

August 2024 ~ Resource #400863



COVID-19 Vaccines 2024-25 (United States)

(modified September 2024)

The first chart below provides dosing and storage information for COVID-19 vaccines approved or authorized in the US. Links to the prescribing information and fact sheets (EUA) for healthcare professionals and the patient package insert are provided in **footnote a**. A second chart provides information and resources to help you address frequently asked questions about COVID-19 vaccination.

Vaccine	Dosing	Storage/Stability
Comirnaty (COVID-19 vaccine, mRNA) 2024 to 2025 formula (Omicron KP.2) for patients ≥12 years of age. Pfizer-BioNTech	 For patients ≥12 years of age: Each dose is 0.3 mL (30 mcg) IM. Administer ≥2 months after any previous COVID-19 vaccine dose. Immunocompromised patients: see footnote b. 	 Prefilled glass syringe: Store in refrigerator (2°C to 8°C). Room temperature (8°C to 25°C): 12 hours total Vials May arrive frozen at ultra-cold temperatures in thermal containers with dry ice. May store in ultra-low temp freezer at -90°C to -60°C or transfer to refrigerator. Refrigerator (2°C to 8°C): 10 weeks. Room temperature (8°C to 25°C): 12 hours total.
 Pfizer-BioNTech COVID- 19 vaccine, mRNA. 2024 to 2025 formula (Omicron KP.2) for patients 5 years through 11 years of age. Emergency Use Authorization BLUE cap and label border. 	 For patients 5 years through 11 years of age. Dose is 0.3 mL (10 mcg) IM. Administer ≥2 months after any previous COVID-19 vaccine dose. Immunocompromised^b individuals should receive at least three doses of COVID-19 vaccine, with at least one dose being the 2024-2025 formula. If not previously vaccinated for COVID-19, give three doses (week 0, week 3, and ≥4 weeks after the second dose). If previously vaccinated with one or two doses of any Pfizer-BioNTech COVID-19 vaccine, complete the remaining dose(s) in the three-dose series as above. If previously vaccinated with ≥3 doses of any Pfizer-BioNTech COVID-19 vaccine, give one dose ≥2 months after the last dose. One or more additional doses may be given.⁸ 	 May arrive frozen at ultra-cold temperatures in thermal containers with dry ice. May store in ultra-low temp freezer at -90°C to -60°C or transfer to a refrigerator. Refrigerator (2°C to 8°C): 10 weeks. Room temperature (8°C to 25°C): 12 hours total.
Pfizer-BioNTech COVID- 19 vaccine, mRNA.	 For patients 6 months through 4 years of age. Dose is 0.3 mL [3 mcg] IM. 	• May arrive frozen at ultra-cold temperatures in thermal containers

--Information in this chart is from the US product information (prescribing information or fact sheet) cited in footnote a, unless otherwise cited.--

Vaccine	Dosing	Storage/Stability
2024 to 2025 formula (Omicron KP.2) for patients 6 months through 4 years of age Emergency Use Authorization YELLOW cap and label border	 No previous COVID-19 vaccine: give three doses (at week 0, at week 3, and ≥8 weeks after the 2nd dose). Previously vaccinated with one dose of any Pfizer-BioNTech COVID-19 vaccine: give two doses (≥3 weeks after receipt of the previous dose, and ≥8 weeks after the 2nd dose). Previously vaccinated with ≥2 doses of any Pfizer-BioNTech COVID-19 vaccine: give a single dose ≥8 weeks after receipt of the last dose. Immunocompromised^b individuals should receive at least three doses of COVID-19 vaccine, with at least one dose being the 2024-2025 formula. If not previously vaccinated for COVID-19, give three doses, as above. If previously vaccinated with one or two doses of any Pfizer-BioNTech COVID-19 vaccine, complete the remaining dose(s) in the three-dose series as above. If previously vaccinated with ≥3 doses of any Pfizer-BioNTech COVID-19 vaccine, give one dose ≥2 months after the last dose. One or more additional doses may be given.⁸ 	 with dry ice. May store in ultra-low temp freezer at -90°C to -60°C or transfer to a refrigerator. Refrigerator (2°C to 8°C): 10 weeks. Room temperature (8°C to 25°C): 12 hours total.
<i>Spikevax</i> COVID-19 vaccine, mRNA. 2024 to 2025 formula (Omicron KP.2) for patients ≥12 years of age. Moderna	 For patients ≥12 years of age. Dose is 0.5 mL (50 mcg) IM. Administer ≥2 months after any previous COVID-19 vaccine dose. Immunocompromised patients: see footnote b. 	 Store frozen between -50°C and -15°C. Refrigerator (2°C to 8°C): 60 days or until the expiration date on the carton, whichever is first. Room temperature (8°C to 25°C): up to 12 hours after thawing.
Moderna COVID-19 vaccine, mRNA. 2024 to 2025 formula (Omicron KP.2) for patients 6 months to 11 years of age	 6 months through 4 years of age (dose is 0.25 mL [25 mcg]): No previous COVID-19 vaccine: give two doses (at month 0 and at month 1). 	• Store frozen between -50°C and -15°C.

Vaccine	Dosing	Storage/Stability
Emergency Use Authorization	 o Previously vaccinated with one dose of any Moderna COVID- 19 vaccine: one dose ≥1 month after receipt of the previous dose. o Previously vaccinated with ≥2 doses of any Moderna COVID- 19 vaccine: one dose ≥2 months after receipt of the last previous dose. 5 years through 11 years of age (dose is 0.25 mL [25 mcg]): give one dose. If previously vaccinated for COVID-19, give ≥2 months after receipt of the last previous dose. Immunocompromised^b individuals should receive at least three doses of COVID-19 vaccine, each dose ≥1 months apart, with at least one dose being the 2024-2025 formula. If previously vaccinated with ≥3 doses, give one dose ≥2 months after the last dose. One or more additional doses may be given.⁸ 	 Refrigerator (2°C to 8°C): 60 days or until the expiration date on the carton, whichever is first. Room temperature (8°C to 25°C): up to 12 hours after thawing.
Novavax COVID-19 vaccine, adjuvanted. 2024 to 2025 formula (Omicron JN.1) for patients ≥12 years of age Emergency Use Authorization	 For patients ≥12 years of age. Dose is 0.5 mL IM. No previous COVID-19 vaccine: give two doses three weeks apart. Previously vaccinated with one dose of any Novavax COVID-119 vaccine: one dose ≥3 weeks after receipt of the previous dose. Previously vaccinated with any other COVID-19 vaccine, or with ≥2 doses of a Novavax COVID-19 vaccine: one dose ≥2 months after receipt of the previous dose. Immunocompromised^b individuals may receive an additional dose ≥2 months after receipt of the previous dose. One or more additional doses may be given. 	• Store in refrigerator (2°C to 8°C).

Abbreviations: EUA = Emergency Use Authorization; IM = intramuscular

- a. US prescribing information or fact sheet (for vaccines with EUA) used in creation of this chart, and corresponding patient package inserts for recipient/caregiver:
 - *Comirnaty* for patients ≥12 years of age (August 2024): https://www.fda.gov/media/151707/download?attachment. (Includes information for recipients/caregivers).
 - Pfizer COVID-19 vaccine for patients 6 months through 11 years of age (August 2024): https://www.fda.gov/media/167211/download?attachment.
 - Fact sheet for recipients/caregivers: https://www.fda.gov/media/167212/download?attachment.

- Spikevax for patients ≥12 years of age (August 2024): https://www.fda.gov/media/155675/download?attachment.
 Patient package insert: https://www.fda.gov/media/155762/download?attachment.
- Moderna COVID-19 vaccine for patients 6 months through 11 years (August 2024): https://www.fda.gov/media/167208/download?attachment.
 - Fact sheet for recipients/caregivers: https://www.fda.gov/media/167209/download?attachment.
- Novavax COVID-19 vaccine for patients ≥12 years of age (August 2024): https://www.fda.gov/media/159897/download?attachment
 - Fact sheet for recipients/caregivers: https://www.fda.gov/media/159898/download?attachment.
- b. **Immunocompromise** = solid organ transplant patients or similar level of immunocompromise. For a full list of CDC-recommended conditions and vaccination recommendations, see CDC guidance at: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html.

---Continue to the next section for a chart, "Frequently Asked Questions About COVID-19 Vaccination."---

Question	Pertinent information or Suggested Resources	
How do COVID-19 vaccines work?	• See the CDC's "COVID-19 Vaccine Basics" at https://www.cdc.gov/covid/vaccines/how-they-work.html.	
Do mRNA vaccines affect DNA?	• No. COVID-19 vaccines to not interact with DNA in any way. ⁵	

Frequently asked questions about COVID-19 vaccination

Question	Pertinent information or Suggested Resources	
Can a COVID-19 vaccine cause a COVID-19 infection?	 No. COVID-19 vaccines do not contain the COVID-19 virus.⁵ 	
Can a patient get a COVID- 19 vaccine if they have a COVID infection?	 Patients with any respiratory virus should delay vaccination to avoid exposing healthcare providers and others to COVID.⁴ Patients can wait three months after symptom onset (or positive test if asymptomatic) to receive a COVID-19 vaccination.⁸ Reinfection is unlikely in the first three months post-infection.⁸ Delaying vaccination for three months may improve vaccine response.⁸ Reasons to get vaccinated sooner include high personal risk of severe disease, close contact with a person at high risk of severe disease, or high COVID-19 transmission in the community.⁴ 	
How effective are COVID-19 vaccines?	 COVID-19 vaccination is the best way to protect against serious COVID-19 illness, hospitalization, and death.¹⁵ Getting a COVID-19 vaccine is a safer and more reliable way to build immunity than getting a COVID-19 infection.¹⁵ For the most current CDC-authored vaccine effectiveness studies, see COVID-19 Vaccine Effectiveness Monthly Update at https://covid.cdc.gov/covid-data-tracker/#vaccine-effectiveness. 	
Can COVID-19 vaccines be given with other vaccines?	• Generally yes, but there are special considerations for mpox vaccination. ⁸	
What are some common adverse effects of COVID-19 vaccines, and what can be done about them?	 As with other vaccines, side effects are usually mild and go away in few days, if they occur at all.¹⁰ Common side effects include fatigue, muscle pain, headache, chills, nausea, fever, and pain, swelling, and redness in the arm where the vaccine was administered.¹⁰ It is not recommended to take analgesics before vaccination to prevent side effects, but they can be taken to treat side effects if they occur.¹⁰ For arm pain and swelling, a clean, cool, wet washcloth can be applied over the area. The patient should keep moving their arm.¹⁰ 	
Do COVID-19 vaccines cause heart problems?	 Many viruses, including COVID-19, can cause myocarditis and pericarditis.⁶ In one study, patients with COVID-19 had almost 16 times the risk of myocarditis compared with patients who did not have COVID-19.¹⁴ Although rare, the COVID-19 vaccine has been associated with myocarditis and pericarditis.⁶ Myocarditis associated with COVID-19 vaccination is less common and less severe than with COVID-19 infection.⁷ Most cases associated with COVID-19 vaccination are mild, transient, and resolve on their own.⁷ 	

Question	Pertinent information or Suggested Resources	
	• Among men 18 to 39 years of age, there were 65.7 cases per million doses of the second Moderna vaccine (original formulation). ⁹	
	• Whether from the virus or vaccine, males 12 to 39 years of age appear to be at highest risk. ^{6,9}	
	• Waiting at least 8 weeks between doses may decrease risk (the minimum dosing interval continued to be recommended for moderately or severely immunocompromised people or others with higher risk of severe disease). ⁸	
Do COVID-19 vaccines cause Bell's palsy?	• It is unclear if mRNA COVID-19 vaccines are associated with Bell's palsy. ¹³	
Can COVID-19 vaccines cause ischemic stroke?	• The CDC and the FDA investigated a potential for increased risk of stroke associated with the Pfizer- BioNTech's COVID-19 vaccine in adults ≥65 years of age after a preliminary safety signal was detected in the Vaccine Safety Datalink (VSD) safety monitoring system. Other safety monitoring systems have not observed similar signals, and the current evidence does not support causality. ¹²	
Do COVID-19 vaccines cause Guillain-Barre syndrome?	• mRNA COVID-19 vaccines do not seem to be associated with Guillain-Barre syndrome. ¹¹	
Will COVID-19 vaccination cause a positive COVID test?	• No. ⁸	
Can antibody testing be used to assess the need for COVID-19 vaccination?	 This is not recommended. Vaccination should proceed regardless of the result.⁸ Antibody testing is appropriate in the context of a clinical trial.⁸ 	
Do patients need to stick with the same vaccine every year?	 Ideally, the same manufacturer should be used for if the vaccine is given in a series (e.g., 6 months through 4 years of age, immunocompromised patients).⁸ For details, see the CDC's <i>Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States</i>: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#Interchangeability. 	
What dose should a child receive if they transition from	• Children who transition from age 4 years to age 5 years during the initial vaccination series should receive one dose of vaccine from the same manufacturer at the dosage for children ages 5 to 11 years of age on or after turning age 5 years of age: ⁸	

Question	Pertinent information or Suggested Resources	
a younger to older age group between doses in a series?	 Moderna: one dose of 2024-2025 Moderna (0.25 mL/25 mcg) 4 to 8 weeks after the first dose; there is no dosage change. Pfizer-BioNTech: one dose of 2024-2025 Pfizer-BioNTech (0.3 mL/10 mcg). If the 10 mcg dose is the second dose, administer 3 to 8 weeks after the first dose; if it is the third dose, administer at least 8 weeks after the second dose. If immunocompromised: 	
	 Children who transition from 4 years of age to 5 years of age during the initial vaccination series should complete the 3-dose series using the dosage for children ages 5 to 11 years of age for all doses received on or after turning age 5 years of age:⁸ Moderna series: 2024-2025 Moderna, 0.25 mL/25 ug; there is no dosage change Pfizer-BioNTech series: 2024-2025 Pfizer-BioNTech, 0.3 mL/10 ug Children who transition from 11 years of age to 12 years of age during the initial vaccination series should complete the 3-dose series using the dosage for people ≥12 years of age for all doses received on or after turning age 12 years:⁸ Moderna series: 2024-2025 Moderna, 0.5 mL/50ug Pfizer-BioNTech series: 2024-2025 Pfizer-BioNTech, 0.3 mL/30 ug 	
Do COVID-19 vaccines prevent "long COVID"?	 Vaccination is the best available tool to prevent long COVID.¹ Vaccination may reduce the risk of long COVID-19 by almost 50%.^{2,3} 	
Can patients who are pregnant or breastfeeding get a COVID vaccine?	• COVID-19 vaccinations are recommended for people who are pregnant, trying to get pregnant, or who might become pregnant in the future, and for people who are breastfeeding. ⁸	

Users of this resource are cautioned to use their own professional judgment and consult any other necessary or appropriate sources prior to making clinical judgments based on the content of this document. Our editors have researched the information with input from experts, government agencies, and national organizations. Information and internet links in this article were current as of the date of publication.

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