



Advisory Commission on Childhood Vaccines (ACCV)

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U.S. Food and Drug Administration
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Pfizer BioNTech COVID-19 Vaccine Authorized for Use in Children 5 through 11 Years of Age

- October 29, 2021- FDA authorized the emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 to include children 5 through 11 years of age.
- For this age group, the Pfizer-BioNTech COVID-19 Vaccine is supplied in multiple dose vials with orange caps and labels with orange borders and is administered intramuscularly as a primary series of 2 doses (0.2 mL each) 3 weeks apart.
- The Fact Sheet for Healthcare Providers Administering Vaccine is available at <https://www.fda.gov/media/153714/download>. The Fact Sheet for Recipients and Caregivers is available at <https://www.fda.gov/media/153717/download>.
- FDA convened its Vaccines and Related Biological Products Advisory Committee on this topic on October 26, 2021.

September 2021

Pfizer BioNTech COVID-19 Vaccine- Authorization of Booster Dose for Certain Populations

- September 22, 2021- FDA amended the Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 Vaccine to allow for use of a single booster dose, to be administered at least six months after completion of the primary series to individuals as follows:
 - 65 years of age and older
 - 18 through 64 years of age at high risk of severe COVID-19
 - 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19.
- FDA convened its Vaccines and Related Biological Products Advisory Committee on this topic on September 17, 2021.

October 2021

Use of a Booster Dose for COVID-19 Vaccines

- October 20, 2021- FDA amended the EUAs for COVID-19 vaccines to allow for the use of a single booster dose as follows:
 - The use of a single booster dose of Moderna COVID-19 Vaccine that may be administered at least 6 months after completion of the primary series to individuals: 65 years of age and older, 18 through 64 years of age at high risk of severe COVID-19 and 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2.
 - The use of a single booster dose of Janssen COVID-19 Vaccine that may be administered at least 2 months after completion of the single-dose primary regimen to individuals 18 years of age and older.
 - The use of each of the available COVID-19 vaccines as a heterologous booster dose in eligible individuals following completion of primary vaccination with a different available COVID-19 vaccine.

October 2021

Use of a Booster Dose for COVID-19 Vaccines continued

- To clarify that a single booster dose of the Pfizer-BioNTech COVID-19 Vaccine may be administered at least 6 months after completion of the primary series to individuals 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2.
- FDA convened its Vaccines and Related Biological Products Advisory Committee on October 14 and 15, 2021 to discuss the administration of a single booster dose for the Moderna COVID-19 Vaccine and Janssen COVID-19 Vaccine respectively.

November 2021

FDA Expands Eligibility for Use of a Single Booster

- November 19, 2021- FDA amended the EUA for both the Moderna and Pfizer-BioNTech COVID-19 vaccines authorizing use of a single booster dose for all individuals 18 years of age and older after completion of primary vaccination with any FDA-authorized or approved COVID-19 vaccine.
- FDA amended the EUA for the Janssen COVID-19 Vaccine authorizing use of a single booster dose for all individuals 18 years of age and older after completion of primary vaccination with a different authorized or approved COVID-19 vaccine.

Vaxneuvance

- Not previously reported- Vaxneuvance was approved in July 2021.
- Indication and Usage- for the prevention of invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F in adults 18 years of age and older.
- The vaccine is manufactured by Merck Sharpe & Dohme Corp.

FDA COVID-19 Website

- FDA has a website dedicated to its COVID-19 activities, including FDA's pandemic response activities pertaining to vaccines, testing, therapeutics, and devices. The website is frequently updated and is a resource for the public, including healthcare providers and industry.
<https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19>



Thank you!