

December 12, 2020

Details Related to FDA's Emergency Use Authorization of Pfizer COVID-19 Vaccine

The Food and Drug Administration late last night granted an [emergency use authorization](#) (EUA) to Pfizer, Inc. for its BNT162b2 mRNA COVID-19 vaccine, paving the way for its immediate administration across the country. Health care workers and nursing home residents will receive first priority and the first shots could be given out within days.

As required by the EUA, Pfizer has made public fact sheets for [providers](#) and [patients](#).

The following information is a summary of the provider fact sheet.

Dosing. The vaccine is a suspension for intramuscular injection administration as a series of two doses, 0.3mL each, 3 weeks apart.

Storage and Handling. The storage and handling of the vaccine is separated into the following three phases:

Storing Frozen Vials Prior to Use. Multiple Dose Vials will arrive in thermal containers with dry ice. Once the product is received, the vial cartons should be removed immediately, stored in an ultra-cold freezer between -80°C to -60°C, and protected from exposure to light. **In instances where an ultra-cold freezer is not available**, the thermal containers in which the product is distributed may be used as **temporary** storage when consistently refilled with dry ice. For additional information regarding temporary storage, providers should consult the re-icing guidelines provided with the thermal container.

Thawing Vials Prior to Dilution. Because the vial is a frozen suspension that does not contain preservatives, it must be thawed and diluted prior to administration. There are two processes that may be used to thaw the frozen vials:

- *Thawed Under Refrigeration.* The product may be **thawed and stored undiluted in a refrigerator for up to 5 days**. Cartons with more vials likely will take 2 to 3 hours to thaw, with less time being necessary for fewer numbers of vials.
- *Thawed at Room Temperature.* The product may be **thawed and stored undiluted at room temperature for 30 minutes**.

Both thawing methods require that the vials reach room temperature prior to dilution. Once the product reaches room temperature, it must be diluted within two hours.

After Dilution. Once diluted, the vials must be stored between 2°C and 25°C for **no more than 6 hours from the time of dilution**. Any vaccine remaining in the vials after 6 hours must be discarded. While storing the diluted vial, there should be minimal exposure to room light and exposure to direct sunlight and ultraviolet light must be avoided. **The product may not be refrozen after dilution.**

Dosing Preparation. For detailed information on the dosing preparation and administration of the vaccine, please see the Pfizer [fact sheet](#) for providers.

Contraindications and Adverse Reactions. The vaccine **should not be administered to** individuals with a known history of severe allergic reaction to any component of the vaccine. Administration sites must have appropriate medical treatments to manage immediate allergic reactions onsite. Adverse reactions may include injection site pain and/or swelling, fatigue, headache fever and nausea, among others.

NEXT STEPS

Visit [AHA's website](#) to review a host of resources on COVID-19 vaccines and therapeutics, including materials on distribution and workforce issues.

FURTHER QUESTIONS

If you have questions, please contact AHA at 800-424-4301.