August, 2025

IMPORTANT PRESCRIBING INFORMATION

Subject: Unapproved Prescribing Information

Certain lots of COMIRNATY® (COVID-19 Vaccine, mRNA) 2025-2026 Formula contain unapproved Prescribing Information inside the cartons.

Dear Healthcare Provider,

The purpose of the letter is to inform vaccination providers that certain lots of COMIRNATY® (COVID-19 Vaccine, mRNA) 2025-2026 Formula contain unapproved Prescribing Information inside the cartons. The inclusion of information, in Sections 6 and 14, on concomitant administration of Pfizer-BioNTech COVID-19 Vaccine, Bivalent with a respiratory syncytial virus (RSV) vaccine or with an RSV vaccine and an influenza vaccine in individuals 65 years of age and older has not been approved by the U.S. Food and Drug Administration (FDA).

Lots affected: MY9547; MY9548; MY9550; NA0587; NA0589; NA0590; NA0738; NA0739; NA0846; NA4451; NA4452; NA4457; NA4459

The FDA-approved Prescribing Information for COMIRNATY® is enclosed and also can be accessed at https://dailymed.nlm.nih.gov/dailymed/.

Indications and Usage

COMIRNATY® is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

COMIRNATY® is approved for use in individuals who are:

- 65 years of age and older, or
- 5 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.

Reporting Adverse Events

Report adverse events following use of COMIRNATY® to Pfizer at 1(877) 829-2619 or to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 and www.vaers.hhs.gov.

Should you have any questions about the use of the COMIRNATY® you can contact Pfizer at 1(877) 829-2619.

Sincerely,

/s/

Paul Balmer, PhD
United States Vaccines Medical Lead