

The Medical Letter[®]

on Drugs and Therapeutics

Volume 64

Published online December 12, 2022

Online
Article

IN THIS ISSUE

**COVID-19 Update: Bivalent Pfizer and Moderna Vaccines Authorized for Children
≥6 Months Old**

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 is prohibited.

Sharing a password with a non-subscriber or otherwise making the contents of this site available to third parties is strictly 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 64

Published online December 12, 2022

Online
Article

IN THIS ISSUE

Bivalent Pfizer and Moderna Vaccines Authorized for Children ≥ 6 Months Old

COVID-19 Update

Bivalent Pfizer and Moderna Vaccines Authorized for Children ≥ 6 Months Old

The FDA has expanded its Emergency Use Authorizations (EUAs) for the COVID-19 vaccines manufactured by Pfizer/BioNTech (*Comirnaty*) and Moderna (*Spikevax*) to permit use of the bivalent formulations of these products (containing mRNA from the original and BA.4/5 Omicron strains of SARS-CoV-2) in children as young as 6 months. The bivalent Pfizer vaccine is authorized for use as the final dose of a 3-dose primary series in children 6 months to 4 years old. The bivalent Moderna vaccine is authorized for use as a booster dose in children 6 months to 5 years old who completed a primary series with the monovalent Moderna vaccine.¹ Bivalent vaccines had previously been authorized for use as a booster dose in persons ≥ 5 years old (Pfizer) or ≥ 6 years old (Moderna).²

CLINICAL STUDIES – No data on use of the bivalent vaccines in young children are available. Expansion of the EUAs was based on the results of efficacy trials of the corresponding monovalent vaccines in these age groups and on immunogenicity and safety trials of bivalent vaccines containing mRNA from the original and BA.1 Omicron strains of SARS-CoV-2 (not authorized in the US) in adults.^{1,3}

RECOMMENDATIONS – CDC guidelines recommend a 3-dose primary series of the **Pfizer** vaccine for children 6 months to 4 years old. Children should receive two doses of the monovalent formulation given 3-8 weeks apart, followed by a dose of the bivalent formulation given ≥ 8 weeks after the second monovalent dose.⁴ The recommended bivalent vaccine

dose is 3 mcg/0.2 mL (maroon-capped vials).⁵ The monovalent Pfizer vaccine is no longer authorized for use as a third primary-series dose in this population. Children who have already completed a three-dose primary series with the monovalent Pfizer vaccine are not currently eligible for booster immunization.^{1,4}

The CDC recommends that children 6 months to 5 years old receive a booster dose of the bivalent **Moderna** vaccine ≥ 2 months after completing a primary series with the monovalent Moderna vaccine.⁴ The booster dose of the bivalent Moderna vaccine in children 6 months to 5 years old is 10 mcg/0.2 mL (yellow-labeled vials).⁶ ■

1. FDA News Release. Coronavirus (COVID-19) update: FDA authorizes updated (bivalent) COVID-19 vaccines for children down to 6 months of age. December 8, 2022. Available at: <https://bit.ly/3FmZHcm>. Accessed December 13, 2022.
2. COVID update: Bivalent vaccine booster doses authorized for children ≥ 5 years old. *Med Lett Drugs Ther* 2022 October 17 (epub).
3. COVID-19 update: Bivalent Pfizer and Moderna COVID-19 vaccines for booster immunization. *Med Lett Drugs Ther* 2022; 64:159.
4. CDC. Interim clinical considerations for use of COVID-19 vaccines currently approved or authorized in the United States. December 9, 2022. Available at: <https://bit.ly/3KgPdxl>. Accessed December 13, 2022.
5. FDA. Pfizer-BioNTech COVID-19 vaccines. December 8, 2022. Available at: <https://bit.ly/3Mz59fj>. Accessed December 13, 2022.
6. FDA. Moderna COVID-19 vaccines. December 8, 2022. Available at: <https://bit.ly/3MwVyWk>. Accessed December 13, 2022.

Additional Content Available Online: COVID-19 Tables/Charts

Please check our website for the latest information on COVID-19, including our continuously updated tables/charts on treatments, vaccines, and dosing recommendations. Available at: www.medicalletter.org/drugs-for-covid-19.

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; Neal H. Steigbigel, M.D., New York University School of Medicine; 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; 2 years - \$298;
3 years - \$398. \$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 2022. ISSN 0025-732X

The
Medical
Letter