



About the Pfizer-BioNTech COVID-19 Vaccine

This document last updated December 20, 2020 12PM

See FULL Emergency Use Authorization at <https://www.fda.gov/media/144413/download> for complete information.

Vaccine Type: Messenger RNA; contains no protein, preservative, or live virus

Dose/Dose Schedule: Two doses of 0.3ml given IM, administered at least 21 days apart

Emergency Use Authorization: Issued December 11, 2020 for individuals 16 and older

- **Phase 3 Trial Participants receiving two doses:** 36,523
 - **FDA Required minimum followup:** 2 Months
- **Manufacturer clinical trial data submitted:** 11/20/2020
- **FDA Review completed:** 12/8/2020
- **Independent Review Panels:** Reviews completed 12/10/2020

Efficacy and Safety data reported in Phase 3 clinical trials:

- Primary efficacy analysis: 95% effective **beginning 7 days after the second dose**
 - 170 confirmed cases of COVID-19 in clinical trial population
 - 162 observed in the placebo group
 - 8 in the vaccine group
- Efficacy was consistent across age, gender, race and ethnicity demographics; observed efficacy in adults over 65 years of age was over 94%
- No Grade 4 safety concerns observed (requiring ER or Hospitalization); the only Grade 3 (prevents daily activity) adverse events greater than 2% in frequency were **fatigue at 3.8% and headache at 2.0%; Fever > 102degF reported in 1.2%**
- Most common side effects, in descending order: Pain at injection site, fatigue, headache, muscle pain, chills, joint pain, fever, injection site swelling, injection site redness, nausea
 - Side effects transient and usually less than 2 - 2.5 days; **more common after 2nd dose**
- Older adults tended to report fewer and milder side effects

Official Contraindications

- Known history of severe reaction to the vaccine or any component of the vaccine

Other Considerations

- Caution advised in known or possible pregnancy, breastfeeding, and patients with known history severe allergic reactions (e.g.: anaphylaxis) to other vaccines or injectable medications
- May be less effective in those receiving immunosuppressive therapy
- Vaccine **should** be offered to individuals who have previously been diagnosed with COVID-19

Vaccine Storage and Stability

- Shipped frozen at -70degC (-94F); stable 6 months
- Refrigerated at 2 to 8degC (36-46F); stable 5 days
- Thaw in refrigerator for 3 hours or room temp for 30 minutes
- Dilute prior to administration; diluted product must be used within 6 hours

References:

1. New England Journal of Medicine, Dec 10, 2020: <https://www.nejm.org/doi/full/10.1056/NEJMoa2034577>
2. UK National Health Service, Dec 10, 2020: <https://www.sps.nhs.uk/articles/pfizer-biontech-covid-19-vaccine-cautions-and-contraindications/>
3. FDA Full Emergency Use Authorization and Fact Sheet for Healthcare Providers, Dec 11, 2020: <https://www.fda.gov/media/144413/download>