

# The Medical Letter<sup>®</sup>

## on Drugs and Therapeutics

Volume 64

June 13, 2022

ISSUE No.  
**1652**

### IN THIS ISSUE

COVID-19 Update: Booster Dose of the Pfizer Vaccine for Children 5-11 Years Old .....p 94

## 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 (Issue 1652)

June 13, 2022

### COVID-19 UPDATE

#### Booster Dose of the Pfizer Vaccine for Children 5-11 Years Old

The FDA has expanded its Emergency Use Authorization for the mRNA COVID-19 vaccine manufactured by Pfizer/BioNTech (*Comirnaty*) to include administration of a booster dose in children 5-11 years old who completed a primary series of the Pfizer vaccine  $\geq 5$  months previously.<sup>1</sup>

**IMMUNOGENICITY** – Expansion of the EUA was based on the results of an immunogenicity trial (summarized in the FDA Fact Sheet) in 67 children 5-11 years old who received a booster dose of the Pfizer vaccine 7-9 months after completing a 2-dose primary series. Geometric mean neutralizing antibody titer (GMT) levels against an ancestral reference strain of SARS-CoV-2 were about 10-fold higher 1 month after the booster dose than they were before it. In a population subset, GMT levels against an Omicron variant of SARS-CoV-2 (B.1.1.529) were about 22-fold higher 1 month after the booster dose than they were 1 month after the second primary-series dose.<sup>2</sup>

**SAFETY** – In a safety trial in 371 children 5-11 years old (summarized in the FDA Fact Sheet), injection-site pain, swelling, and erythema, fatigue, headache, muscle pain, and chills were common following administration of a booster dose of the Pfizer vaccine. The rates of these adverse effects were similar to those with primary-series doses of the vaccine. Most adverse effects were mild to moderate in severity.<sup>2</sup>

**DOSAGE AND ADMINISTRATION** – In children 5-11 years old, the booster dose of the Pfizer vaccine is the same as the dose for primary immunization (10 mcg IM). A single booster dose may be given  $\geq 5$  months after completion of a 2-dose or, in moderately or severely immunocompromised children, a 3-dose primary series.<sup>2</sup> ■

1. FDA News Release. Coronavirus (COVID-19) update: FDA expands eligibility for Pfizer-BioNTech COVID-19 vaccine booster dose to children 5 through 11 years. May 17, 2022. Available at: <https://bit.ly/3PsFgPd>. Accessed May 23, 2022.
2. 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. May 17, 2022. Available at: <https://bit.ly/3jX9xri>. Accessed May 23, 2022.

**PRESIDENT:** Mark Abramowicz, M.D.; **VICE PRESIDENT:** Gianna Zuccotti, M.D., M.P.H., F.A.C.P., Harvard Medical School **VICE PRESIDENT, 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](mailto:custserv@medicalletter.org)

##### Permissions:

To reproduce any portion of this issue, please e-mail your request to: [permissions@medicalletter.org](mailto: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](mailto:SubQuote@medicalletter.org)  
Call: 800-211-2769  
Special rates available for bulk  
subscriptions.

Get Connected:    

Copyright 2022. ISSN 0025-2859

