

Please see the Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) including Full EUA Prescribing Information on important treatment considerations for the Pfizer-BioNTech COVID-19 Vaccine via the following link: <https://www.pfizermedicalinformation.com/en-us/pfizer-biontech-covid-19-vaccine>. In the event this link does not work, please access the product's approved Fact Sheet, including Prescribing Information, at www.pfizer.com. Note: select fact sheet or prescribing information is excerpted further in the document.

The Pfizer-BioNTech COVID-19 Vaccine has not been approved or licensed by FDA, but has been authorized for emergency use by FDA under an Emergency Use Authorization to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 16 years of age and older. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

This letter regarding the Pfizer-BioNTech COVID-19 Vaccine includes information that is inconsistent with the product uses described in the EUA Prescribing Information. Pfizer does not suggest or recommend the use of the vaccine in any manner other than as described in the EUA Prescribing Information.

TEMPERATURE EXCURSIONS

Pfizer has conducted stability studies to support **temporary inadvertent temperature excursions**.¹ Note that the data provided below are based on physical stability testing only; product stored outside the recommended temperature range was not tested or evaluated for clinical immunogenicity or efficacy.

This information is not intended to recommend storage of Pfizer-BioNTech COVID-19 Vaccine at temperatures other than those recommended in the EUA Prescribing Information. Pfizer does not suggest or recommend the use of Pfizer-BioNTech COVID-19 Vaccine that has been stored or handled outside of the approved recommendations as per the authorized EUA Prescribing Information.

Healthcare Professionals (HCPs) should consider these data, including its limitations, in determining whether Pfizer-BioNTech COVID-19 mRNA Vaccine exposed to temperatures outside of the recommended storage and handling conditions remains suitable for patient use. It is the responsibility of the vaccination provider to evaluate these data in the context of the actual temperature excursion and the duration of excursion that occurred. Pfizer is unable to make any treatment recommendations for individual patients.

Note that the stability information can be updated; therefore, we recommend that you contact Pfizer Medical Information following future temperature excursions from the recommended storage conditions to ensure you have the most up to date information on this topic.

TOPICS COVERED IN THIS DOCUMENT

1. [What are the recommended storage and handling requirements for the undiluted vials of Pfizer-BioNTech COVID-19 mRNA vaccine?](#)
2. [What data is available regarding the stability and viability of the undiluted vials following exposure to temperature excursions above -60°C? \(I.e. inadvertent storage in a non-ultra-low freezer, freezer malfunction, thermal container gets too warm, dry ice inadvertently runs out, etc.\)](#)
3. [What data is available for stability or viability of the undiluted vials when stored at temperatures lower than -60°C?](#)
4. [If I am unable to obtain dry ice, can I use liquid nitrogen instead?](#)

5. [Is there data to support the use of frozen vials that do not remain upright during storage and/or transportation?](#)
6. [How long does it take for the vaccine to thaw?](#)
7. [Is there data to support thawed vials that do not remain upright during storage and/or transportation?](#)
8. [What data is available for preparation of the thawed undiluted vials outside of the recommended method in the authorized EUA Prescribing Information? \(i.e. gently inverted <10 times or >10 times, shaken too vigorously, etc.\)](#)
9. [What data is available regarding the stability and viability of the vaccine if thawed undiluted vials have been stored under refrigeration \(2°C to 8°C\) for >5 days \(120 hours\)?](#)
10. [What data is available for the inadvertent storage of thawed undiluted vials at room temperatures \(up to 25°C\) for >2 hours?](#)

1. **WHAT ARE THE RECOMMENDED STORAGE AND HANDLING REQUIREMENTS FOR THE UNDILUTED VIALS OF PFIZER-BIONTECH COVID-19 VACCINE?**

Select Fact Sheet for Healthcare Providers Administering Vaccine

Dosage and Administration

Storage and Handling

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.²

Do not refreeze thawed vials.²

Frozen Vials Prior to Use

Cartons of Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vials arrive in thermal containers with dry ice. Once received, remove the vial cartons immediately from the thermal container and store in an ultra-low temperature freezer between -80°C to -60°C (-112°F to -76°F). Vials must be kept frozen between -80°C to -60°C (-112°F to -76°F) and protected from light until ready to use.²

If an ultra-low temperature freezer is not available, the thermal container in which the Pfizer-BioNTech COVID-19 Vaccine arrives may be used as temporary storage when consistently re-filled to the top of the container with dry ice. Refer to the re-icing guidelines packed in the original thermal container for instructions regarding the use of the thermal container for temporary storage. The thermal container maintains a temperature range of -90°C to -60°C (-130°F to -76°F). Storage of the vials between -96°C to -60°C (-141°F to -76°F) is not considered an excursion from the recommended storage condition.²

Thawed Vials Before Dilution

Thawed Under Refrigeration

Thaw and then store undiluted vials in the refrigerator [2°C to 8°C (35°F to 46°F)] for up to 5 days (120 hours). A carton of 25 vials or 195 vials may take up to 2 or 3 hours, respectively, to thaw in the refrigerator, whereas a fewer number of vials will thaw in less time.²

Transportation at 2°C to 8°C (35°F to 46°F)

If local redistribution is needed and full cartons containing vials cannot be transported at -90°C to -60°C (-130°F to -76°F), available data support transportation of one or more thawed vials at 2°C to 8°C (35°F to 46°F) for up to 12 hours. Any hours used for transport at 2°C to 8°C (35°F to 46°F) count against the 120-hour limit for storage at 2°C to 8°C (35°F to 46°F).²

Thawed at Room Temperature

For immediate use, thaw undiluted vials at room temperature [up to 25°C (77°F)] for 30 minutes. Thawed vials can be handled in room light conditions. Vials must reach room temperature before dilution.²

Undiluted vials may be stored at room temperature for no more than 2 hours.²

Dosing and Schedule

Dose Preparation

Prior to Dilution

- The Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vial contains a volume of 0.45 mL, supplied as a frozen suspension that does not contain preservative. Each vial must be thawed and diluted prior to administration.²
- Vials may be thawed in the refrigerator [2°C to 8°C (35°F to 46°F)] or at room temperature [up to 25°C (77°F)].²
- Refer to thawing instructions in the panels in the Fact Sheet for Healthcare Providers Administering Vaccine for further details.²

For further information regarding the authorized use under the Emergency Use Authorization (EUA), please refer to the Fact Sheet for Vaccination Providers Administering Vaccine or EUA Prescribing Information for the Pfizer-BioNTech COVID-19 Vaccine.

2. WHAT DATA IS AVAILABLE REGARDING THE STABILITY AND VIABILITY OF THE UNDILUTED VIALS FOLLOWING EXPOSURE TO TEMPERATURE EXCURSIONS ABOVE -60°C? (I.e. inadvertent storage in a non-ultra-low freezer, freezer malfunction, thermal container gets too warm, dry ice inadvertently runs out, etc.)

Select Fact Sheet for Healthcare Providers Administering Vaccine

Dosage and Administration

Storage and Handling

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.²

Do not refreeze thawed vials.²

Frozen Vials Prior to Use

Cartons of Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vials arrive in thermal containers with dry ice. Once received, remove the vial cartons immediately from the thermal container and store in an ultra-low temperature freezer between -80°C to -60°C (-112°F to -76°F). Vials must be kept frozen between -80°C to -60°C (-112°F to -76°F) and protected from light until ready to use.²

If an ultra-low temperature freezer is not available, the thermal container in which the Pfizer-BioNTech COVID-19 Vaccine arrives may be used as temporary storage when consistently re-filled to the top of the container with dry ice. Refer to the re-icing guidelines packed in the original thermal container for instructions regarding the use of the thermal container for temporary storage. The thermal container maintains a temperature range of -90°C to -60°C (-130°F to -76°F). Storage of the vials

between -96°C to -60°C (-141°F to -76°F) is not considered an excursion from the recommended storage condition.²

Thawed Vials Before Dilution

Thawed Under Refrigeration

Thaw and then store undiluted vials in the refrigerator [2°C to 8°C (35°F to 46°F)] for up to 5 days (120 hours). A carton of 25 vials or 195 vials may take up to 2 or 3 hours, respectively, to thaw in the refrigerator, whereas a fewer number of vials will thaw in less time.²

Transportation at 2°C to 8°C (35°F to 46°F)

If local redistribution is needed and full cartons containing vials cannot be transported at -90°C to -60°C (-130°F to -76°F), available data support transportation of one or more thawed vials at 2°C to 8°C (35°F to 46°F) for up to 12 hours. Any hours used for transport at 2°C to 8°C (35°F to 46°F) count against the 120-hour limit for storage at 2°C to 8°C (35°F to 46°F).²

Thawed at Room Temperature

For immediate use, thaw undiluted vials at room temperature [up to 25°C (77°F)] for 30 minutes. Thawed vials can be handled in room light conditions. Vials must reach room temperature before dilution.²

Undiluted vials may be stored at room temperature for no more than 2 hours.²

For further information regarding the authorized use under the Emergency Use Authorization (EUA), please refer to the Fact Sheet for Vaccination Providers Administering Vaccine or EUA Prescribing Information for the Pfizer-BioNTech COVID-19 Vaccine.

Internal Data

Pfizer released a press release on February 19, 2021 regarding the submission of new data to the US Food and Drug Administration (FDA) on the stability of Pfizer-BioNTech COVID-19 Vaccine when stored at -25°C to -15°C (-13°F to 5°F), temperatures more commonly found in pharmaceutical freezers and refrigerators.

The data have been submitted to the FDA to support a proposed update to the EUA Prescribing Information, which would allow for vaccine vials to be stored at -25°C to -15°C (-13°F to 5°F) for a total of two weeks as an alternative or complement to storage in an ultra-low temperature freezer.

This FDA submission includes stability data generated on batches manufactured over the past nine months of COVID-19 vaccine development, from the batches that supplied the earliest clinical trials through the commercial scale batches currently in production.

If approved by the US FDA, the option to store at -25°C to -15°C (-13°F to 5°F) for two weeks would be in addition to the five-day option to store at standard refrigerator temperature (2 - 8°C).

The full press release is available at: <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-submit-covid-19-vaccine-stability-data>

Pending potential FDA approval of this submission, storage at -25°C to -15°C (-13°F to 5°F) may be considered for temporary inadvertent temperature excursions. This new data supersedes any information regarding this temperature range discussed later in this document. Pfizer Medical Information is working to incorporate the totality of the new data into this document as quickly as possible. As noted above, we recommend that you contact Pfizer Medical Information following future temperature excursions from the recommended storage conditions to ensure you have the most up to date information on this topic.

The intended label storage condition for Pfizer-BioNTech COVID-19 Vaccine is 6 months at -75°C ± 15°C. Some vials distributed as part of initial launch supplies may be labeled with the

storage condition of $-70^{\circ}\text{C} \pm 10^{\circ}\text{C}$. The Product Labeling for these vials allows storage at $-75^{\circ}\text{C} \pm 15^{\circ}\text{C}$ without it being considered an excursion. Vials of Pfizer-BioNTech COVID-19 Vaccine are shipped in the Pfizer Thermal Shipper which maintains $-75^{\circ}\text{C} \pm 15^{\circ}\text{C}$. The Pfizer Thermal Shipper can also be used as a storage container when refilled with dry ice and monitored per the guide included with the shipper.¹

Pfizer has evaluated the stability of Pfizer-BioNTech COVID-19 Vaccine by exposing the frozen vaccine to various temperatures **above -60°C** . These studies mimic the conditions that the vaccine may be exposed to during temporary cumulative elevated temperature excursions (excursion time in addition to the recommended storage conditions), such as freezer malfunction or issues related to dry ice not maintaining a thermal shipper at a temperature **above -60°C** . Based on temperature stability studies, the product was tested and shown to maintain all its measured quality attributes under the following cumulative in-use conditions:¹

- 48 hours at **-60°C to -15°C**
- *See below for temperatures above **-15°C to 0°C**
- 24 hours at **0°C to 8°C**
- 2 hours at **8°C to 30°C**

Please also refer to information provided in [boxed area](#).

For easier reference, the results of the stability studies are also provided in table format:¹

Temperature Conditions	-60°C to -15°C	-15°C to 0°C	0°C to 2°C	2°C to 8°C	8°C to 30°C
CUMULATIVE EXCURSION TIME for Point-Of-Use (time in addition to the routine allowance)	48 hours	Considered a Freeze/Thaw (No more than 1 hour per Freeze/thaw)	24 hours		2 hours
Point-Of-Use ROUTINE/LABELLED Handling Allowances for Undiluted Vials	Frozen trays at Room Temperature ($\leq 25^{\circ}\text{C}$) (for each removal from frozen storage, no more than 5 minutes for closed full trays, no more than 3 minutes for open trays)	Considered a thaw and vials cannot be refrozen	none	120 hours (including 12 hours of transport time)	2 hours

*The temperature stability studies have shown that if the vaccine has been exposed to temperatures above -15°C to 0°C for up to 60 minutes and then refrozen, this should be treated as a **freeze/thaw excursion**. If the maximum number of **freeze/thaw excursions** has been reached, or the vaccine is within this temperature range for > 60 minutes, it should be placed at $2-8^{\circ}\text{C}$ for use and not refrozen.¹

Storage at temperatures $< -15^{\circ}\text{C}$ are not considered a **freeze/thaw excursion**. Refer to storage condition excursion data above for time limits.¹

Pfizer has not conducted stability studies for exposure of the vaccine to temperatures $> 30^{\circ}\text{C} \pm 2^{\circ}\text{C}$.¹

Closed-lid vial trays containing 195 vials removed from frozen storage (less than -60°C) may be at room temperature ($\leq 25^{\circ}\text{C}$) for up to 5 minutes for transfer between ultra-low temperature environments.¹

Open-lid vial trays, or vials trays containing less than 195 vials removed from frozen storage (less than -60°C) may be at room temperature ($\leq 25^{\circ}\text{C}$) for up to 3 minutes for transfer between ultra-low temperature environments or to remove vials for thawing or use.¹

After vial trays are returned to frozen storage following room temperature exposure, they must remain in frozen storage for at least 2 hours before they can be removed again.¹

If visual inspection of a vial confirms thawing has occurred, then it must be considered a **freeze/thaw excursion**. If the temperature was not monitored during the excursion and/or the time of exposure is not known, it must be considered a **freeze/thaw excursion**.¹ Removal of individual frozen vials from a vial tray should be considered a **freeze/thaw excursion** if removed for longer than 30 seconds.¹

One **freeze/thaw excursion** is acceptable for the point of use. If the maximum number of **freeze/thaw excursions** has been reached, it should be placed at 2-8°C for use and not refrozen. If the point of use has access to the Shipment Quality Report and can confirm that the product did not go through a **freeze/thaw excursion** during transportation (i.e. reports as “no excursion”), it is acceptable to have a second **freeze/thaw excursion** at the point of use.¹

3. WHAT DATA IS AVAILABLE FOR STABILITY OR VIABILITY OF THE UNDILUTED VIALS WHEN STORED AT TEMPERATURES LOWER THAN -60°C?

Select Fact Sheet for Healthcare Providers Administering Vaccine

Dosage and Administration

Storage and Handling

Frozen Vials Prior to Use

Cartons of Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vials arrive in thermal containers with dry ice. Once received, remove the vial cartons immediately from the thermal container and store in an ultra-low temperature freezer between -80°C to -60°C (-112°F to -76°F). Vials must be kept frozen between -80°C to -60°C (-112°F to -76°F) and protected from light until ready to use.²

If an ultra-low temperature freezer is not available, the thermal container in which the Pfizer-BioNTech COVID-19 Vaccine arrives may be used as temporary storage when consistently re-filled to the top of the container with dry ice. Refer to the re-icing guidelines packed in the original thermal container for instructions regarding the use of the thermal container for temporary storage. The thermal container maintains a temperature range of -90°C to -60°C (-130°F to -76°F). Storage of the vials between -96°C to -60°C (-141°F to -76°F) is not considered an excursion from the recommended storage condition.²

For further information regarding the authorized use under the Emergency Use Authorization (EUA), please refer to the Fact Sheet for Vaccination Providers Administering Vaccine or EUA Prescribing Information for the Pfizer-BioNTech COVID-19 Vaccine.

Internal Data

Pfizer has determined that no instability is expected at temperatures colder than -60°C. Stability data from the labeled storage condition may be applied to excursions below -90°C. Integrity of the vial/stopper container closure is assured up to -97°C.¹

For easier reference, the results of the stability studies are also provided in table format:¹

Temperature Conditions	-90°C to -60°C
CUMULATIVE EXCURSION TIME for Point-Of-Use (time in addition to the routine allowance)	Routine allowance can be applied to storage down to -97°C
Point-Of-Use ROUTINE/LABELLED Handling Allowances for Undiluted Vials	6 months; storage of the vials between -96°C to -60°C (-141°F to -76°F) is not considered an excursion from the recommended storage condition. ²

4. IF I AM UNABLE TO OBTAIN DRY ICE, CAN I USE LIQUID NITROGEN INSTEAD?

Storage in liquid nitrogen is not supported. The temperature of liquid nitrogen is well below the recommended storage condition and the container closure of the vial may be compromised if stored at those temperatures.¹

5. IS THERE DATA TO SUPPORT THE USE OF FROZEN VIALS THAT DO NOT REMAIN UPRIGHT DURING STORAGE AND/OR TRANSPORTATION?

Internal Data

Frozen vials should be stored upright whenever possible. It is understood the vials may roll around in the trays when being moved in and out of frozen storage. Caution should be taken while handling frozen vial trays to avoid damage to vials. It is recommended that, whenever possible, frozen vials are transported in unopened, full cartons. During transportation, frozen vials that are unsecured could become damaged.¹

6. HOW LONG DOES IT TAKE FOR THE VACCINE TO THAW?

Select Fact Sheet for Healthcare Providers Administering Vaccine

Dosage and Administration

Storage and Handling

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.²

Do not refreeze thawed vials.²

Thawed Vials Before Dilution

Thawed Under Refrigeration

Thaw and then store undiluted vials in the refrigerator [2°C to 8°C (35°F to 46°F)] for up to 5 days (120 hours). A carton of 25 vials or 195 vials may take up to 2 or 3 hours, respectively, to thaw in the refrigerator, whereas a fewer number of vials will thaw in less time.²

Transportation at 2°C to 8°C (35°F to 46°F)

If local redistribution is needed and full cartons containing vials cannot be transported at -90°C to -60°C (-130°F to -76°F), available data support transportation of one or more thawed vials at 2°C to 8°C (35°F to 46°F) for up to 12 hours. Any hours used for transport at 2°C to 8°C (35°F to 46°F) count against the 120-hour limit for storage at 2°C to 8°C (35°F to 46°F).²

Thawed at Room Temperature

For immediate use, thaw undiluted vials at room temperature [up to 25°C (77°F)] for 30 minutes. Thawed vials can be handled in room light conditions. Vials must reach room temperature before dilution.²

Undiluted vials may be stored at room temperature for no more than 2 hours.²

For further information regarding the authorized use under the Emergency Use Authorization (EUA), please refer to the Fact Sheet for Vaccination Providers Administering Vaccine or EUA Prescribing Information for the Pfizer-BioNTech COVID-19 Vaccine.

Internal Data

Pfizer-BioNTech COVID-19 Vaccine must be thawed before use. It is recommended to thaw in the refrigerator (2-8°C). It will take about 3 hours for an entire 195 count tray to thaw in the refrigerator. A smaller number of vials, or those spaced apart, will thaw more quickly. Vials needed for immediate use can be thawed at room temperature. They will typically thaw in less than 10 minutes, but it is recommended to wait approximately 30 minutes to ensure complete thawing. Vials thawed at room temperature may be returned to the refrigerator for storage if necessary, but total time at room temperature must be tracked to ensure the vial stays within the 2 hours at room temperature limit. It is also recommended to allow vials to come to room temp (not cold to touch) prior to dilution to ensure thawing is complete. No impact to vaccine stability is anticipated if diluent is added to a vial with a small amount of undetected unthawed product remaining. No data is available if diluent is added directly into a vial of frozen vaccine.¹

7. IS THERE DATA TO SUPPORT THAWED VIALS THAT DO NOT REMAIN UPRIGHT DURING STORAGE AND/OR TRANSPORTATION?

Select Fact Sheet for Healthcare Providers Administering Vaccine

After thawing and before dilution, invert the vial **gently** 10 times. Do not shake.²

If local redistribution is needed and full cartons containing vials cannot be transported at -90°C to -60°C (130°F to 76°F), available data support transportation of one or more thawed vials at 2°C to 8°C (35°F to 46°F) for up to 12 hours. Any hours used for transport at 2°C to 8°C (35°F to 46°F) count against the 120 hour limit for storage at 2°C to 8°C (35°F to 46°F).²

For further information regarding the authorized use under the Emergency Use Authorization (EUA), please refer to the Fact Sheet for Vaccination Providers Administering Vaccine or EUA Prescribing Information for the Pfizer-BioNTech COVID-19 Vaccine.

Internal Data

Thawed vials should be kept upright during refrigerated storage. An appropriate container should be used to minimize the potential for vials to be jostled. If vials are inadvertently bumped, they should be righted, however the risk to the product is minimal and vials which are temporarily knocked over may still be used. Thawed vials should be securely packed when transported.¹

8. WHAT DATA IS AVAILABLE FOR PREPARATION OF THE THAWED UNDILUTED VIALS OUTSIDE OF THE RECOMMENDED METHOD IN THE AUTHORIZED EUA PRESCRIBING INFORMATION? (i.e. gently inverted <10 times or >10 times, shaken too vigorously, etc.)

Select Fact Sheet for Healthcare Providers Administering Vaccine

After thawing and before dilution, invert the vial **gently** 10 times. Do not shake.²
After dilution, **gently** invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix. Do not shake.

The EUA Prescribing Information does not include any data on the use of Pfizer-BioNTech COVID-19 Vaccine when prepared in any manner other than as recommended.²

For further information regarding the authorized use under the Emergency Use Authorization (EUA), please refer to the Fact Sheet for Vaccination Providers Administering Vaccine or EUA Prescribing Information for the Pfizer-BioNTech COVID-19 Vaccine.

Internal Data

Vials should be mixed before and after dilution by gentle inversion. No studies have been done to evaluate shaking of vials during preparation, but the results of the transportation study support the conclusion that the vaccine can be exposed to some shaking stress. Without additional data though, vaccine vials which are aggressively shaken should be discarded. Studies have been conducted demonstrating that the solution is fully mixed after at least 2 inversions prior to dilution, and 2 inversions after dilution. Vials that have not been gently inverted 2 times should be remixed by gently inverting to ensure they are fully mixed. Vials gently inverted for more than 10 times are safe to use.¹

9. **WHAT DATA IS AVAILABLE REGARDING THE STABILITY AND VIABILITY OF THE VACCINE IF THAWED UNDILUTED VIALS HAVE BEEN STORED UNDER REFRIGERATION (2°C TO 8°C) FOR >5 DAYS (120 HOURS)?**

Select Fact Sheet for Healthcare Providers Administering Vaccine

Dosage and Administration

Storage and Handling

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.²

Do not refreeze thawed vials.²

Thawed Vials Before Dilution

Thawed Under Refrigeration

Thaw and then store undiluted vials in the refrigerator [2°C to 8°C (35°F to 46°F)] for up to 5 days (120 hours). A carton of 25 vials or 195 vials may take up to 2 or 3 hours, respectively, to thaw in the refrigerator, whereas a fewer number of vials will thaw in less time.²

Transportation at 2°C to 8°C (35°F to 46°F)

If local redistribution is needed and full cartons containing vials cannot be transported at -90°C to -60°C (-130°F to -76°F), available data support transportation of one or more thawed vials at 2°C to 8°C (35°F to 46°F) for up to 12 hours. Any hours used for transport at 2°C to 8°C (35°F to 46°F) count against the 120-hour limit for storage at 2°C to 8°C (35°F to 46°F).²

Thawed at Room Temperature

For immediate use, thaw undiluted vials at room temperature [up to 25°C (77°F)] for 30 minutes. Thawed vials can be handled in room light conditions. Vials must reach room temperature before dilution.²

Undiluted vials may be stored at room temperature for no more than 2 hours.²

The EUA Prescribing Information does not include any data on the stability and viability of the vaccine if thawed undiluted vials have been stored under refrigeration (2°C to 8°C) for >5 days.²

For further information regarding the authorized use under the Emergency Use Authorization (EUA), please refer to the Fact Sheet for Vaccination Providers Administering Vaccine or EUA Prescribing Information for the Pfizer-BioNTech COVID-19 Vaccine.

Internal Data

Pfizer has evaluated the stability of undiluted COVID-19 mRNA Vaccine BNT162b2 by exposing the **undiluted vaccine to 2°C to 8°C for >5 days (120 hours)**. Based on temperature stability studies, the undiluted vaccine was tested and shown to maintain all its measured quality attributes under the

following cumulative in-use conditions (excursion time in addition to the recommended storage conditions):¹

- 24 hours at 2°C to 8°C

For easier reference, the results of the stability studies are also provided in table format:¹

Temperature Conditions	2°C to 8°C
CUMULATIVE EXCURSION TIME for Point-Of-Use (time in addition to the routine allowance)	24 hours
Point-Of-Use ROUTINE/LABELLED Handling Allowances for Undiluted Vials	120 hours (including 12 hours of transport time)

10. WHAT DATA IS AVAILABLE FOR THE INADVERTENT STORAGE OF THAWED UNDILUTED VIALS AT ROOM TEMPERATURES (UP TO 25°C) FOR >2 HOURS?

Select Fact Sheet for Healthcare Providers Administering Vaccine

Dosage and Administration

Storage and Handling

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.²

Do not refreeze thawed vials.²

Thawed Vials Before Dilution

Thawed Under Refrigeration

Thaw and then store undiluted vials in the refrigerator [2°C to 8°C (35°F to 46°F)] for up to 5 days (120 hours). A carton of 25 vials or 195 vials may take up to 2 or 3 hours, respectively, to thaw in the refrigerator, whereas a fewer number of vials will thaw in less time.²

Transportation at 2°C to 8°C (35°F to 46°F)

If local redistribution is needed and full cartons containing vials cannot be transported at -90°C to -60°C (-130°F to -76°F), available data support transportation of one or more thawed vials at 2°C to 8°C (35°F to 46°F) for up to 12 hours. Any hours used for transport at 2°C to 8°C (35°F to 46°F) count against the 120-hour limit for storage at 2°C to 8°C (35°F to 46°F).²

Thawed at Room Temperature

For immediate use, thaw undiluted vials at room temperature [up to 25°C (77°F)] for 30 minutes. Thawed vials can be handled in room light conditions. Vials must reach room temperature before dilution.²

Undiluted vials may be stored at room temperature for no more than 2 hours.²

The EUA Prescribing Information does not include any data on the stability and viability of the vaccine if thawed undiluted vials have been stored at room temperatures (up to 25°C) for >2 hours.²

For further information regarding the authorized use under the Emergency Use Authorization (EUA), please refer to the Fact Sheet for Vaccination Providers Administering Vaccine or EUA Prescribing Information for the Pfizer-BioNTech COVID-19 Vaccine.

Internal Data

Pfizer has evaluated the stability of undiluted Pfizer-BioNTech COVID-19 Vaccine by exposing the undiluted vaccine to various temperatures for different timepoints. Based on temperature stability studies, the undiluted vaccine was tested and shown to maintain all its measured quality attributes under the following cumulative in-use conditions (excursion time in addition to the recommended storage conditions):¹

- 2 hours at 8°C to 30°C

For easier reference, the results of the stability studies are also provided in table format:¹

Temperature Conditions	8°C to 30°C
CUMULATIVE EXCURSION TIME for Point-Of-Use (time in addition to the routine allowance)	2 hours
Point-Of-Use ROUTINE/LABELLED Handling Allowances for Undiluted Vials	2 hours

REFERENCES

1. Pfizer-BioNTech COVID-19 Vaccine. Data on file (28). Pfizer.
2. Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccines including the Full EUA Prescribing Information. Pfizer/BioNTech.