

The Medical Letter[®]

on Drugs and Therapeutics

Volume 66

October 28, 2024

ISSUE No.
1714

IN THIS ISSUE

COVID-19 Update: Novavax Vaccine for 2024-2025p 175

Important Copyright Message

FORWARDING OR COPYING IS A VIOLATION OF U.S. AND INTERNATIONAL COPYRIGHT LAWS

The Medical Letter, Inc. publications are protected by U.S. and international copyright laws. Forwarding, copying, or any distribution of this material without permission to a nonsubscriber is prohibited.

Sharing a password with a nonsubscriber or otherwise making the contents of this site available to third parties is prohibited.

By accessing and reading the attached content I agree to comply with U.S. and international copyright laws and these terms and conditions of The Medical Letter, Inc.

For further information click: [Subscriptions](#), [Site Licenses](#), [Reprints](#)
or call customer service at: 800-211-2769

The Medical Letter®

on Drugs and Therapeutics

Volume 66 (Issue 1714)

October 28, 2024

Take CME Exams

COVID-19 Update

Novavax Vaccine for 2024-2025

A 2024-2025 formulation of the Novavax adjuvanted protein subunit COVID-19 vaccine that more closely targets currently circulating SARS-CoV-2 variants is available now under an FDA Emergency Use Authorization (EUA) for use in persons ≥ 12 years old.^{1,2} The 2024-2025 formulations of the mRNA COVID-19 vaccines manufactured by Pfizer/BioNTech (*Comirnaty*) and Moderna (*Spikevax*) were licensed by the FDA last month for use in persons ≥ 12 years old and made available under EUAs for use in persons 6 months to 11 years old.³

THE NEW FORMULATION – The 2024-2025 formulation of the Novavax vaccine contains the spike protein of the JN.1 Omicron strain of SARS-

CoV-2. Currently prevalent “FLiRT” variants (e.g., KP.2, KP.2.3, KP.3, KP.3.1.1, LB.1) are descended from the JN.1 strain.^{4,5} The Pfizer and Moderna 2024-2025 vaccines code for the spike protein of the KP.2 strain.³

EFFECTIVENESS – As with the mRNA COVID-19 2024-2025 vaccines, no clinical studies evaluating the immunogenicity or effectiveness of the 2024-2025 Novavax vaccine are available. Authorization of the new formulation was based on the immunogenicity, safety, and efficacy of previous vaccine formulations.^{1,2}

Observational studies suggest that all of the 2023-2024 formulations of the COVID-19 vaccines available in the US were effective in reducing the incidence of COVID-19, but data specific to the Novavax vaccine are limited. In a case-control analysis of 14,860 COVID-19 nucleic acid amplification tests administered at

Table 1. Recommendations for 2024-2025 COVID-19 Vaccines^{1,2}

Age	Dose/Vial Color	Not Previously Vaccinated	Previously Vaccinated
Pfizer/BioNTech Vaccine (<i>Comirnaty</i>) – mRNA vaccine			
6 months-4 years	3 mcg/0.3 mL; yellow cap and label	Three 3-mcg doses: 1st at week 0, 2nd at week 3, and 3rd ≥ 8 weeks after dose 2 ^{3,4}	1 previous Pfizer dose: One 3-mcg dose ≥ 3 weeks later and 1 dose ≥ 8 weeks after dose 2 ⁴ ≥ 2 previous Pfizer doses: One 3-mcg dose ≥ 8 weeks after last dose
5-11 years	10 mcg/0.3 mL; blue cap and label	One 10-mcg dose	One 10-mcg dose ≥ 2 months after last dose of any mRNA COVID-19 vaccine
≥ 12 years	30 mcg/0.3 mL; gray cap and label	One 30-mcg dose	One 30-mcg dose ≥ 2 months after last dose of any COVID-19 vaccine
Moderna Vaccine (<i>Spikevax</i>) – mRNA vaccine			
6 months-4 years	25 mcg/0.25 mL; dark blue cap/green label	Two 25-mcg doses 1 month apart ³	1 previous Moderna dose: One 25-mcg dose ≥ 1 month after last dose ≥ 2 previous Moderna doses: One 25-mcg dose ≥ 2 months after last dose
5-11 years	25 mcg/0.25 mL; dark blue cap/green label	One 25-mcg dose	One 25-mcg dose ≥ 2 months after last dose of any mRNA COVID-19 vaccine
≥ 12 years	50 mcg/0.5 mL; dark blue cap/blue label	One 50-mcg dose	One 50-mcg dose ≥ 2 months after last dose of any COVID-19 vaccine
Novavax Vaccine – adjuvanted protein subunit vaccine			
≥ 12 years	5 mcg (plus 50 mcg adjuvant)/0.5 mL; blue cap and label	Two 5-mcg doses 3 weeks apart ⁵	One 5-mcg dose ≥ 2 months after last dose of any COVID-19 vaccine

1. The 2024-2025 vaccines contain a monovalent component that corresponds to the KP.2 (Pfizer and Moderna) or JN.1 (Novavax) Omicron variant of SARS-CoV-2.
 2. For immunocompetent persons. Persons with moderate or severe immunocompromise may receive additional doses of the 2024-2025 COVID-19 vaccines based on the clinical judgement of a healthcare provider, personal preference of the patient, and other circumstances; additional doses should be given ≥ 2 months after the last 2024-2025 COVID-19 vaccine dose.
 3. All doses should be from the same manufacturer.
 4. In children who turn 5 years old before completion of the vaccination series, instead administer one 10-mcg Pfizer vaccine dose ≥ 2 months after the last 3-mcg dose.
 5. According to the CDC, an 8-week interval between doses might be optimal for some patients, especially adolescent and young adult males, to reduce the risk of myocarditis and pericarditis (<https://bit.ly/3KgPdxl>).

community pharmacies to immunocompetent adults with COVID-like symptoms between September 2023 and May 2024, receipt of any 2023-2024 COVID-19 vaccine at least 7 days before the test was associated with a decreased incidence of SARS-CoV-2 infection. The estimated adjusted vaccine efficacy was 45%; it was 58% for infections likely caused by the XBB.1.5 variant, which the 2023-2024 vaccines targeted, and 37% for infections likely caused by the JN.1 variant.^{6,7}

In similar analyses of tests administered to adults with COVID-like illness within 10 days before or 3 days after an emergency department/urgent care visit (n=245,504) or a hospitalization (n=77,103) between September 2023 and May 2024, receipt of any 2023-2024 COVID-19 vaccine at least 7 days before the test was associated with a decreased incidence of COVID-19 requiring an emergency department/urgent care visit (estimated adjusted vaccine efficacy 36%) or hospitalization (estimated adjusted vaccine efficacy 42%). Among hospitalized immunocompetent persons, the estimated adjusted vaccine efficacy against critical illness was 58%.^{6,8}

ADVERSE EFFECTS – Adverse effects of previous formulations of the Novavax vaccine have included injection-site pain/tenderness, fatigue/malaise, myalgia, arthralgia, headache, nausea, and vomiting. Hypersensitivity reactions, myocarditis, and pericarditis have occurred rarely; the incidence of myocarditis and pericarditis is highest in adolescent and young adult males.⁹

DOSAGE RECOMMENDATIONS – The 2024-2025 Novavax COVID-19 vaccine is indicated for use in persons ≥ 12 years old. Generally, persons who have not been vaccinated against COVID-19 previously should receive 2 doses 3-8 weeks apart. Those who have been vaccinated against COVID-19 previously should receive a single 0.5-mL dose

≥ 2 months after their last COVID-19 vaccine dose. Additional doses, each given ≥ 8 weeks after the previous dose, can be considered for persons with immunocompromise (solid-organ transplant recipients and equivalent).^{2,10}

CDC RECOMMENDATIONS – The CDC recommends that all persons ≥ 6 months old be immunized with a 2024-2025 COVID-19 vaccine formulation. Persons ≥ 12 years old can receive a Pfizer, Moderna, or Novavax vaccine. Persons 6 months to 11 years old should receive a Pfizer or Moderna vaccine.¹⁰ ■

1. FDA News Release. FDA authorizes updated Novavax COVID-19 vaccine to better protect against currently circulating variants. August 30, 2024. Available at: <https://bit.ly/4g8ZpY6>. Accessed October 9, 2024.
2. FDA. Fact sheet for healthcare providers administering vaccine: Emergency Use Authorization of Novavax COVID-19 vaccine, adjuvanted (2023-2024 formula), for individuals 12 years of age and older. August 2024. Available at: <https://bit.ly/46M6kBa>. Accessed October 9, 2024.
3. COVID-19 update: New Pfizer and Moderna vaccine formulations for 2024-2025. *Med Lett Drugs Ther* 2024; 66:151.
4. COVID-19 Real-Time Learning Network. COVID-19 variant update. September 17, 2024. Available at: <https://bit.ly/3XslucR>. Accessed October 9, 2024.
5. CDC. COVID data tracker. Variant proportions. September 28, 2024. Available at: <https://bit.ly/3Ka3HhH>. Accessed October 9, 2024.
6. R Link-Gelles. Effectiveness of COVID-19 (2023-2024 formula) vaccines. ACIP Meeting COVID-19 Vaccines. June 27, 2024. Available at: <https://bit.ly/4gA1ixl>. Accessed October 9, 2024.
7. R Link-Gelles et al. Early estimates of updated 2023-2024 (monovalent XBB.1.5) COVID-19 vaccine effectiveness against symptomatic SARS-CoV-2 infection attributable to co-circulating Omicron variants among immunocompetent adults - increasing community access to testing program, United States, September 2023-January 2024. *MMWR Morb Mortal Wkly Rep* 2024; 73:77.
8. J DeCuir et al. Interim effectiveness of updated 2023-2024 (monovalent XBB.1.5) COVID-19 vaccines against COVID-19-associated emergency department and urgent care encounters and hospitalization among immunocompetent adults aged ≥ 18 Years – VISION and IVY Networks, September 2023-January 2024. *MMWR Morb Mortal Wkly Rep* 2024; 73:180.
9. CDC. Clinical considerations: myocarditis and pericarditis after receipt of COVID-19 vaccines among adolescents and young adults. October 10, 2023. Available at: <https://bit.ly/3yXicot>. Accessed October 9, 2024.
10. CDC. Interim clinical considerations for use of COVID-19 vaccines in the United States. September 6, 2024. Available at: <https://bit.ly/3KgPdxl>. Accessed October 9, 2024.

PRESIDENT: Mark Abramowicz, M.D.; **VICE PRESIDENT, EDITOR IN CHIEF:** Jean-Marie Pflomm, Pharm.D.; **ASSOCIATE EDITORS:** Susan M. Daron, Pharm.D., Amy Faucard, MLS, Michael P. Viscusi, Pharm.D. **CONSULTING EDITORS:** Joanna Esterow, PA-C, Mordechai Sacks, DMSc, PA-C, Brinda M. Shah, Pharm.D., F. Peter Swanson, M.D.

CONTRIBUTING EDITORS: Carl W. Bazil, M.D., Ph.D., Columbia University College of Physicians and Surgeons; Ericka L. Crouse, Pharm.D., B.C.P.P., C.G.P., F.A.S.H.P., F.A.S.C.P., Virginia Commonwealth University; Vanessa K. Dalton, M.D., M.P.H., University of Michigan Medical School; Eric J. Epstein, M.D., Albert Einstein College of Medicine; David N. Juurlink, BPhM, M.D., Ph.D., Sunnybrook Health Sciences Centre; Richard B. Kim, M.D., University of Western Ontario; Sandip K. Mukherjee, M.D., F.A.C.C., Yale School of Medicine; Dan M. Roden, M.D., Vanderbilt University School of Medicine; Esperance A.K. Schaefer, M.D., M.P.H., Harvard Medical School; Arthur M. F. Yee, M.D., Ph.D., F.A.C.R., Weill Medical College of Cornell University

MANAGING EDITOR AND DIRECTOR OF CONTENT OPERATIONS: Susie Wong; **EDITORIAL ASSISTANT:** Karrie Ferrara

FULFILLMENT AND SYSTEMS MANAGER: Cristine Romatowski; **EXECUTIVE DIRECTOR OF SALES:** Elaine Reaney-Tomaselli

EXECUTIVE DIRECTOR OF MARKETING AND COMMUNICATIONS: Joanne F. Valentino; **INTERIM PUBLISHER:** Jean-Marie Pflomm, Pharm.D.

Founded in 1959 by Arthur Kallet and Harold Aaron, M.D.

Copyright and Disclaimer: The Medical Letter, Inc. is an independent nonprofit organization that provides healthcare professionals with unbiased drug prescribing recommendations. The editorial process used for its publications relies on a review of published and unpublished literature, with an emphasis on controlled clinical trials, and on the opinions of its consultants. The Medical Letter, Inc. does not sell advertising or receive any commercial support. No part of the material may be reproduced or transmitted by any process in whole or in part without prior permission in writing. The Medical Letter, Inc. does not warrant that all the material in this publication is accurate and complete in every respect. The Medical Letter, Inc. and its editors shall not be held responsible for any damage resulting from any error, inaccuracy, or omission.

Subscription Services

Address:

The Medical Letter, Inc.
145 Huguenot St. Ste. 312
New Rochelle, NY 10801-7537
www.medicalletter.org

Customer Service:

Call: 800-211-2769 or 914-235-0500
Fax: 914-632-1733
E-mail: custserv@medicalletter.org

Permissions:

To reproduce any portion of this issue,
please e-mail your request to:
permissions@medicalletter.org

Subscriptions (US):

1 year - \$159; \$65 per year
for students, interns, residents,
and fellows in the US and Canada.
Reprints - \$45 per issue or article

Site License Inquiries:

E-mail: SubQuote@medicalletter.org
Call: 800-211-2769
Special rates available for bulk
subscriptions.

Get Connected: 

Copyright 2024. ISSN 1523-2859

The
Medical
Letter