

At-A-Glance: Pfizer-BioNTech COVID-19 Vaccine

On December 11, 2020, the Food and Drug Administration (FDA) issued an emergency use authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine. Vaccine providers should reference FDA's [Fact Sheet for Healthcare Providers Administering Vaccines](#) for complete information. APhA summarized the information below to assist pharmacists, pharmacy technicians, and pharmacy interns.

Considerations for Use

The CDC Advisory Committee on Immunization Practices (ACIP) [interim recommendation](#) is for persons aged ≥ 16 years for the prevention of COVID-19.

Administration

- 2 doses (30 Qg, 0.3 mL each) are administered I.M. separated by 3 weeks (21 days).
 - **1st Dose:** Day 0
 - **2nd Dose:** Day 21. Administration between days 17 and 21 is considered valid. After day 21, administer at earliest opportunity.
- Both doses are needed for protection. Efficacy of single dose has not been systematically evaluated.
- Routine prophylaxis for the purposes of preventing symptoms is not recommended at this time.

Interchangeability

- **Not interchangeable** with other COVID-19 vaccine products.
- Complete the vaccine series with the same product.
- If 2 doses of different mRNA COVID-19 vaccine products are inadvertently administered, no additional doses of either product are recommended at this time.

Coadministration with other vaccines

- Administer alone. Administer at least 14 days before or after administration of other vaccines.
- If inadvertently administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine.

Postvaccination symptoms

- Before vaccination, counsel about expected local and systemic postvaccination symptoms, which may include pain at the injection site, fatigue, headache, muscle pain, chills, joint pain, fever, injection site swelling, injection site redness, nausea, malaise, and lymphadenopathy.
- Acetaminophen or ibuprofen may be taken for treatment of postvaccination symptoms.
- Unless a person develops a contraindication, they should be encouraged to complete the series even if they develop postvaccination symptoms.

At-A-Glance: Pfizer-BioNTech COVID-19 Vaccine (continued)



Contraindications and precautions

- Recommend against use in individuals with known history of severe allergic reaction to any component of the Pfizer-BioNTech COVID-19 vaccine. Persons who have had a severe allergic reaction to any vaccine or injectable therapy (I.M., I.V., or subcutaneous) should not receive the vaccine at this time.
- Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the vaccine.
- Vaccine providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions:
 - Persons with a history of anaphylaxis: 30 minutes
 - All other persons: 15 minutes

Considerations Related to Infection and Testing

Persons with a history of SARS-CoV-2 infection

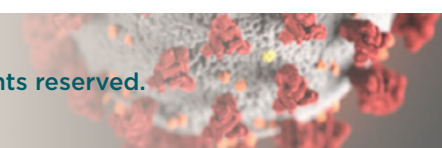
- Vaccination should be offered to persons regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection.
- Viral or serologic testing for acute or prior infection, respectively, is not recommended for the purpose of vaccine decision making.

Persons with known current SARS-CoV-2 infection

- Vaccination should be deferred until recovery from acute illness (if person had symptoms) and criteria have been met to discontinue isolation.
- No minimal recommended interval between infection and vaccination.
 - Reinfection is uncommon in the 90 days after initial infection, so persons may defer vaccination until the end of this period, if desired.

Persons who previously received passive antibody therapy for COVID-19

- Vaccination should be deferred for at least 90 days to avoid interference of the treatment with vaccine-induced immune responses.



At-A-Glance: Pfizer-BioNTech COVID-19 Vaccine (continued)

Persons with a known SARS-CoV-2 exposure

- **Community or outpatient setting:** Defer vaccination until quarantine period has ended.
- **Residents of congregate health care settings (e.g., long-term care facilities):** They can be vaccinated. Employ appropriate infection prevention and control procedures.

Impact on SARS-CoV-2 testing

- **Viral tests:**
 - Prior receipt of the Pfizer-BioNTech COVID-19 vaccine will not affect the results of SARS-CoV-2 nucleic acid amplification or antigen tests.
- **Antibody tests:**
 - Currently available antibody tests for SARS-CoV-2 assess IgM and/or IgG to spike or nucleocapsid proteins.
 - Pfizer-BioNTech COVID-19 vaccine contains mRNA that encodes the spike protein; thus, a positive test for spike protein IgM/IgG could indicate either prior infection or vaccination.
 - To evaluate for evidence of prior infection in an individual with a history of Pfizer-BioNTech COVID-19 vaccination, use a test specifically evaluating IgM/IgG to the nucleocapsid protein.

Special Populations

Persons with underlying medical conditions

- Vaccine may be administered to persons with underlying medical conditions who have no contraindications to vaccination.

Immunocompromised persons

- Data are not currently available to establish safety and efficacy of vaccine in these groups.
- These individuals may still receive COVID-19 vaccine unless otherwise contraindicated.
- Individuals should be counseled about—
 - Unknown vaccine safety and efficacy profiles in immunocompromised persons.
 - Potential for reduced immune responses.
 - Need to continue to follow all current guidance to protect themselves against COVID-19.

At-A-Glance: Pfizer-BioNTech COVID-19 Vaccine (continued)

Pregnant women

- No data on the safety of COVID-19 vaccines in pregnant women; studies are ongoing, and more are planned.
- Consider risk versus benefit. Issues to consider:
 - Level of COVID-19 community transmission (risk of acquisition)
 - Her personal risk of contracting COVID-19 (by occupation or other activities)
 - The risks of COVID-19 to her and potential risks to the fetus
 - The efficacy of the vaccine
 - The known side effects of the vaccine
 - The lack of data about the vaccine during pregnancy
- Pregnant women who experience fever following vaccination should be counseled to take acetaminophen as fever has been associated with adverse pregnancy outcomes.

Breastfeeding/Lactating women

- No data on the safety of COVID-19 vaccines in lactating women or the effects of mRNA vaccines on the breastfed infant or milk production/excretion.
- mRNA vaccines are not considered live virus vaccines and are not thought to be a risk to the breastfeeding infant.
- If a lactating woman is part of a group (e.g., health care personnel) who is recommended to receive a COVID-19 vaccine, she may choose to be vaccinated.

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