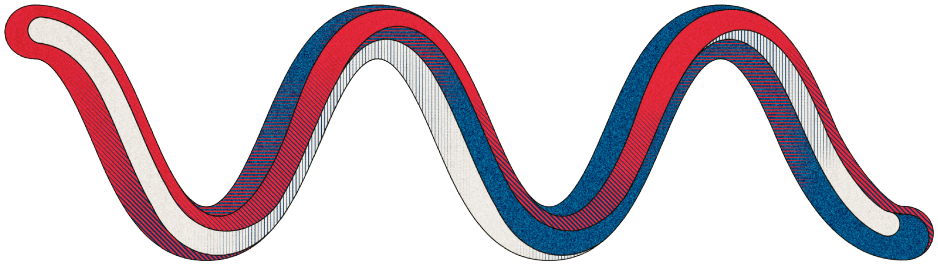
spikevax®
COVID-19 Vaccine, mRNA
by moderna®

SPIKEVAX 2025–2026 FORMULA



PRODUCT INFORMATION GUIDE

First [and only] FDA-approved COVID-19 vaccine for high-risk individuals as young as 6 months of age[1–5*†]

*Children and adolescents with ≥1 underlying condition are at high risk for severe COVID-19 outcomes. Select underlying conditions include medical complexity, genetic, neurologic, and metabolic conditions, congenital heart disease, obesity, diabetes, asthma or chronic lung disease, sickle cell disease, and immunocompromised status.[2]

Risk for severe COVID-19 outcomes in adults increases with age and presence of ≥1 underlying conditions. Select underlying conditions include cancer, cerebrovascular disease, chronic kidney disease, chronic liver diseases, chronic lung diseases, diabetes type 1 and 2, heart conditions, and overweight or obesity.[2]

†Moderna COVID-19 Vaccine was previously available for pediatric populations under Emergency Use Authorization (EUA).

INDICATION

SPIKEVAX® (COVID-19 Vaccine, mRNA) is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

SPIKEVAX is approved for use in individuals who are:

- 65 years of age and older, or
- 6 months through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.

IMPORTANT SAFETY INFORMATION

Contraindications

Do not administer SPIKEVAX® to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component of SPIKEVAX or to individuals who had a severe allergic reaction (e.g., anaphylaxis) following a previous dose of a Moderna COVID-19 vaccine.

Please see continued IMPORTANT SAFETY INFORMATION throughout, and scan or click the QR code on page 6 for Full Prescribing Information.

Proven Protection—Now Updated for the 2025–2026 Season[1,6]

spikevax®
COVID-19 Vaccine, mRNA

New Season, Updated Vaccine

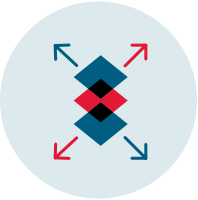
Adults aged **65 years and older**

Individuals aged **6 months–64 years with ≥1 underlying condition*** that puts them at high risk for severe outcomes from COVID-19

Pre-filled Syringes Enable Streamlined Workflow

Available as a ready-to-use formulation with no reconstitution required

Spikevax is ready to use once thawed to room temperature



Flexible Storage On Your Terms

Spikevax can be stored frozen up to expiration date or thawed in the refrigerator for up to 60 days

*Children and adolescents with ≥1 underlying condition are at high risk for severe COVID-19 outcomes. Select underlying conditions include medical complexity, genetic, neurologic, and metabolic conditions, congenital heart disease, obesity, diabetes, asthma or chronic lung disease, sickle cell disease, and immunocompromised status.[2]

Risk for severe COVID-19 outcomes in adults increases with age and presence of ≥1 underlying conditions. Select underlying conditions include cancer, cerebrovascular disease, chronic kidney disease, chronic liver diseases, chronic lung diseases, diabetes type 1 and 2, heart conditions, and overweight or obesity.[2]

IMPORTANT SAFETY INFORMATION (CONT.)

Warnings and Precautions

- **Management of Acute Allergic Reactions:** Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of SPIKEVAX.
- **Myocarditis and Pericarditis:** Postmarketing data with authorized or approved mRNA COVID-19 vaccines have demonstrated increased risks of myocarditis and pericarditis, with onset of symptoms typically in the first week following vaccination. The observed risk has been highest in males 12 years through 24 years of age.
- **Syncope (fainting):** May occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.
- **Altered Immunocompetence:** Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished immune response to SPIKEVAX.
- **Limitations of Vaccine Effectiveness:** SPIKEVAX may not protect all vaccine recipients.

Please see continued IMPORTANT SAFETY INFORMATION throughout, and scan or click the QR code on page 6 for Full Prescribing Information.

Available Exclusively as Pre-filled Syringes and Dosed Based on Patient Age[1]

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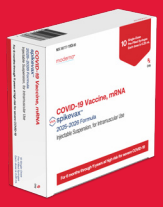
COVID-19 Vaccine, mRNA

Pre-filled syringes are supplied in paperboard tray cartons

0.25 mL dose

For individuals
6 months–11 years of age

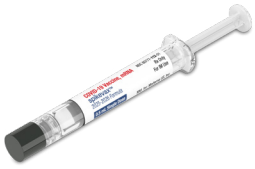
Single-dose pre-filled syringe
Product dimensions (in^3):
3.91 x 0.54 x 0.54
Weight (lb): 0.01



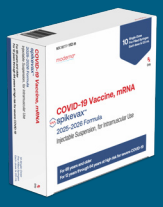
Paperboard tray carton of 10 single-dose pre-filled syringes
Product dimensions (in^3):
4.33 x 4.02 x 1.38
Weight (lb): 0.19

0.5 mL dose

For individuals
12 years of age and older



Single-dose pre-filled syringe
Product dimensions (in^3):
3.91 x 0.54 x 0.54
Weight (lb): 0.01



Paperboard tray carton of 10 single-dose pre-filled syringes
Product dimensions (in^3):
4.33 x 4.02 x 1.38
Weight (lb): 0.20

IMPORTANT SAFETY INFORMATION (CONT.)

Adverse Reactions

The most commonly reported (>10%) adverse reactions in participants 6 - 36 months of age: irritability/crying, pain at the injection site, sleepiness, loss of appetite, fever, erythema, swelling at the injection site, and axillary (or groin) swelling/tenderness.

The most commonly reported (>10%) adverse reactions in participants 37 months - 11 years of age were: pain at the injection site, fatigue, headache, myalgia, chills, nausea/vomiting, axillary (or groin) swelling/tenderness, fever, erythema, swelling at the injection site, and arthralgia.

The most commonly reported (≥10%) adverse reactions in participants 12 years and older were: pain at the injection site, headache, fatigue, myalgia, arthralgia, chills, and axillary swelling/tenderness, nausea/vomiting, and swelling at the injection site.

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Storage, Handling, and Dosing

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Guidance on proper preparation of Spikevax: stock storage to administration[1]

Shipped Frozen

Frozen Storage (Stock)*

Store frozen at **-58 °F to 5 °F (-50 °C to -15 °C)**

Thawing From Frozen

Refrigeration Thaw Duration:
36 °F to 46 °F (2 °C to 8 °C)

- **Single syringe (removed from carton):** 1 hour and 40 minutes
- **Carton of 10 syringes:** 2 hours and 40 minutes

OR

Room Temperature Thaw Duration:
59 °F to 77 °F (15 °C to 25 °C)

- **Single syringe (removed from carton):** 40 minutes
- **Carton of 10 syringes:** 1 hour and 20 minutes

Storage After Thawing†

Refrigeration:
36 °F to 46 °F (2 °C to 8 °C)
Beyond use date: Must not exceed 60 days or up to the carton expiration date, whichever comes first

OR

Room Temperature:
46 °F to 77 °F (8 °C to 25 °C)
Beyond use date: Must not exceed 12 hours

Preparing for Use

- With tip cap upright, remove tip cap by twisting counterclockwise until tip cap releases. Remove tip cap in a slow, steady motion. Avoid pulling tip cap while twisting
- Attach the needle by twisting in a clockwise direction until the needle fits securely on the syringe
- Immunizer should select a needle of appropriate size and gauge for intramuscular injection
- Discard after single use

Transportation of Thawed Syringes at 36 °F to 46 °F (2 °C to 8 °C): Thawed pre-filled syringes can be transported at 36 °F to 46 °F (2 °C to 8 °C) in shipping containers qualified to maintain 36 °F to 46 °F (2 °C to 8 °C). Once thawed and transported at 36 °F to 46 °F (2 °C to 8 °C), pre-filled syringes should not be refrozen and should be stored at 36 °F to 46 °F (2 °C to 8 °C) until use, for up to 60 days or carton expiration date, whichever comes first.[1]

*During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.[1]
†After thawing, do not refreeze. Do not shake. Thawed syringes can be handled in room light conditions.[1]

Spikevax is administered intramuscularly[1]

Number of Previous Doses of Moderna COVID-19 Vaccine(s) Received‡	Individuals 6–23 Months of Age
0§	**2 doses,¶ 0.25 mL each** | Dose 1: Month 0; Dose 2: Month 1
1	**Single dose, 0.25 mL** | 1 month after receipt of a previous dose of Moderna COVID-19 vaccine‡
≥2	**Single dose, 0.25 mL** | ≥2 months after receipt of the last previous dose of Moderna COVID-19 vaccine‡

	Individuals ≥2 Years of Age Irrespective of COVID-19 Vaccination Status
2–11 years of age	**Single dose, 0.25 mL** | If previously vaccinated, ≥2 months after receipt of the last previous dose of COVID-19 vaccine
≥12 years of age	**Single dose, 0.5 mL** | If previously vaccinated, ≥2 months after receipt of the last previous dose of COVID-19 vaccine

‡Previous dose refers to a dose of any authorized Moderna COVID-19 Vaccine.
§Not previously vaccinated with any COVID-19 vaccine.
¶Individuals turning from 23 months to 2 years of age during the vaccination series should receive both doses with Spikevax.

IMPORTANT SAFETY INFORMATION (CONT.)

Reporting Adverse Events and Vaccine Administration Errors
To report suspected adverse reactions, contact ModernaTX, Inc. at 1-866-663-3762 or VAERS at 1-800-822-7967 or https://vaers.hhs.gov.

Please see continued IMPORTANT SAFETY INFORMATION throughout, and scan or click the QR code on page 6 for Full Prescribing Information.

Product Ordering and Billing

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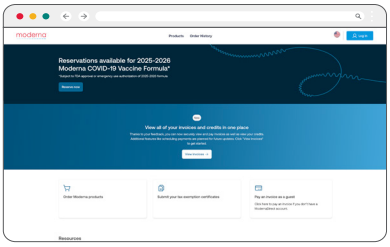
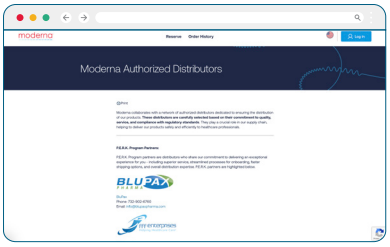
Place your order today via Moderna Direct or one of our trusted authorized distributor partners



Scan or click the QR code to **create your Moderna Direct account** or **login** to your existing account.



Scan or click the QR code to learn more about our **authorized distributors**.

Product identification codes[1,7]

Type	Code	Description
Individuals 6 Months–11 Years of Age		
NDC	80777-113-80 (10-digit) | 80777-0113-80 (11-digit)	Paperboard tray carton of 10 single-dose pre-filled syringes
	80777-113-09 (10-digit) | 80777-0113-09 (11-digit)	Single-dose pre-filled syringe
CVX	311	SARS-CoV-2 (COVID-19) vaccine, mRNA, spike protein, LNP, preservative free, 25 mcg/0.25 mL dose
MVX	MOD	Moderna
Individuals ≥12 Years of Age		
NDC	80777-112-96 (10-digit) | 80777-0112-96 (11-digit)	Paperboard tray carton of 10 single-dose pre-filled syringes
	80777-112-01 (10-digit) | 80777-0112-01 (11-digit)	Single-dose pre-filled syringe
CVX	312	SARS-CoV-2 (COVID-19) vaccine, mRNA, spike protein, LNP, preservative free, 50 mcg/0.5 mL dose
MVX	MOD	Moderna

Diagnosis and procedural codes

Type	Code	Description
CPT®[7,8]*	91321	**Vaccine Product Code** Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, 25 mcg/0.25 mL dosage, for intramuscular use in patients aged 6 months–11 years
	91322	**Vaccine Product Code** Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, 50 mcg/0.5 mL dosage, for intramuscular use in patients aged 12 years and older
	90480	**Vaccine Administration Code** Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) (coronavirus disease [COVID-19]) vaccine, single dose
ICD-10-CM[9]	Z23	Encounter for immunization

*CPT is a registered trademark of the American Medical Association (AMA).

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For Colorado and Connecticut price disclosure, please visit https://modernadirect.com/wac-disclosure.

Please scan or click the QR code or ask your representative for Full Prescribing Information.

COVID-19, coronavirus disease 2019; CPT, Current Procedural Terminology; CVX, vaccine administered; FDA, US Food and Drug Administration; ICD-10-CM, International Classification of Disease, Tenth Revision, Clinical Modification; LNP, lipid nanoparticle; mRNA, messenger RNA; MVX, Manufacturer of Vaccine; NDC, National Drug Code; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.

References: 1. Spikevax Prescribing Information. Moderna; 2025. **2.** CDC. Accessed August 27, 2025. https://www.cdc.gov/covid/risk-factors/index.html **3.** mNEXSPIKE Prescribing Information. Moderna; 2025. **4.** COMIRNATY Prescribing Information. Pfizer Inc; 2025. **5.** NUVAXOVID Prescribing Information. Novavax Inc; 2025. **6.** FDA. Accessed August 27, 2025. https://www.fda.gov/vaccines-blood-biologics/industry-biologics/covid-19-vaccines-2025-2026-formula-use-united-states-beginning-fall-2025 **7.** CDC. Accessed August 4, 2025. https://www.cdc.gov/iis/code-sets/fall-season-respiratory-codes.html **8.** CMS. Accessed August 4, 2025. https://www.cms.gov/medicare/payment/covid-19/coding-covid-19-vaccine-shots **9.** ICD10Data.com. 2024 ICD-10-CM diagnosis code Z23. Accessed July 31, 2025. https://www.icd10data.com/ICD10CM/Codes/Z00-Z99/Z20-Z29/Z23-/Z23

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