

The Medical Letter[®]

on Drugs and Therapeutics

Volume 63

November 29, 2021

ISSUE No.
1638

IN THIS ISSUE

Pfizer/BioNTech COVID-19 Vaccine Authorized for Children 5-11 Years Oldp 185

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 63 (Issue 1638)

November 29, 2021

Take CME Exams

IN BRIEF

Pfizer/BioNTech COVID-19 Vaccine Authorized for Children 5-11 Years Old

The FDA has issued an Emergency Use Authorization (EUA) for a lower-strength (10 mcg/0.2 mL) formulation of the mRNA-based COVID-19 vaccine manufactured by Pfizer/BioNTech (*Comirnaty*) for use in children 5-11 years old.¹ The original formulation of *Comirnaty* (30 mcg/0.3 mL) is FDA-licensed for use in persons ≥ 16 years old and available under an EUA for use in adolescents 12-15 years old.^{2,3}

CLINICAL STUDIES — A study compared the immunogenicity of a 10-mcg dose of *Comirnaty* in 264 children 5-11 years old with that of a 30-mcg dose in 253 persons 16-25 years old. Geometric mean titer levels of anti-SARS-CoV-2 neutralizing antibodies 1 month after the second dose in the two groups were similar (1197.6 vs 1146.5), and 99.2% of persons in each group experienced a seroresponse.⁴

In an observer-blind efficacy trial, 1968 children 5-11 years old with no evidence of prior SARS-CoV-2 infection were randomized 2:1 to receive *Comirnaty* 10 mcg or placebo at 0 and 3 weeks. There were 3 cases of COVID-19 with onset ≥ 7 days after the second dose in children who received the vaccine and 16 cases in those who received placebo; the vaccine efficacy rate was 90.7%. No cases of severe COVID-19 or hospitalizations due to COVID-19 occurred in either group.⁴

ADVERSE EFFECTS — The 10-mcg dose of *Comirnaty* appears to be better tolerated in children 5-11 years old than the 30-mcg dose is in adolescents 12-15 years old. In the efficacy trial, fatigue, headache, muscle pain, and injection-site pain and redness were common following administration of the vaccine. Most adverse effects were mild or moderate

in severity and occurred at a higher frequency after the second dose. No serious adverse effects related to vaccination, including myocarditis/pericarditis and anaphylaxis, were reported.⁴⁻⁶

DOSAGE AND ADMINISTRATION — The new *Comirnaty* formulation is supplied in vials with orange rather than purple caps. After the contents are diluted with 1.3 mL of normal saline, each vial provides ten 10 mcg/0.2 mL doses of the vaccine. Children 5-11 years old should receive two 10-mcg primary doses of the vaccine intramuscularly 3 weeks apart.⁷ Booster doses of *Comirnaty* have not been authorized for use in children to date. ■

Additional Content Available Online

COVID-19 Vaccine Dosing Recommendations

http://medicalletter.org/downloads/1636f_table.pdf

COVID-19 Vaccine Comparison Chart

http://medicalletter.org/downloads/1621g_table.pdf

1. FDA News Release. FDA authorizes Pfizer-BioNTech COVID-19 vaccine for emergency use in children 5 through 11 years of age. October 29, 2021. Available at: <https://bit.ly/3waEUDC>. Accessed November 10, 2021.
2. FDA authorizes Pfizer-BioNTech COVID-19 vaccine. *Med Lett Drugs Ther* 2021; 63:1.
3. In brief: Pfizer/BioNTech COVID-19 vaccine authorized for adolescents 12-15 years old. *Med Lett Drugs Ther* 2021; 63:81.
4. EB Walter et al. Evaluation of the BNT162b2 Covid-19 vaccine in children 5 to 11 years of age. *N Engl J Med* 2021 November 9 (epub).
5. FDA. Fact sheet for health care providers administering vaccine (vaccination providers). Emergency Use Authorization (EUA) of the Pfizer-BioNTech COVID-19 vaccine to prevent coronavirus disease 2019 (COVID-19). For 5-11 years of age. October 29, 2021. Available at: <https://bit.ly/3jX9xri>. Accessed November 10, 2021.
6. FDA. Fact sheet for health care providers administering vaccine (vaccination providers). Emergency Use Authorization (EUA) of the Pfizer-BioNTech COVID-19 vaccine to prevent coronavirus disease 2019 (COVID-19). For 12 years of age and older. October 29, 2021. Available at: <https://bit.ly/3bBH5GV>. Accessed November 10, 2021.
7. CDC News Release. CDC recommends pediatric COVID-19 vaccine for children 5-11 years. November 2, 2021. Available at: <https://bit.ly/3k1T12T>. Accessed November 10, 2021.

PRESIDENT: Mark Abramowicz, M.D.; **VICE PRESIDENT AND EXECUTIVE EDITOR:** Gianna Zuccotti, M.D., M.P.H., F.A.C.P., Harvard Medical School
VICE PRESIDENT AND EDITOR IN CHIEF: Jean-Marie Pflomm, Pharm.D.; **ASSOCIATE EDITORS:** Susan M. Daron, Pharm.D., Amy Faucard, MLS, Corinne Z. Morrison, Pharm.D., 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 editors do not warrant that all the material in this publication is accurate and complete in every respect. The 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 2021. ISSN 1523-2859

