Drug of the Month
SPIKEVAX
COVID-19 Vaccine 2024-2025 Formulation

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use SPIKEVAX safely and effectively. See full prescribing information for SPIKEVAX.
SPIKEVAX (COVID-19 Vaccine, mRNA)
Injectable suspension, for intramuscular use
2024-2025 Formula
Initial U.S. Approval: 2022

----------RECENT MAJOR CHANGES----------

Dosage and Administration,
Preparation for Administration (2.1) 1/2025

----------INDICATIONS AND USAGE----------

SPIKEVAX 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) in individuals 12 years of age and older. (1)

----------DOSAGE AND ADMINISTRATION----------
- **For intramuscular use.**
- **SPIKEVAX is administered as a single 0.5 mL dose. (2.3)**
- **For individuals previously vaccinated with any COVID-19 vaccine, administer the dose of SPIKEVAX at least 2 months after the last dose of COVID-19 vaccine. (2.3)**

----------DOSAGE FORMS AND STRENGTHS----------

SPIKEVAX is an injectable suspension.
A single dose is 0.5 mL. (3)

----------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. (4)

----------WARNINGS AND PRECAUTIONS----------

Postmarketing data with authorized or approved mRNA COVID19 vaccines demonstrate increased risks of myocarditis and pericarditis, particularly within the first week following vaccination. For SPIKEVAX, the observed risk is highest in males 18 years through 24 years of age. (5.2)

----------ADVERSE REACTIONS----------

Most commonly reported adverse reactions following administration of SPIKEVAX or Moderna COVID-19 Vaccine, Bivalent containing the same amount of mRNA as the SPIKEVAX 2024-2025 Formula (≥10%):

• Participants 12 years through 17 years of age: pain at the injection site (up to 90.6%), fatigue (up to 58.1%), headache (up to 56.3%), myalgia (up to 40.1%), chills (up to 30.2%), axillary swelling/tenderness (up to 27.8%), arthralgia (up to 23.9%), nausea/vomiting (up to 17.9%), and swelling at the injection site (up to 13.3%). (6)
• Participants 18 years through 64 years of age: pain at injection site (up to 86.3%), fatigue (up to 62.0%), headache (up to 58.9%), myalgia (up to 49.6%), arthralgia (up to 41.9%), chills (up to 40.3%), axillary swelling/tenderness (up to 24.8%), and nausea/vomiting (up to 16.7%). (6)
• Participants 65 years of age and older: pain at injection site (up to 76.3%), fatigue (up to 58.1%), myalgia (up to 47.4%),

headache (up to 42.1%), arthralgia (up to 39.5%), chills (up to 18.4%), and axillary swelling/tenderness (up to 14.3%). (6)

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.
See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.
Revised: 1/2025

For further information, see complete package insert:
https://www.fda.gov/media/155675/download?attachment