

The Medical Letter[®]

on Drugs and Therapeutics

Volume 63

May 31, 2021

ISSUE No.

1625

IN THIS ISSUE

In Brief: Pfizer/BioNTech COVID-19 Vaccine Authorized for Adolescents 12-15 Years Old ...p 81

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 1625)

May 31, 2021

Take CME Exams

IN BRIEF

Pfizer/BioNTech COVID-19 Vaccine Authorized for Adolescents 12-15 Years Old

On May 10, 2021, the FDA expanded its Emergency Use Authorization (EUA) for the Pfizer/BioNTech mRNA-based COVID-19 vaccine to include adolescents 12-15 years old.¹ The vaccine has been authorized for use in persons ≥ 16 years old since December 2020.²

Expansion of the EUA was based on the results of an observer-blind trial (summarized in the FDA Fact Sheet) in 2260 adolescents 12-15 years old who were randomized 1:1 to receive the Pfizer/BioNTech vaccine or placebo at 0 and 3 weeks. There were 0 cases of COVID-19 with onset ≥ 7 days after the second dose among SARS-CoV-2-naive subjects who received the vaccine and 16 cases among those who received placebo. Compared to persons 16-25 years old who received the Pfizer/BioNTech vaccine, vaccinated adolescents 12-15 years old had numerically higher geometric mean titer levels of SARS-CoV-2 neutralizing antibodies (1239.5 vs 705.1) and similar adverse effects.³

With the expansion of the EUA, the FDA has added a warning to the vaccine Fact Sheet describing a risk of syn-cope following injection; the risk is higher in adolescents than in adults.³ Clinical trials evaluating use of the vaccine in children 6 months to 11 years old are ongoing.⁴ ■

1. FDA News Release. Coronavirus (COVID-19) update: FDA authorizes Pfizer-BioNTech COVID-19 vaccine for emergency use in adolescents in another important action in fight against pandemic. May 10, 2021. Available at: <https://bit.ly/3y4KYhO>. Accessed May 11, 2021.
2. FDA authorizes Pfizer-BioNTech COVID-19 vaccine. Med Lett Drugs Ther 2021; 63:1.
3. 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). Available at: <https://bit.ly/37fX1NG>. Accessed May 11, 2021.
4. Pfizer Press Release. Pfizer-BioNTech announce positive topline results of pivotal COVID-19 vaccine study in adolescents. March 31, 2021. Available at: <https://bit.ly/3h3i1MT>. Accessed May 11, 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; Franco M. Muggia, M.D., New York University Medical Center; 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

FULLFILLMENT 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

The
 Medical
 Letter