

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](http://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 **inadvertent temporary temperature excursions**.<sup>1</sup> 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 EUA Prescribing Information.**

Healthcare Professionals (HCPs) should consider these data, including the limitations, in determining whether Pfizer-BioNTech COVID-19 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.

The expiry date on the product packaging label reflects the shelf-life of the product when stored in accordance with the product labelling recommendations. Pfizer cannot make any claims as to the shelf life of the product subjected to storage conditions outside of those recommended in the product labelling.

Please take note product specifications and manufacturing standards may change over time. As such, previously provided information may require updating.

## TOPICS COVERED IN THIS DOCUMENT

- [WHAT ARE THE RECOMMENDED STORAGE AND HANDLING REQUIREMENTS FOR PFIZER-BIONTECH COVID-19 VACCINE DURING AND AFTER DILUTION?](#)
- [IS THE PERIOD OF TIME IT TAKES TO THAW THE VACCINE AT ROOM TEMPERATURE OR IN THE REFRIGERATOR INCLUDED IN THE TIME ALLOWED AFTER DILUTION \(I.E. WHEN DOES THE TIMEFRAME START\)?](#)
- [WHAT DATA IS AVAILABLE FOR THE PREPARATION OF THE VIALS OUTSIDE OF THE RECOMMENDED METHOD IN THE EUA PRESCRIBING INFORMATION? \(i.e. gently inverted <10 times or >10 times, shaken too vigorously, etc.\)](#)

- [CAN A DILUENT OTHER THAN 0.9% SODIUM CHLORIDE INJECTION, USP \(SUCH AS STERILE WATER FOR INJECTION, D5W, ETC.\) BE USED TO DILUTE THE VACCINE?](#)
- [IS THERE ANY DATA FOR USE OF A DILUTION VOLUME OTHER THAN 1.8 ML?](#)
- [IS THERE ANY DATA FOR ADDING THE DILUENT TO THE VIAL BEFORE THE VACCINE IS FULLY THAWED?](#)
- [WHY IS A 21 GAUGE OR NARROWER NEEDLE RECOMMENDED TO BE USED WHEN ADDING THE DILUENT? CAN I USE A LARGER GAUGE NEEDLE?](#)
- [WHAT DOES THE SPRAY CONTAIN THAT CAN RESULT IF I FORGET TO WITHDRAW AIR PRIOR TO REMOVING THE DILUENT NEEDLE FROM THE VIAL? DOES IT IMPACT THE DOSE?](#)
- [WHAT DATA IS AVAILABLE FOR VIALS OR DOSING SYRINGES CONTAINING DILUTED VACCINE STORED BETWEEN 2 TO 25°C FOR >6 HOURS FROM THE POINT OF DILUTION?](#)
- [WHAT DATA ARE AVAILABLE TO SUPPORT THE USE OF A VIAL ADAPTER OR A VIAL ACCESS DEVICE?](#)
- [IS THERE DATA FOR THE STERILITY/STABILITY AND TIMEFRAME FOLLOWING REMOVAL OF THE FLIP-OFF CAP WITH AN INTACT ALUMINUM OVERSEAL \(UNPUNCTURED\)?](#)
- [WHAT ARE THE RECOMMENDED STORAGE AND HANDLING REQUIREMENTS FOR PFIZER-BIONTECH COVID-19 VACCINE PRIOR TO ADMINISTRATION?](#)
- [WHAT DATA IS AVAILABLE FOR INADVERTENT ADMINISTRATION OF VACCINE WITH PARTICULATES OR DISCOLORATION?](#)
- [CAN A FILTER BE USED DURING THE DILUTION, PREPARATION OR ADMINISTRATION OF THE VACCINE?](#)

## **WHAT ARE THE RECOMMENDED STORAGE AND HANDLING REQUIREMENTS FOR PFIZER-BIONTECH COVID-19 VACCINE DURING AND AFTER DILUTION?**

### **Select EUA Prescribing Information**

#### **Preparation for Administration**

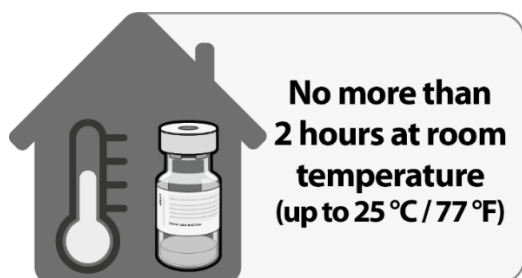
##### Prior to Dilution

- The Pfizer BioNTech COVID-19 Vaccine Multiple Dose Vial contains a frozen suspension that does not contain preservative and must be thawed and diluted prior to administration.
- 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)]
- Refer to thawing instructions in the panels below.<sup>2</sup>

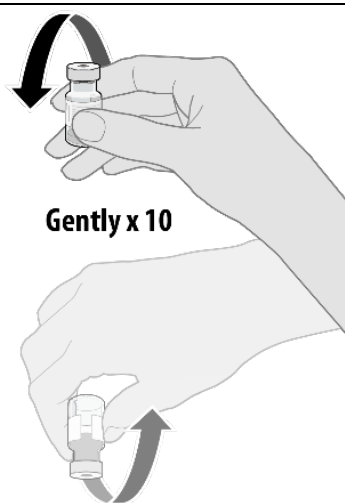
##### Dilution

- Dilute the vial contents using 1.8 mL of 0.9% Sodium Chloride Injection, USP (not provided) to form the Pfizer-BioNTech COVID-19 Vaccine.
- ONLY use 0.9% Sodium Chloride Injection, USP as the diluent. This diluent is not packaged with the vaccine and must be sourced separately. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.
- Refer to dilution and dose preparation instructions in the panels below.<sup>2</sup>

## THAWING PRIOR TO DILUTION<sup>2</sup>

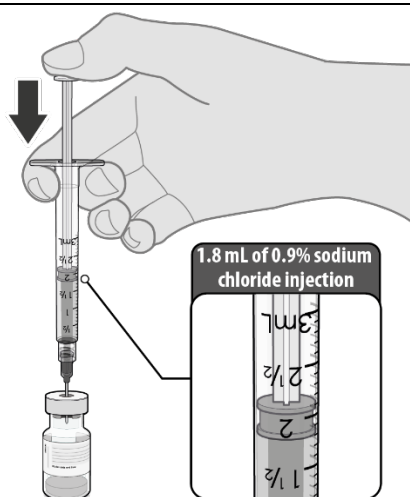


- Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by:
  - Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)]. A carton of vials may take up to 3 hours to thaw, and thawed vials can be stored in the refrigerator for up to five days (120 hours).
  - Allowing vial(s) to sit at room temperature [up to 25°C (77°F)] for 30 minutes.
- Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours.

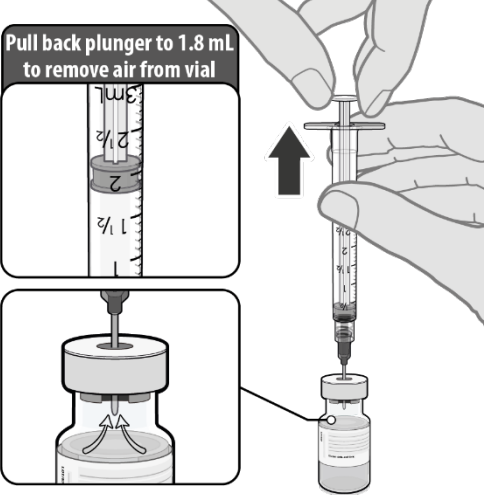
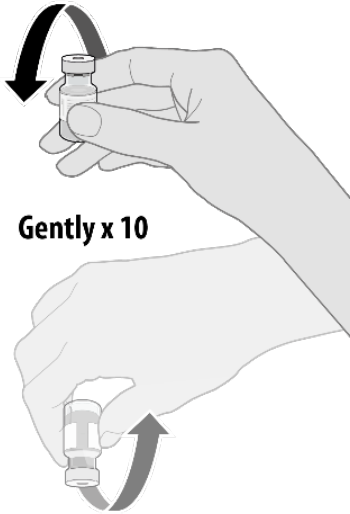
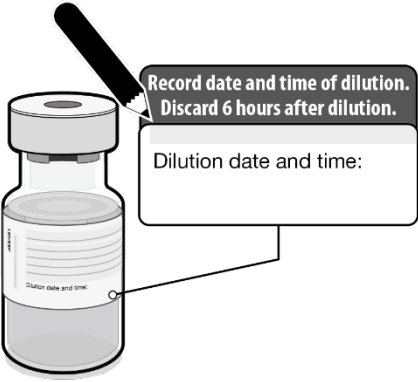


- Before dilution invert vaccine vial gently 10 times.
- Do not shake.
- Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles.
- Do not use if liquid is discolored or if other particles are observed.

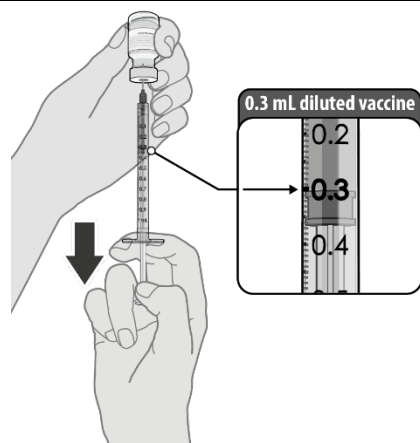
## DILUTION<sup>2</sup>



- Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent.
- Using aseptic technique, withdraw 1.8 mL of diluent into a transfer syringe (21-gauge or narrower needle).
- Cleanse the vaccine vial stopper with a single-use antiseptic swab.
- Add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.

 <p>Pull back plunger to 1.8 mL to remove air from vial</p> <p>The diagram illustrates the process of drawing air into a syringe. On the left, a syringe is shown with the plunger pulled back to the 1.8 mL mark. An arrow points to the right, where the syringe is inserted into a vial. Below this, the syringe is shown drawing air from the vial. To the right, a hand is shown holding the syringe and drawing air into it.</p>	<ul style="list-style-type: none"><li>• Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe.</li></ul>
 <p>Gently x 10</p> <p>The diagram shows a hand holding a vial and gently inverting it. A curved arrow indicates the motion of the vial being turned over. The text 'Gently x 10' is written below the hand.</p>	<ul style="list-style-type: none"><li>• Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix.</li><li>• <u>Do not shake.</u></li><li>• Inspect the vaccine in the vial.</li><li>• The vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains particulate matter.</li></ul>
 <p>Record date and time of dilution. Discard 6 hours after dilution.</p> <p>Dilution date and time:</p> <p>The diagram shows a vial with a label that has a space for 'Dilution date and time:'. A speech bubble points to the label with the text 'Record date and time of dilution. Discard 6 hours after dilution.' The vial is shown with a syringe needle inserted into the stopper.</p>	<ul style="list-style-type: none"><li>• Record the date and time of dilution on the Pfizer-BioNTech COVID-19 Vaccine vial label.</li><li>• Store between 2°C to 25°C (35°F to 77°F).</li><li>• Discard any unused vaccine 6 hours after dilution.</li></ul>

## PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF PFIZER-BIONTECH COVID-19 VACCINE<sup>2</sup>



- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.3 mL of the Pfizer-BioNTech COVID-19 Vaccine.
- Administer immediately.

### Administration Information

Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be an off-white suspension. During the visual inspection,

- verify the final dosing volume of 0.3 mL.
- confirm there are no particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains particulate matter.<sup>2</sup>

Administer the Pfizer-BioNTech COVID-19 Vaccine intramuscularly.<sup>2</sup>

### Storage and Handling

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.<sup>2</sup>

Do not refreeze thawed vials.<sup>2</sup>

#### 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.<sup>2</sup>

##### **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.<sup>2</sup>

Vials must reach room temperature before dilution.<sup>2</sup>

Undiluted vials may be stored at room temperature for no more than 2 hours.<sup>2</sup>

#### Vials After Dilution

After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Any vaccine remaining in vials must be discarded after 6 hours. Do not refreeze.<sup>2</sup>

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.

## **IS THE PERIOD OF TIME IT TAKES TO THAW THE VACCINE AT ROOM TEMPERATURE OR IN THE REFRIGERATOR INCLUDED IN THE TIME ALLOWED AFTER DILUTION (I.E. WHEN DOES THE TIMEFRAME START)?**

### **Select EUA Prescribing Information**

#### **Storage and Handling**

##### 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.<sup>2</sup>

###### **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.<sup>2</sup>

Vials must reach room temperature before dilution.<sup>2</sup>

Undiluted vials may be stored at room temperature for no more than 2 hours.<sup>2</sup>

##### Vials After Dilution

After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Any vaccine remaining in vials must be discarded after 6 hours. Do not refreeze.<sup>2</sup>

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.

Vials thawed at room temperature must be diluted within 2 hours. The allowable 2 hours at room temperature timeframe prior to dilution starts when the vials are removed from the refrigerator or freezer. The allowable time in the refrigerator (5 days or 120 hours), starts when the vaccine is removed from storage under ultra-low temperatures. From the point of dilution, the vaccine may be stored at 2 to 30°C for up to 6 hours.<sup>1</sup>

**WHAT DATA IS AVAILABLE FOR THE PREPARATION OF THE VIALS OUTSIDE OF THE RECOMMENDED METHOD IN THE FACT SHEET? (i.e, gently inverted <10 times or >10 times, shaken too vigorously, etc.)**

The EUA Prescribing Information states that after thawing and before dilution, invert the vials **gently** 10 times. Also, after dilution the EUA Prescribing Information states to **gently** invert the diluted vial 10 times to mix. Do not shake.<sup>2</sup>

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.<sup>2</sup>

Pfizer has conducted a transportation study to mimic the conditions that the vaccine may be exposed to during temporary elevated temperature excursions, such as transportation from a central site to a vaccination site. The study exposed thawed vials to shaking and vibration profiles anticipated during ground transportation. The product was tested and shown to maintain all its measured quality attributes at 2°C to 8°C for up to 12 hours of simulated ground transportation.<sup>1</sup>

Vials should be mixed before and after dilution by gentle inversion. No studies have been conducted to evaluate shaking of vials during vaccine preparation, but the results of the transportation study support the conclusion that the vaccine can be exposed to some shaking stress. Without additional data, vaccine vials which are aggressively shaken should be discarded.<sup>1</sup>

Studies have not been conducted regarding the effect of mixing by gently inverting the vials for <10 times or >10 times. However, vials that have not been gently inverted 10 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.<sup>1</sup>

**CAN A DILUENT OTHER THAN 0.9% SODIUM CHLORIDE INJECTION, USP (SUCH AS STERILE WATER FOR INJECTION, D5W, ETC.) BE USED TO DILUTE THE VACCINE?**

As stated in the EUA Prescribing Information, dilute the vial contents using 1.8 mL of 0.9% Sodium Chloride Injection, USP (not provided) to form the Pfizer-BioNTech COVID-19 Vaccine. ONLY use 0.9% Sodium Chloride Injection, USP as the diluent. This diluent is not packaged with the vaccine and must be sourced separately. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent. Using aseptic technique, withdraw 1.8 mL of diluent into a transfer syringe (21-gauge or narrower needle). Cleanse the vaccine vial stopper with a single-use antiseptic swab. Add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.<sup>2</sup>

Pfizer has not investigated the use of any other solution to dilute the vaccine. Vials that have been diluted with any diluent other than sterile 0.9% Sodium Chloride Injection should not be used and should be discarded.<sup>1</sup>

**IS THERE ANY DATA FOR USE OF A DILUTION VOLUME OTHER THAN 1.8 ML?**

As stated in the EUA Prescribing Information, the Pfizer BioNTech COVID-19 Vaccine Multiple Dose Vial contains a frozen suspension that does not contain preservative and must be thawed and diluted prior to administration. Dilute the vial contents using 1.8 mL of 0.9% Sodium Chloride Injection, USP (not provided) to form the Pfizer-BioNTech COVID-19 Vaccine.<sup>2</sup>

The EAU Prescribing Information does not include any data on the stability and viability of the vaccine if a volume other than 1.8 mL is used to prepare the vaccine.<sup>2</sup>

Alternate dilution volumes may impact the dose. A 1.5 mL dilution would result in a 34.6 microgram dose per injection, and there will not be enough volume in the vial to withdraw the fifth dose. A 2 mL dilution would result in a 28 microgram dose per injection. Dilutions between 1.5 and 2 mL are not expected to impact efficacy. Vials that have been diluted with any other diluent volume should not be used and should be discarded.<sup>1</sup>

## **IS THERE ANY DATA FOR ADDING THE DILUENT TO THE VIAL BEFORE THE VACCINE IS FULLY THAWED?**

### **Select EAU Prescribing Information**

#### **Storage and Handling**

##### 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.<sup>2</sup>

###### **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.<sup>2</sup>

Vials must reach room temperature before dilution.<sup>2</sup>

Undiluted vials may be stored at room temperature for no more than 2 hours.<sup>2</sup>

Do not refreeze thawed vials.<sup>2</sup>

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.

Pfizer BioNTech COVID-19 Vaccine must be thawed before use. It is recommended to thaw in the refrigerator (2°C to 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.<sup>1</sup> Vials diluted by adding the diluent directly into vials of frozen vaccine should not be used and should be discarded.

## **WHY IS A 21 GAUGE OR NARROWER NEEDLE RECOMMENDED TO BE USED WHEN ADDING THE DILUENT? CAN I USE A LARGER GAUGE NEEDLE?**

As stated in the EUA Prescribing Information, dilute the vial contents using 1.8 mL of 0.9% Sodium Chloride Injection, USP (not provided) to form the Pfizer-BioNTech COVID-19 Vaccine. ONLY use 0.9% Sodium Chloride Injection, USP as the diluent. This diluent is not packaged with the vaccine and must be sourced separately. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent. Using aseptic technique, withdraw 1.8 mL of diluent into a transfer syringe (21-gauge or narrower needle). Cleanse the vaccine vial stopper with a single-use antiseptic swab. Add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.<sup>2</sup>

A 21 gauge or narrower needle must be used to add the diluent. Use of a larger needle does not harm the vaccine but may result in leaking from the stopper when doses are withdrawn. Stoppers meet USP<381>, ISO 8871-5, and Ph Eur 3.2.9 requirements for functional testing of the stopper (penetrability, fragmentation, and self-sealing capacity) when punctured up to 10 times with a 21 gauge needle and with an 18 gauge needle, however use of an 18 gauge needle in dose preparation studies led to leaking during dose withdrawal.<sup>1</sup>



## **WHAT DOES THE SPRAY CONTAIN THAT CAN RESULT IF I FORGET TO WITHDRAW AIR PRIOR TO REMOVING THE DILUTENT NEEDLE FROM THE VIAL? DOES IT IMPACT THE DOSE?**

The EUA Prescribing Information states that the vial pressure should be equalized before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe.<sup>2</sup>

The instructions for use instruct the preparer to equalize the pressure in the vial after adding the diluent by withdrawing 1.8 mL of air prior to removing the diluent needle from the vial. Failure to equalize the pressure results in a small spray of 0.9% sodium chloride when the needle is pulled out of the stopper. This spray consists only of diluent, not vaccine, and has no safety impact to the preparer or impact to the dose.<sup>1</sup>

## **WHAT DATA IS AVAILABLE FOR VIALS OR DOSING SYRINGES CONTAINING DILUTED VACCINE STORED BETWEEN 2 TO 25°C FOR >6 HOURS FROM THE POINT OF DILUTION?**

The EUA Prescribing Information states that, after dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution. Record the date and time of dilution on the Pfizer BioNTech COVID-19 Vaccine vial label. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Discard any unused vaccine 6 hours after dilution. Any vaccine remaining in vials must be discarded after 6 hours. Do not refreeze. Syringes prepared with a 0.3 mL dose of diluted vaccine should be administered immediately. Pfizer-BioNTech COVID-19 Vaccine does not contain preservative.<sup>2</sup>

The EAU Prescribing Information does not include any data on the stability and viability of diluted vaccine if stored between 2°C to 25°C for > 6 hours.<sup>2</sup>

### **Internal Data**

#### ***Vials***

The in-use period for the diluted vial is 6 hours between 2°C and 30°C. Some countries have limited the label conditions to between 2°C and 25°C due to concerns around the potential for microbiological growth at warmer temperatures. Pfizer has conducted physical and chemical stability studies which have shown that the vaccine maintains all its measured quality attributes when diluted vaccine is stored in the **vial** at 2°C to 32°C for up to 24 hours.<sup>1</sup>

Pfizer has not studied or cannot support storage of diluted vaccine **in vials** that have been stored between 2°C to 32°C for >24 hours, at temperatures <2°C or at temperatures >32°C. Vials stored in this manner, should not be used and should be discarded.<sup>1</sup>

#### ***Syringes***

Pfizer has conducted physical and chemical stability studies which have shown that the vaccine maintains all its measured quality attributes when diluted vaccine is stored in **polycarbonate and polypropylene syringes with stainless steel needles** for 6 hours at 2°C to 30°C ± 2°C. Degradation of RNA in the vaccine has been observed when stored for longer than 6 hours in syringes. Microbiological risk was assessed through a microbiological challenge study which showed that microbiological growth has a greater potential to occur after 6 hours.<sup>1</sup>

Pre-drawing diluted vaccine into syringes prior to use can increase the risk of medication errors.<sup>1</sup> Pfizer has not studied or cannot support storage of diluted vaccine **in syringes** that have been stored between 2°C to 32°C for >6 hours, at temperatures <2°C or at temperatures >32°C. Diluted vaccine stored in syringes in this manner should not be used and should be discarded.

## **WHAT DATA ARE AVAILABLE TO SUPPORT THE USE OF A VIAL ADAPTER OR A VIAL ACCESS DEVICE?**

Compatibility and dose recovery were confirmed with the BD Smart Site 13 mm vented vial access device. Other 13 mm vial adapters that do not have filters in the fluid path have not been evaluated to ensure the total number of doses can be recovered from the vial.<sup>1</sup>

## **IS THERE DATA FOR THE STERILITY/STABILITY AND TIMEFRAME FOLLOWING REMOVAL OF THE FLIP-OFF CAP WITH AN INTACT ALUMINUM OVERSEAL (UNPUNCTURED)?**

Removal of the flip-off cap with no impact on the underlying aluminum overseal (i.e. aluminum overseal remains intact, unpunctured) does not compromise the sterility/stability of the vaccine.<sup>1</sup>

## **WHAT ARE THE RECOMMENDED STORAGE AND HANDLING REQUIREMENTS FOR PFIZER-BIONTECH COVID-19 VACCINE AFTER DILUTION AND DOSE PREPARATION PRIOR TO ADMINISTRATION?**

### **Select EUA Prescribing Information**

#### **Administration Information**

Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be an off-white suspension. During the visual inspection.<sup>2</sup>

- verify the final dosing volume of 0.3 mL, and
- confirm there are no particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains particulate matter.

Administer Pfizer-BioNTech COVID-19 Vaccine intramuscularly.<sup>2</sup>

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.

## **WHAT DATA IS AVAILABLE FOR INADVERTENT ADMINISTRATION OF VACCINE WITH PARTICULATES OR DISCOLOURATION?**

The EUA Prescribing Information states that the liquid in the vial should be inspected prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles. Do not use if liquid is discolored or if other particles are observed. The diluted vaccine will be an off-white suspension. Visually inspect each dose in the dosing syringe prior to administration to verify the final dosing volume of 0.3 mL and to confirm there are no particulates and that no discoloration is observed. Do not administer if vaccine is discolored or contains particulate matter.<sup>2</sup>

Diluted vaccine with visible particulates or discoloration should not be used and should be discarded. Pfizer does not have data to support administration of discolored vaccine. If vaccine with particulate matter was inadvertently administered, it is not expected to impact safety or efficacy of the vaccine but should be reported.<sup>1</sup>

## **CAN A FILTER BE USED DURING THE DILUTION, PREPARATION OR ADMINISTRATION OF THE VACCINE?**

A filter is not required at any point in the dilution, preparation or administration of the vaccine. Pfizer has no data on the use of a filter with the vaccine and a filter should not be used to remove particulates from diluted vaccine. If a filter was used to remove particulates or during vaccine preparation, the vaccine should not be used and should be discarded.<sup>1</sup>

## REFERENCES

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