Pfizer-BioNTech COVID-19 Vaccine

On December 11, 2020, the U.S. Food and Drug Administration issued the first emergency use authorization (EUA) for a vaccine for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older. The emergency use authorization allows the Pfizer-BioNTech COVID-19 Vaccine to be distributed in the U.S.

Emergency Use Authorization Status:

Authorized

Name:

Pfizer-BioNTech COVID-19 Vaccine

Manufacturer:

Pfizer Inc.

Authorized Use

For the prevention of 2019 coronavirus disease (COVID-19) for individuals 16 years of age and older

Common Side Effects

The most commonly reported side effects, which typically lasted several days, were pain at the injection site, tiredness, headache, muscle pain, chills, joint pain, and fever. Of note, more people experienced these side effects after the second dose than after the first dose, so it is important for vaccination providers and recipients to expect that there may be some side effects after either dose, but even more so after the second dose. Learn more (/media/144414/download).

Additional Information

- Letter of Authorization (/media/144412/download)
- Fact Sheet for Healthcare Providers Administering Vaccine (/media/144413/download)
- Fact Sheet for Recipients and Caregivers (/media/144414/download)
- FDA Decision Memorandum (/media/144416/download)

- Press Release (/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19)
- 12/10/2020 Advisory Committee Meeting Information (/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-10-2020-meeting-announcement)