

December 19, 2020

Summary of FDA Emergency Use Authorization of Moderna's COVID-19 Vaccine

Details on Dosing, Storage and Preparation of mRNA-1273, Which Is Slated to Begin Shipping Immediately

The Food and Drug Administration last night granted an [emergency use authorization](#) (EUA) to Moderna for its mRNA-1273 COVID-19 vaccine, paving the way for its immediate administration across the country.

Like Pfizer's already-approved vaccine, Moderna's mRNA-1273 vaccine is administered in two doses, albeit 28 days apart, compared to Pfizer's 21 days. Unlike the Pfizer vaccine, Moderna's mRNA-1273 vaccine does not require ultracold storage; rather, it can be shipped and stored long-term at standard freezer temperatures of minus-20 degrees Celsius (minus-4 degrees Fahrenheit) for six months. Furthermore, the Moderna vaccine remains stable at standard refrigerator temperatures of 2-8 degrees Celsius (36-46 degrees Fahrenheit) for 30 days.

As required under the EUA, Moderna has released fact sheets for [providers](#) and for [patients](#).

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

Dosing

The product is authorized for use in individuals 18 years of age or older. The vaccine is administered intramuscularly as a series of two doses one month apart. Each dose is 0.5mL.

Storage and Handling

Storage Prior to Use. The product should be stored frozen (between minus-25 to minus-15 degrees Celsius) in the original cartons to protect from light. Vials can be stored refrigerated (between 2 and 8 degrees Celsius) for **up to 30 days**; unpunctured vials can be stored unrefrigerated (between 8 and 25 degrees Celsius) for **up to 12 hours**.

Note that vials **should not be stored on dry ice or below minus-40 degrees Celsius. The vials cannot be refrozen once thawed**

Storage after Vial Puncture. Once the first dose from a vial is withdrawn, the vial should be held between 2 and 25 degrees Celsius. Any product that remains unused must be discarded after six hours.

Dosing Preparation

The vaccine comes in a multiple-dose vial, which contains a frozen suspension without any preservative. Prior to administration, the vials must be thawed using one of two methods:

- Thaw the product in refrigerated conditions (between 2 and 8 degrees Celsius) for two-and-a-half hours, and then let the product stand at room temperature for 15 minutes prior to administration; or
- Thaw the product at room temperature (between 15 and 25 degrees Celsius) for one hour.

Once thawed, the vial should be gently swirled, **not shaken**. The vial should be gently swirled again prior to each withdrawal for administration. **Do not dilute the vaccine.**

Note that the product is a white to off-white suspension and may contain white or translucent product-related particulates. If other particulate matter or concerning discoloration is found during visual inspection prior to administration, that specific dose should not be administered and should be discarded.

Contraindications and Adverse Reactions

The vaccine should not be administered to individuals with known histories of severe allergic reaction to any component of this product. Providers should ensure the availability of appropriate medical equipment to manage any immediate allergic reactions that may present in individuals who have just received the vaccine. Adverse reactions may include, but are not limited to, pain, swelling or erythema at the injection site, fatigue, headache, chills, fever and nausea.

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.