

Important Safety Information on Pfizer-BioNTech COVID-19 Vaccine: Updated Storage and Transportation Conditions



2021/03/08

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) is being updated to reflect:**
 - **alternative and more flexible storage and/or transportation conditions of the frozen vials; and**
 - **transportation conditions of the thawed undiluted vials.**
- **Pfizer-BioNTech has provided stability data to support the storage and/or transport of the Pfizer-BioNTech COVID-19 Vaccine at -25°C to -15°C for **up to 2 weeks**. Vials stored/transported at -25°C to -15°C for up to 2 weeks may be returned (**once**) to the recommended storage condition of -80°C to -60°C.**
- **Pfizer-BioNTech has also provided stability data to support transportation of thawed undiluted vials at 2°C to 8°C for **up to 12 hours**. Thawed undiluted vials should be stored at 2°C to 8°C for no more than 120 hours (5 days). **Any hours used for transport at 2°C to 8°C count against the 120-hour limit.****
- **The review of data provided by Pfizer-BioNTech confirms the maintenance of the vaccine quality under these new storage and transportation conditions.**
- **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](https://www.covid-vaccine.canada.ca) website or at [pfizer.ca](https://www.pfizer.ca) and [CVDvaccine.ca](https://www.CVDvaccine.ca), should be used for complete storage, stability, and transportation as well as other product information.**

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, Pfizer-BioNTech has submitted data to Health Canada to support alternative temperature for transportation and storage conditions.

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 prior to use, the vaccine should only be stored/transported in an ultra-low temperature freezer between -80°C to -60°C. Based on updated information, vials may also be stored/transported at -25°C to -15°C for a period of **up to 2 weeks**. Vials must be kept frozen and protected from light, in the original cartons, until ready to use. Vials stored/transported at -25°C to -15°C for **up to 2 weeks** may be returned **once** to the recommended storage condition of -80°C to -60°C.

In addition, available updated data support transportation of thawed undiluted vials at 2°C to 8°C for **up to 12 hours**. Thawed undiluted vials should be stored at 2°C to 8°C for no more than 120 hours (5 days). **Any hours used for transport at 2°C to 8°C count against the 120-hour limit for storage at 2°C to 8°C.**

Health Canada has authorized updates to the Pfizer-BioNTech COVID-19 Vaccine PM to reflect the new information.

Information for healthcare professionals

The Pfizer-BioNTech COVID-19 Vaccine PM is being updated to reflect more flexible storage and transportation conditions.

Healthcare professionals are advised that:

- **Frozen vials prior to use and transportation of frozen vials:**
 - Once received, vial cartons should be removed immediately from the thermal container and preferably stored in an ultra-low temperature freezer between -80°C to -60°C until the expiry date printed on the label.
 - Vials may also be stored and/or transported at -25°C to -15°C, for **up to 2 weeks**.

- Vials stored and/or transported at -25°C to -15°C for **up to 2 weeks**, may be returned **once** to the recommended storage condition of -80°C to -60°C.
- Total time the vials are stored and /or transported at -25°C to -15°C should be tracked and not exceed 2 weeks.
- Vials must be kept frozen and protected from light, in the original cartons, until ready to use.
- **Transportation of thawed undiluted vials:**
 - The thawed undiluted vials may be transported at 2°C to 8°C for **up to 12 hours**. Thawed undiluted vials should be stored at 2°C to 8°C for no more than 120 hours (5 days). **Any hours used for transport at 2°C to 8°C count against the 120-hour limit for storage at 2°C to 8°C.**
- The review of the data provided by Pfizer-BioNTech confirms the maintenance of the vaccine quality under these new storage and transportation conditions.
- 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](https://www.covid-vaccine.canada.ca) website or at [pfizer.ca](https://www.pfizer.ca) and [CVDvaccine.ca](https://www.CVDvaccine.ca), should be used for additional storage, stability, and transportation details as well as complete product information

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 update to the storage and transportation conditions has been implemented to facilitate storage requirements for vaccination sites. 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 worked with Pfizer Canada ULC to prepare this update 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 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: hc.brdd.dgo.enquiries.sc@canada.ca

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