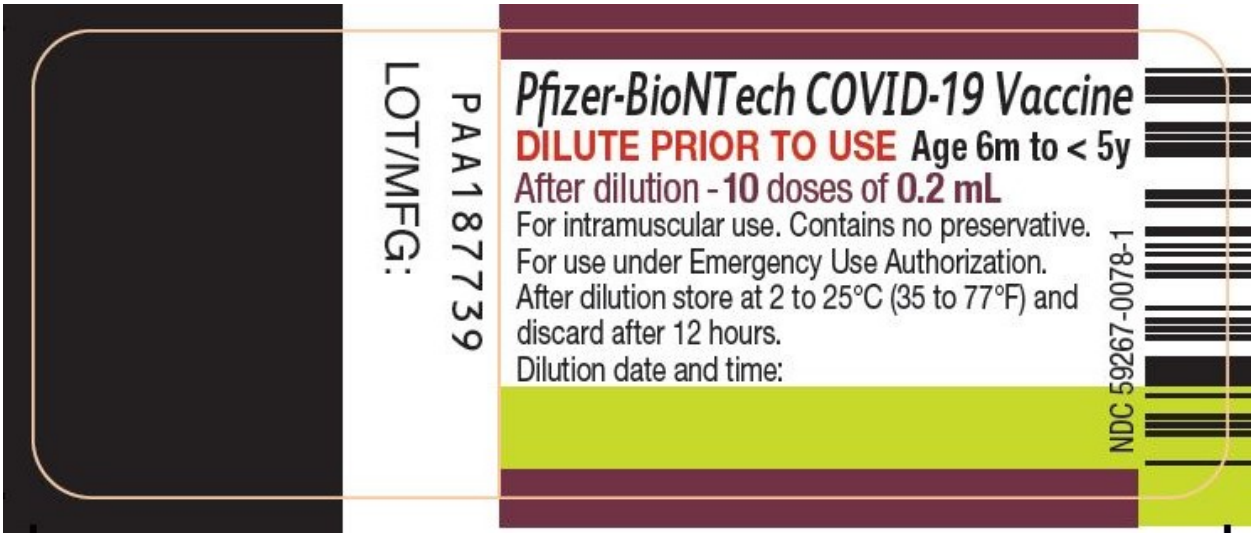
Vratislav Hadrava M.D., Ph.D.
Vice President & Medical Director
Pfizer Canada ULC

Reference

1. COMIRNATY (COVID-19 Vaccine, mRNA) Product Monograph. Mainz (Germany): BioNTech Manufacturing GmbH; 2022.

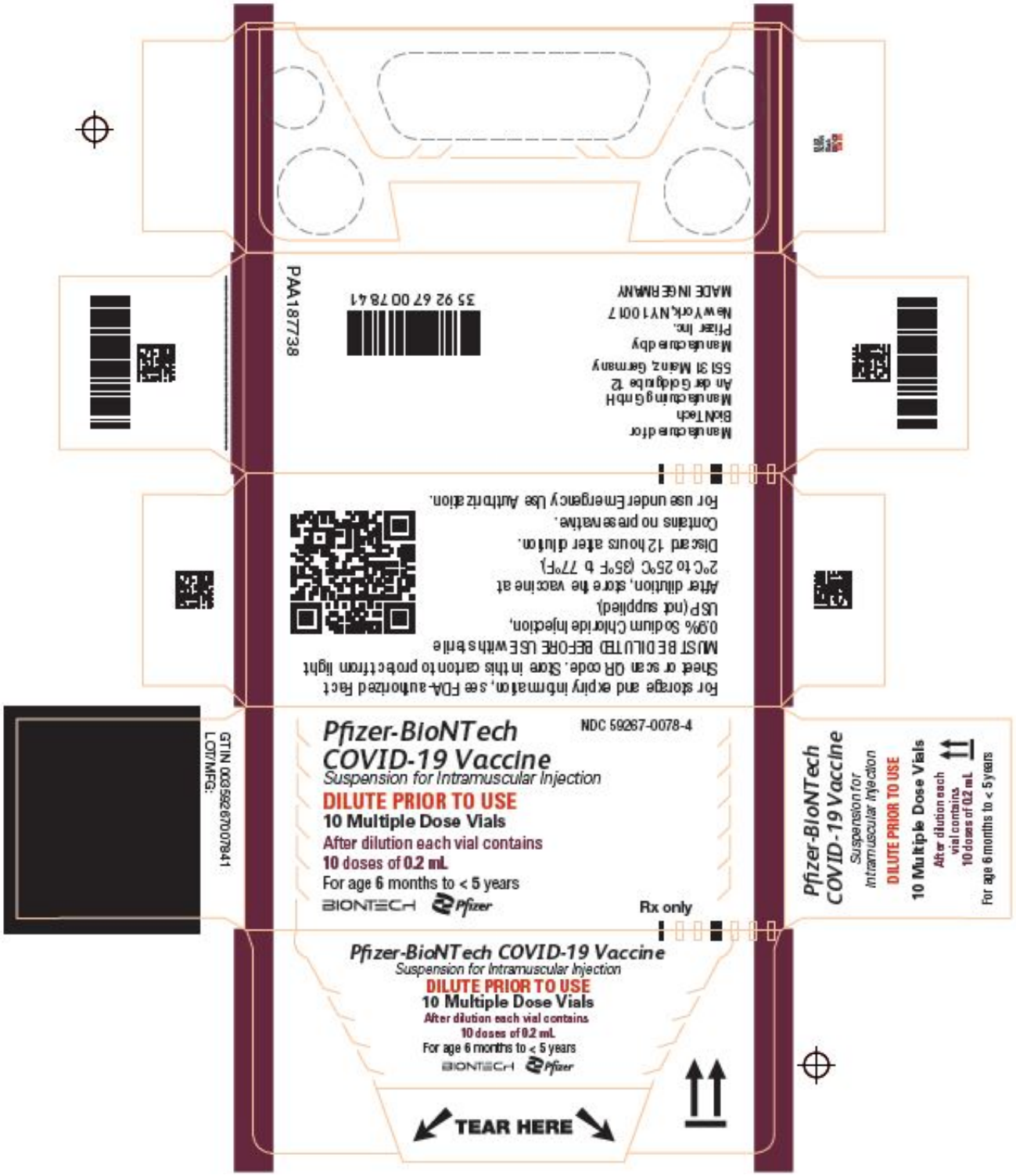
Appendix A – Pfizer-BioNTech COVID-19 Vaccine (COMIRNATY) for Children Aged 6 Months to less than 5 Years: MAROON Cap and Label Border - DILUTE PRIOR TO USE: Vial and Carton Labels with English-only labelling

Vial Label



Packaging no. LOT/MFG:	***Pfizer-BioNTech COVID-19 Vaccine*** **DILUTE PRIOR TO USE Age 6m to <5y** After dilution – **10** doses of **0.2 mL** For intramuscular use. Contains no preservative. For use under Emergency Use Authorization. After dilution store at 2 to 25°C (35 to 77°F) and discard after 12 hours. Dilution date and time:	NDC:

Carton Label (10-vials)



FRONT PANEL:

Pfizer-BioNTech COVID-19 Vaccine
Suspension for Intramuscular Injection
DILUTE PRIOR TO USE
10 Multiple Dose Vials
After dilution each vial contains
10 doses of **0.2 mL**
For age **6** months to **<5** years

BIONTECH Pfizer

↙ **TEAR HERE** ↘ ↑ ↑

TOP PANEL:

Pfizer-BioNTech NDC 59267-0078-4
COVID-19 Vaccine
Suspension for Intramuscular Injection
DILUTE PRIOR TO USE
10 Multiple Dose Vials
After dilution each vial contains
10 doses of **0.2 mL**
For age **6** months to **<5** years

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.
MUST BE DILUTED BEFORE USE with sterile 0.9% Sodium Chloride Injection, USP (not supplied).
After dilution, store the vaccine at 2°C to 25°C (35°F to 77°F).
Discard 12 hours after dilution.
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 Packaging no.

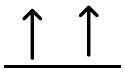
MADE IN GERMANY

SIDE PANEL

GTIN
LOT/MFG:

SIDE PANEL

Pfizer-BioNTech
COVID-19 Vaccine
Suspension for
Intramuscular Injection
DILUTE PRIOR TO USE



10 Multiple Dose Vials
After dilution each
vial contains
10 doses of **0.2 mL**
For age **6** months to **<5** years