Guardian Consulting Services, Inc.

Consultant Pharmacists for Healthcare Organizations, Industry, and the Community

About the Moderna COVID-19 Vaccine

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See FULL Emergency Use Authorization at https://www.fda.gov/media/144637/download for complete information.

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

Dose/Dose Schedule: Two doses of 0.5ml given IM, administered one month apart

Emergency Use Authorization: Issued December 18, 2020 for use in individuals 18 and over

- **Phase 3 Trial Participants:** 30,351
  - **FDA Required minimum followup:** 2 Months
- **Manufacturer clinical trial data submitted:** 11/30/2020
- **FDA Review completed:** 12/17/2020
- **Independent Review Panels:** Reviews completed 12/18/2020

Efficacy and Safety data reported in Phase 3 clinical trials:

- Primary efficacy analysis: 94.1% effective ***beginning 7 days after the second dose***
  - 196 confirmed cases of COVID-19 in clinical trial population
    - 185 observed in the placebo group
    - 11 in the vaccine group
- Efficacy was consistent across age, gender, race and ethnicity demographics.
- As of November 25th, 2020, serious adverse events from the Phase 3 clinical trial participants were reported in 147 individuals receiving the vaccine, and 153 who received placebo.
  - In the vaccine group: one case of intractable nausea and vomiting; and one case of Bell's palsy occurring 32 days after receipt of vaccine
- Most common side effects, in descending order: Pain at injection site, fatigue, headache, muscle pain, joint pain, chills, nausea/vomiting, axillary swelling, fever, swelling at injection site
  - Side effects usually transient and 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

- Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration.
- 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 -25 to -15C (-13 to +5F); do not store on dry ice or below -40C (-40F)
- May be stored at 2 to 8degC (36 to 46F) up to 30 days prior to first use. Do not re-freeze.
- Unpunctured vials may be stored at 8 to 25C (46 to 77F) up to 12 hours
- After first dose removed, maintain at 2 to 25C (36 to 77F), discard after 6 hours. Do not re-freeze.

References:

1. US FDA: https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid
2. The British Medical Journal, Nov 17, 2020: https://www.bmj.com/content/371/bmj.m4471
3. FDA Full Emergency Use Authorization and Fact Sheet for Healthcare Providers, Dec 18, 2020: https://www.fda.gov/media/144637/download
4. COCA Crisis Standards of Care: https://emergency.cdc.gov/coca/ppt/2020/12.18.2020_COCA_Pfizer-BioNTech-and-Moderna_COMBINED-2.pdf