

Comirnaty and Pfizer-BioNTech COVID-19 Vaccine

August 23, 2021: FDA approves Comirnaty (COVID-19 Vaccine, mRNA), which was previously known as Pfizer-BioNTech COVID-19 Vaccine, for the prevention of COVID-19 disease in individuals 16 years of age and older. View [Comirnaty information](https://www.fda.gov/vaccines-blood-biologics/comirnaty) (<https://www.fda.gov/vaccines-blood-biologics/comirnaty>), [press release](#) (</news-events/press-announcements/fda-approves-first-covid-19-vaccine>) and [frequently asked questions](https://www.fda.gov/vaccines-blood-biologics/qa-comirnaty-covid-19-vaccine-mrna) (<https://www.fda.gov/vaccines-blood-biologics/qa-comirnaty-covid-19-vaccine-mrna>).

[Comirnaty Information](#)

[Pfizer-BioNTech Fact Sheets](#)

[Pfizer-BioNTech Fact Sheet Translations](#)

On August 23, 2021, the FDA approved the first COVID-19 vaccine. The vaccine has been known as the Pfizer-BioNTech COVID-19 Vaccine, and will now be marketed as [Comirnaty](/vaccines-blood-biologics/comirnaty) (</vaccines-blood-biologics/comirnaty>), for the prevention of COVID-19 disease in individuals 16 years of age and older. The vaccine also continues to be available under emergency use authorization (EUA), including for individuals 12 through 15 years of age and for the administration of a third dose in certain immunocompromised individuals.

[Comirnaty](/vaccines-blood-biologics/comirnaty) (</vaccines-blood-biologics/comirnaty>) Information

Information	Last Updated
Package Insert (/media/151707/download)	August 23, 2021
Summary Basis for Regulatory Action (https://www.fda.gov/media/151733/download)	August 23, 2021
Approval Letter (https://www.fda.gov/media/151710/download)	August 23, 2021
FAQ for Comirnaty (COVID-19 Vaccine mRNA) (/vaccines-blood-biologics/qa-comirnaty-covid-19-vaccine-mrna) (Español (/vaccines-blood-biologics/preguntas-y-respuestas-sobre-comirnaty-vacuna-de-arnm-contr-el-covid-19))	August 23, 2021

Pfizer-BioNTech Fact Sheets (English) and FAQs

Information	Last Updated
Fact Sheet for Healthcare Providers Administering Vaccine (/media/144413/download)	August 23, 2021
Fact Sheet for Recipients and Caregivers (/media/144414/download)	August 23, 2021
Frequently Asked Questions on the Pfizer-BioNTech COVID-19 Vaccine (/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine-frequently-asked-questions)	August 23, 2021

Pfizer-BioNTech Regulatory Information

Information	Date
Letter of Authorization (Reissued) (/media/150386/download)	August 23, 2021
Concurrence Letter (/media/151731/download)	August 22, 2021
Decision Memorandum (https://www.fda.gov/media/151613/download)	August 12, 2021
Letter Granting EUA Amendment (https://www.fda.gov/media/148877/download)	May 19, 2021
FDA Decision Memorandum (/media/148542/download)	May 10, 2021
Letter Granting EUA Amendment (/media/147390/download)	April 6, 2021
Letter Granting EUA Amendment (/media/145493/download)	January 22, 2021
Letter Granting EUA Amendment (/media/144955/download)	January 6, 2021
FDA Decision Memorandum (/media/144416/download)	December 11, 2020
Advisory Committee Meeting Information (/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-10-2020-meeting-announcement)	December 10, 2020

Media Materials and Webcasts

Information	Date
Press Release (/news-events/press-announcements/fda-approves-first-covid-19-vaccine)	August 23, 2021
Press Release (/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-vaccine-dose-certain-immunocompromised)	August 12, 2021
FDA In Brief (/news-events/press-announcements/fda-brief-fda-authorizes-longer-time-refrigerator-storage-thawed-pfizer-biontech-covid-19-vaccine)	May 19, 2021

Fact Sheet	Language
MERKBLATT FÜR EMPFÄNGER UND BETREUER (/media/144617/download) (June 25, 2021)	Deutsch (German)
પ્રાપ્તકર્તાઓ અને કાળજી રાખનારા માટે ફેક્ટ શીટ (/media/144742/download) (June 25, 2021)	ગુજરાતી (Gujarati)
FEY ENFOMASYON POU MOUN K'AP RESEVWA AVEK MOUN K'AP BAY SWEN (/media/144618/download) (June 25, 2021)	Kreyòl Ayisyen (Haitian Creole)
प्राप्तकर्ताओं और देखभाल कर्ताओं के लिए तथ्य पत्र/फैक्ट शीट (/media/144619/download) (June 25, 2021)	हिन्दी (Hindi)
DAIM NTAWV QHIA TSEEB RAU COV NEEG TAU KEV PAB THIAB COV NEEG ZOY TU (/media/144653/download) (June 25, 2021)	Hmoob (Hmong)
SCHEDE INFORMATIVA PER RICEVENTI E ASSISTENTI (/media/145507/download) (June 25, 2021)	Italiano (Italian)
ワクチン接種を受ける人と介護従事者のためのファクトシート (/media/145509/download) (June 25, 2021)	日本 (Japanese)
បញ្ជីហេតុការណ៍សម្រាប់អ្នកទទួលនិងអ្នកថែទាំ (/media/144760/download) (June 25, 2021)	ភាសាអង់គ្លេស (Khmer)
환자와 의료진을 위한 정보지 (/media/144620/download) (June 25, 2021)	한국어 (Korean)
PEPA IN MELELE KO REMOOL ÑAN RO REJ LOLOORJAKE Ājmuur IM AENŌMMAN (/media/144743/download) (June 25, 2021)	Pālle (Marshallese)
Bich'í' azláágo Aa'áhál yání Yaa' áháyánígíí Yaa'áko nízín doo gi Bit' Íishjáán Alnééh (/media/144621/download) (June 25, 2021)	Bilagáanaa Bizaad jí (Navajo)
ARKUSZ INFORMACYJNY DLA OSÓB SZCZEPIONYCH I ICH OPIEKUNÓW (/media/144622/download) (June 25, 2021)	Polski (Polish)
FICHA TÉCNICA PARA RECEPTORES E CUIDADORES (/media/144623/download) (June 25, 2021)	Português (Portuguese)
ИНФОРМАЦИОННЫЙ БЮЛЛЕТЕНЬ ДЛЯ РЕЦИПИЕНТОВ И СПЕЦИАЛИСТОВ ПО УХОДУ (/media/144624/download) (June 25, 2021)	Русский (Russian)

Fact Sheet	Language
<p><u>XAASHIDA MACLUUMAADKA EE LOOGU TALAGALAY TALLAAL QAATAYAASHA IYO DARYEELAYAASHA (/media/144662/download)</u> (June 25, 2021)</p>	Soomaali (Somali)
<p><u>HOJA INFORMATIVA PARA RECEPTORES Y PROVEDORES DE CUIDADO (/media/144625/download)</u> (August 23, 2021)</p>	Español (Spanish)
<p><u>FACT SHEET PARA SA MGA TATANGGAP AT TAGAPAG-ALAGA (/media/144663/download)</u> (June 25, 2021)</p>	Tagalog (Tagalog)
<p><u>TỜ THÔNG TIN CHO NGƯỜI NHẬN VÀ NHỮNG NGƯỜI CHĂM SÓC (/media/144626/download)</u> (June 25, 2021)</p>	Tiếng Việt (Vietnamese)
<p><u>אינפארמאציע בלאט פאר די וועלכע באקומען און פאר הילפער (גבאים) (/media/144627/download)</u> (June 25, 2021)</p>	אידיש (Yiddish)