

Moderna COVID-19 Vaccines

Moderna COVID-19 Vaccine, Bivalent Now Authorized For All Doses

April 18, 2023: FDA authorizes changes to simplify use of bivalent mRNA COVID-19 vaccines. Read the [press release \(/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-changes-simplify-use-bivalent-mrna-covid-19-vaccines\)](#) and listen to the [media call \(https://youtu.be/bT5XM9Rti_A\)](#) [↗](#) (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>).

[Fact Sheets](#)

[Fact Sheet Translations](#)

[Información sobre las vacunas para el COVID-19 \(https://www.fda.gov/about-fda/fda-en-espanol/informacion-sobre-las-vacunas-para-el-covid-19\)](https://www.fda.gov/about-fda/fda-en-espanol/informacion-sobre-las-vacunas-para-el-covid-19)

On April 18, 2023, the Food and Drug Administration amended the emergency use authorization (EUA) of Moderna COVID-19 Vaccine, Bivalent to simplify the vaccination schedule for most individuals. This action includes authorizing the current bivalent vaccine (Original and Omicron BA.4/BA.5 strains) to be used for all doses administered to individuals 6 months of age and older. The [monovalent Moderna COVID-19 Vaccine \(/vaccines-blood-biologics/industry-biologics/coronavirus-covid-19-cber-regulated-biologics\)](#) is no longer authorized for use in the United States.

Moderna COVID-19 Vaccine, Bivalent is now authorized for use as follows:

Individuals 6 months through 5 years of age:

- **Unvaccinated individuals:** Two doses of Moderna COVID-19 Vaccine, Bivalent are administered. The second dose is administered 1 month after the first.
- **Individuals who have received one dose of Moderna COVID-19 Vaccine:** A single dose of Moderna COVID-19 Vaccine, Bivalent is administered 1 month after the dose of Moderna COVID-19 Vaccine.
- **Individuals who have received two doses of Moderna COVID-19 Vaccine:** A single dose of Moderna COVID-19 Vaccine, Bivalent is administered at least 2 months after the last dose of Moderna COVID-19 Vaccine.

Individuals 6 years of age and older:

- **Unvaccinated individuals:** A single dose of Moderna COVID-19 Vaccine, Bivalent.
- **Individuals who have received one or more doses of a monovalent COVID-19 vaccine:** A single dose of Moderna COVID-19 Vaccine, Bivalent is administered at least 2 months after any monovalent COVID-19 vaccine.
- **Individuals 65 years of age and older who have received one dose of a bivalent COVID-19 vaccine:** A dose of Moderna COVID-19 Vaccine, Bivalent may be administered at least 4 months after the dose of the bivalent COVID-19 vaccine.

Immunocompromised individuals 6 months of age and older:

- For immunocompromised individuals 6 months through 5 years of age who have received two doses (Moderna COVID-19 Vaccine or Moderna COVID-19 Vaccine, Bivalent), a single additional dose of Moderna COVID-19 Vaccine, Bivalent may be administered at least 1 month following the most recent dose of Moderna COVID-19 Vaccine, Bivalent; additional doses of Moderna COVID-19 Vaccine, Bivalent may be administered at the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances.
- For immunocompromised individuals 6 years of age and older, a single additional age-appropriate dose of Moderna COVID-19 Vaccine, Bivalent may be administered at least 2 months following the initial dose of a bivalent COVID-19 vaccine; additional age-appropriate doses of Moderna COVID-19 Vaccine, Bivalent may be administered at the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances.

Moderna COVID-19 Vaccine Fact Sheets and Materials

Material	Audience	Last Updated
Fact Sheet (/media/167209/download)	Recipient and Caregiver	April 18, 2023
Fact Sheet (/media/167208/download)	Healthcare Professionals	April 18, 2023
Dear Healthcare Provider Letter (/media/167210/download)	Healthcare Professionals	April 18, 2023

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Moderna COVID-19 Vaccine Regulatory Information (Emergency Use Authorization)

Information	Date
Decision Memorandum (/media/167306/download)	April 18, 2023
Letter of Authorization (/media/144636/download) , (Reissued)	April 18, 2023

Federal Register Notices

Title	Date
<p>Authorizations of Emergency Use of Two Biological Products During the COVID-19 Pandemic: Availability (https://www.federalregister.gov/documents/2021/01/19/2021-01022/authorizations-of-emergency-use-of-two-biological-products-during-the-covid-19-pandemic-availability).</p>	January 19, 2021

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Translations of the Fact Sheet for Recipients and Caregivers

<p>关于具有紧急使用授权 (EUA) 的预防2019年冠状病毒疾病(Covid-19)的 莫德纳二价疫苗的受种者和照顾者情况说明书 (/media/167289/download), (April 18, 2023)</p>	中文 (Chinese, Simplified)
<p>코로나바이러스 감염증 2019(코로나19) 예방을 위한 긴급사용승인(EUA)을 받은 모더나 코로나19 2가 백신 접종자 및 보호자를 위한 사실 보고서 (/media/167286/download), (April 18, 2023)</p>	한국어 (Korean)
<p>HOJA DE INFORMACIÓN PARA RECEPTORES Y CUIDADORES SOBRE LA VACUNA BIVALENTE CONTRA EL COVID-19 DE MODERNA QUE CUENTA CON AUTORIZACIÓN DE USO DE EMERGENCIA (EUA) PARA PREVENIR LA ENFERMEDAD DEL CORONAVIRUS 2019 (COVID-19) (/media/167285/download), (April 18, 2023)</p>	Español (Spanish)
<p>FACT SHEET PARA SA MGA TUMATANGGAP AT TAGAPAG-ALAGA TUNGKOL SA BAKUNANG MODERNA PARA SA COVID-19 NA BIVALENT ALIN ANG MAY AWTORISASYON PARA SA PANG-EMERHENSYANG PAGGAMIT (EUA) PARA MAIWASAN ANG SAKIT NA CORONAVIRUS 2019 (COVID-19) (/media/167287/download), (April 18, 2023)</p>	Tagalog (Tagalog)
<p>TỜ THÔNG TIN DÀNH CHO NGƯỜI NHẬN VẮC-XIN VÀ NGƯỜI CHĂM SÓC VỀ VẮC-XIN NGỪA COVID-19 MODERNA, LƯU ÝNG TRỊ GIẤY PHÉP SỬ DỤNG KHẨN CẤP (EUA) ĐỂ PHÒNG CHỐNG BỆNH VI-RÚT CORONA 2019 (COVID-19) (/media/167288/download), (April 18, 2023)</p>	Tiếng Việt (Vietnamese)