

From: <Moderna>

Date: <MM/DD/YYYY>

To: <Variable>

Subject Line Option 1: Helping protect your patients with [Spikevax]

Subject Line Option 2: More information on [Spikevax's] efficacy in protecting patients



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Helping to protect your high-risk* patients¹

Dear [HCP's Name],

As COVID-19 continues to evolve, helping to protect your patients from infection can be challenging. Please find important information on [Spikevax (Original)] efficacy against COVID-19 infection, especially for those at high risk for severe infection.¹

Demonstrated efficacy¹

In clinical trials, [Spikevax (Original)] demonstrated clinical effectiveness against COVID-19 infection across a diverse population, including those at high risk for severe COVID-19 infection, and has been updated to target [new variants].¹

[Spikevax (Original)] is about 94% (95% CI: 89.3%–96.8%) effective against COVID-19 infection in adults ≥18 years of age (n=14,134) according to primary endpoint in the COVE trial.¹

94.1% (95% CI: 89.3%–96.8%) effective against COVID-19 infection in adults studied 14 days after dose 2 (median length of 92 days follow-up) based on the COVE case definition^{1,†}

Data analysis as of November 2020, prior to the emergence of the Delta variant²

Patients with pre-existing conditions¹

The COVE trial showed similar efficacy across participants, including those with medical comorbidities associated with a high risk of severe COVID-19 infection.^{1,2}

Risk factors for severe COVID-19 infection —
no. participants (%) at baseline²:

Risk factors	[Spikevax (Original)] (n=15,181)
Chronic lung disease	710 (4.7%)
Significant cardiac disease	752 (5.0%)
Severe obesity	1,025 (6.8%)
Diabetes	1,435 (9.5%)
Liver disease	100 (0.7%)
Human immunodeficiency virus infection	92 (0.6%)

Supporting your high-risk patients

Encourage your patients at high risk of severe COVID-19 infection to make [Spikevax] part of their health routine.^{3,4}

[[Choose/Consider] [Spikevax]]

[API]

COVE trial description: The COVE trial is a phase 3, 1:1 randomised, stratified, observer-blind, placebo-controlled trial evaluating the efficacy and safety of [Spikevax (Original)].

Primary endpoints^{1,2}:

- Determining safety and efficacy of [Spikevax (Original)] in preventing COVID-19
- Reactogenicity of 2 injections of [Spikevax (Original)] given 1 month apart

* Risk for severe COVID-19 infection in the [Spikevax (Original)] phase 3 COVE trial included participants who had at least one of the following risk factors: chronic lung disease; cardiac disease; severe obesity; diabetes; liver disease; or infection with the human immunodeficiency virus.²

† COVE case definition: at least 2 systemic symptoms or at least 1 respiratory symptom and a positive RT-PCR assay.^{1,2}

RT-PCR = reverse transcription polymerase chain reaction.

REFERENCES

1. [Spikevax Summary of Product Characteristics. Moderna; 2024.]
2. Baden LR, El Sahly HM, Essink B, et al. Efficacy and safety of the mRNA-1273 SARS-CoV-2 vaccine. *N Engl J Med.* 2021;384(5):403–416. doi:10.1056/NEJMoa2035389
3. World Health Organization. Coronavirus disease (COVID-19): vaccines and vaccine safety. Updated December 5, 2023. [Accessed August 2, 2024.] [https://www.who.int/news-room/questions-and-answers/item/coronavirus-disease-\(covid-19\)-vaccines](https://www.who.int/news-room/questions-and-answers/item/coronavirus-disease-(covid-19)-vaccines)
4. World Health Organization. WHO roadmap on uses of COVID-19 vaccines in the context of Omicron and high population immunity. Updated November 10, 2023. [Accessed August 2, 2024.] <https://www.who.int/publications/i/item/WHO-2019-nCoV-Vaccines-SAGE-Prioritization-2023.1>



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