Important Safety Information on Pfizer-BioNTech COVID-19 Vaccine: Updated Dosage and Administration and Post-Market Adverse Reaction Information

2021/02/08

Audience
Healthcare professionals including infectious disease physicians, pharmacists, family physicians, public health officials, nurses and nurse practitioners. Healthcare professionals at the identified Points of Use (POUs). Pfizer is distributing Pfizer-BioNTech COVID-19 Vaccine doses directly to POUs, vaccination locations where administration of the vaccine will occur, as outlined by the provincial governments and public health authorities.

Key messages

- **The Pfizer-BioNTech COVID-19 Vaccine Product Monograph (PM) and vial and carton labels are being updated to reflect an increase in the number of doses that can be extracted from each vial, from 5 doses per vial to 6 doses. This global label update to 6 doses has been implemented to minimize vaccine wastage and facilitate access to the vaccine supply during the pandemic.**
- **It is possible to extract a 6th dose of 0.3 mL of the diluted vaccine using low dead-volume syringes and/or needles. In order to ensure consistent withdrawal of 6 doses of 0.3 mL, it is important to minimize volume loss during dose extractions.**
- **If standard syringes and needles are used, there may not be sufficient volume to extract a 6th dose. Excess vaccine from multiple vials should not be pooled to create extra doses.**
- **The PM has also been updated with post-market adverse reaction information identified during pharmacovigilance activities. Severe allergic reactions, including anaphylaxis, have been reported during mass vaccination outside of clinical trials. This new information does not change the benefit-risk profile of this product.**
- **The updated PM, which is available in French and English on Health Canada's Drug Product Database, the federal government's covid-vaccine.canada.ca website or at pfizer.ca and CVDvaccine.ca, should be used for complete product information. Updated vial and carton labels with English-only labelling (see Appendix A) are also available on the federal government's covid-vaccine.canada.ca website or at CVDvaccine.ca.**

What is the issue?
Pfizer-BioNTech COVID-19 Vaccine was authorized on December 9, 2020, for use in accordance with the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19. Since the time of authorization, new information pertaining to dosage and administration, as well as to post-market adverse reactions, has been identified.

Products affected
Pfizer-BioNTech COVID-19 Vaccine, suspension for intramuscular injection, multiple dose vials. After dilution, the vial contains 6† doses (each dose is 0.3 mL).
DIN: 02509210

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

Background information
Pfizer-BioNTech COVID-19 Vaccine is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

At the time of authorization, the Pfizer-BioNTech COVID-19 Vaccine Product Monograph (PM) and vial and carton labels indicated that, after dilution, each vial contained 5 doses of 0.3 mL of vaccine. Based on updated information, it is possible to extract a 6th dose of 0.3 mL using low dead-volume syringes and/or needles.

In addition, post-market adverse reaction information has been identified during pharmacovigilance activities. Severe allergic reactions, including anaphylaxis, have been reported during mass vaccination outside of clinical trials. This new information does not change the benefit-risk profile of this product.

Health Canada has authorized updates to the Pfizer-BioNTech COVID-19 Vaccine PM, the terms and conditions of authorization imposed by Health Canada and vial and carton labels to reflect the new information.

The PM for Pfizer-BioNTech COVID-19 Vaccine, which is approved by Health Canada and available in French and English, should be used for complete product information. The PM is available on Health Canada's Drug Product Database, on the federal government's covid-vaccine.canada.ca website, or at pfizer.ca and CVDvaccine.ca. Updated vial and carton labels with English-only labelling (see Appendix A) are also available on the federal government's covid-vaccine.canada.ca website or at CVDvaccine.ca.

As an extraordinary measure to provide earlier access to vaccine supplies in the context of the global pandemic, Health Canada authorized the importation, sale, and advertising of Pfizer-BioNTech COVID-19 Vaccine with vial and carton labels that are in English-only and meant for the initial global distribution of the vaccine.

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† 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.

The terms and conditions imposed by Health Canada, which includes a requirement for Pfizer/BioNTech to develop Canadian-specific labelling in French and English for the vaccine vials and cartons, continue to apply. For more information on this issue, please consult the previously issued communication published on the Recalls and Safety Alerts Database on the Healthy Canadians Web Site. Also in accordance with the terms and conditions imposed by Health Canada, Pfizer Canada ULC is required to submit adverse reaction reports without delay and monthly safety reports for Pfizer-BioNTech COVID-19 Vaccine.

The use of Pfizer-BioNTech COVID-19 Vaccine is permitted under an interim authorization in accordance with the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19.

Patients should be advised of the nature of the authorization.

Information for consumers
Pfizer-BioNTech COVID-19 Vaccine is a vaccine used to prevent COVID-19 disease caused by the SARS-CoV-2 virus.

Health Canada authorized the sale of this COVID-19 vaccine under an Interim Order, on December 9, 2020. Since the time of authorization, new information about dosing and side effects has been identified.

In particular, cases of severe allergic reactions have been reported in some people receiving the vaccine outside of clinical trials. These reactions are not unexpected and do not affect Health Canada recommendations regarding the use of this vaccine.

There is a remote chance that Pfizer-BioNTech COVID-19 Vaccine could cause a severe allergic reaction. People who are allergic to any of the ingredients in this vaccine should not receive the vaccine. People that experienced a severe allergic reaction after their first dose of Pfizer-BioNTech COVID-19 Vaccine should not receive a second dose.

A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of Pfizer-BioNTech COVID-19 Vaccine. For this reason, vaccination providers should ask vaccine recipients to stay at the place where they received their vaccine for monitoring after vaccination. If vaccine recipients develop any symptoms that could be an allergic reaction, healthcare professionals should provide medical attention right away.

Symptoms of an allergic reaction include:

- hives (bumps on the skin that are often very itchy)
- swelling of the face, tongue or throat
- difficulty breathing
- a fast heartbeat
- dizziness and weakness

Information for healthcare professionals
The use of low dead-volume syringes and/or needles allows the extraction of a 6th dose of 0.3 mL of the diluted Pfizer-BioNTech COVID-19 Vaccine. If standard syringes and needles are used, there may not be sufficient volume to extract a 6th dose. In order to ensure consistent withdrawal of 6 doses of 0.3 mL, it is important to minimize volume loss during dose extractions.

Healthcare professionals are advised that (regardless of the type of syringe and/or needle used):

- each dose must contain 0.3 mL of the vaccine.
- if the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, to discard the vial and any excess volume.
- excess vaccine from multiple vials should not be pooled to create extra doses.

Healthcare professionals should also be aware that severe allergic reactions, including anaphylaxis, have been reported during mass vaccination outside of clinical trials. This new information does not change the benefit-risk profile of this product.

Healthcare professionals are advised that:

- as with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event following the administration of this vaccine.
- people who receive the vaccine should be kept under observation for at least 15 minutes after immunization.
- 30 minutes is a preferred interval when there is a specific concern about a possible vaccine reaction.
- a second dose of the vaccine should not be given to those who have experienced anaphylaxis to the first dose of Pfizer-BioNTech COVID-19 Vaccine.

Action taken by Health Canada
On September 16, 2020, Canada's Minister of Health approved an Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19 to expedite the authorization for the importation, sale, and advertising of drugs used in relation to COVID-19 while taking into consideration urgent public health needs. The Interim Order will expire after one year. Health Canada authorized the use of Pfizer-BioNTech COVID-19 Vaccine under the Interim Order on December 9, 2020, and this vaccine has been added to the "List of authorized drugs, vaccines and expanded indications" for COVID-19.

An alignment with the global label update to 6 doses has been implemented to minimize vaccine wastage and facilitate access to the vaccine supply during the pandemic. Health Canada, in collaboration with Pfizer/BioNTech, has updated the

PM for Pfizer-BioNTech COVID-19 Vaccine (COVID-19 mRNA Vaccine) to reflect this new information. Health Canada has also authorized updates to the global vial and carton labels.

Health Canada also continues to closely monitor reports of severe allergic reactions associated with Pfizer-BioNTech COVID-19 Vaccine. Health Canada will take action if any new safety issues are confirmed.

Health Canada has worked with Pfizer Canada ULC to prepare this alert for the Pfizer-BioNTech COVID-19 Vaccine. 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 Pfizer-BioNTech COVID-19 Vaccine should be reported to Pfizer Canada ULC or your local Health Unit.

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: hc.brdd.dgo.enquiries.sc@canada.ca

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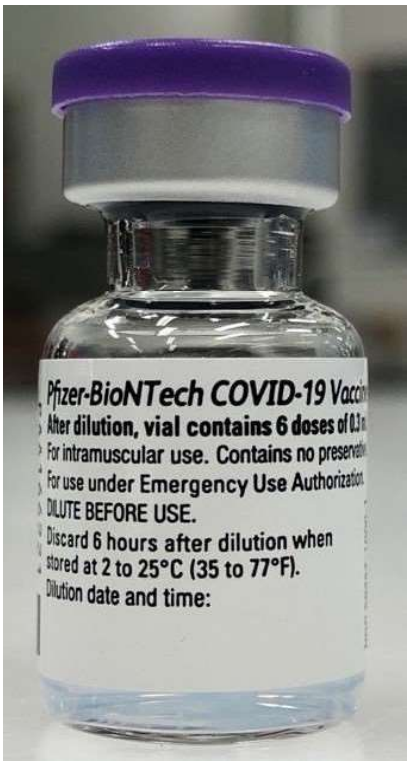
Vratislav Hadrava M.D., Ph.D.
Vice President & Medical Director
Pfizer Canada ULC

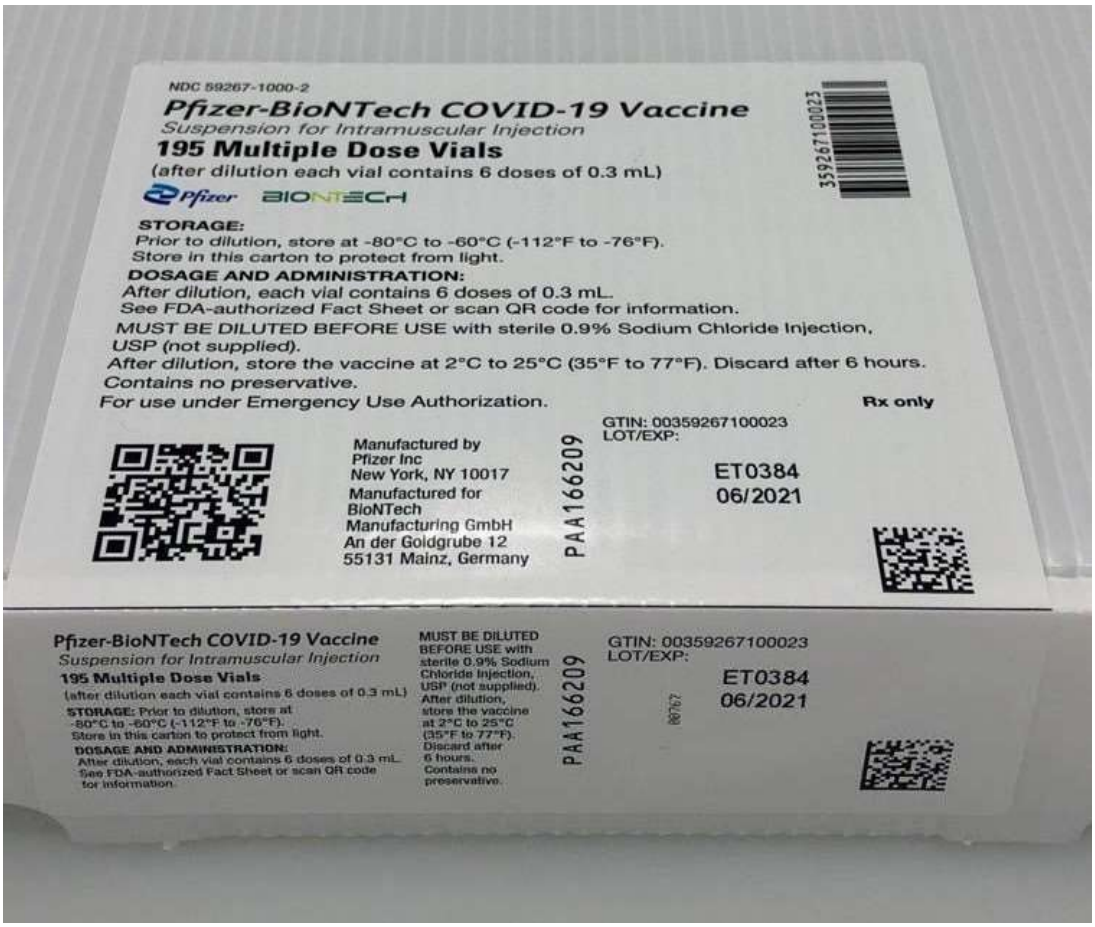
Appendix A – Updated vial and carton labels for Pfizer-BioNTech COVID-19 Vaccine with English-only labelling

Vial



Pfizer-BioNTech COVID-19 Vaccine
After dilution, vial contains 6 doses of 0.3 mL
For intramuscular use. Contains no preservative.
For use under Emergency Use Authorization.
DILUTE BEFORE USE. Discard 6 hours after dilution when stored at 2 to 25°C (35 to 77°F).
Dilution date and time:

Carton



Main Panel

Pfizer-BioNTech COVID-19 Vaccine
Suspension for Intramuscular Injection

195 Multiple Dose Vials
(after dilution each vial contains 6 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 6 doses of 0.3 mL
See FDA-authorized Fact Sheet or scan QR code for information.
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 after 6 hours.
Contains no preservative.
For use under Emergency Use Authorization.

Manufactured by
Pfizer Inc
New York, NY 10017
Manufactured for
BioNTech
Manufacturing GmbH
An der Goldgrube 12
55131 Manz, Germany

MADE IN GERMANY

Side Panel

Pfizer-BioNTech COVID-19 Vaccine
Suspension for Intramuscular Injection
195 Multiple Dose Vials
(after dilution each vial contains 6 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 6 doses of 0.3 mL
See FDA-authorized Fact Sheet or scan QR code for information.

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 after 6 hours.
Contains no preservative.