

## Pfizer-BioNTech COVID-19 Vaccines

*Comirnaty and Pfizer-BioNTech COVID-19 Vaccine and Pfizer-BioNTech COVID-19 Vaccine, Bivalent*

August 31, 2022: **FDA authorizes updated COVID-19 vaccine boosters.** View [press release \(/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-pfizer-biontech-bivalent-covid-19-vaccines-use\)](/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-pfizer-biontech-bivalent-covid-19-vaccines-use) and [press conference \(https://youtu.be/QNFES1RLf1M\)](https://youtu.be/QNFES1RLf1M). [⏏ \(http://www.fda.gov/about-fda/website-policies/website-disclaimer\)](http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Comirnaty Information

Pfizer-BioNTech Fact Sheets

Pfizer-BioNTech 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>)

On August 23, 2021, FDA announced the first approval of a COVID-19 vaccine. The vaccine has been known as the Pfizer-BioNTech COVID-19 Vaccine, and the approved vaccine is marketed as Comirnaty, for the prevention of COVID-19 in individuals 12 years of age and older.

Comirnaty is a monovalent COVID-19 vaccine that is approved for use as a two-dose primary series for the prevention of COVID-19 in individuals 12 years of age and older. It is also authorized for emergency use to provide a third primary series dose to individuals 12 years of age and older with certain kinds of immunocompromise.

Pfizer-BioNTech COVID-19 Vaccine is a monovalent COVID-19 vaccine that is authorized for emergency use to prevent COVID-19 as a:

- Three-dose primary series for individuals 6 months through 4 years of age.
- Two-dose primary series for individuals 5 years of age and older.
- Third primary series dose for individuals 5 years of age and older who have been determined to have certain kinds of immunocompromise.
- Single booster dose for individuals 5 through 11 years of age at least five months after completing a primary series of the Pfizer-BioNTech COVID-19 Vaccine.

Pfizer-BioNTech COVID-19 Vaccine, Bivalent is authorized for use to prevent COVID-19 in individuals 12 years of age and older as a single booster dose administered at least 2 months after either:

- Completion of primary vaccination with any authorized or approved monovalent COVID-19 vaccine, or
- Receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine.

On February 11, 2022, in consultation with FDA, CDC updated the [emergency use instructions \(https://www.cdc.gov/vaccines/covid-19/eui/downloads/Pfizer-Caregiver.pdf\)](https://www.cdc.gov/vaccines/covid-19/eui/downloads/Pfizer-Caregiver.pdf) to provide information about the primary, additional, and booster doses of the Pfizer COVID-19 vaccines in certain individuals.

^  
Top ()

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

Information	Last Updated
<a href="/media/151707/download">Package Insert (/media/151707/download)</a> (purple cap)	July 8, 2022
<a href="/media/154834/download">Package Insert (/media/154834/download)</a> (gray cap)	July 8, 2022
<a href="/vaccines-blood-biologics/comirnaty">Regulatory Information (/vaccines-blood-biologics/comirnaty)</a>	August 25, 2022
<a href="/vaccines-blood-biologics/qa-comirnaty-covid-19-vaccine-mrna">FAQ for Comirnaty (COVID-19 Vaccine mRNA) (/vaccines-blood-biologics/qa-comirnaty-covid-19-vaccine-mrna)</a> (Español ( <a href="/vaccines-blood-biologics/preguntas-y-respuestas-sobre-comirnaty-vacuna-de-arnm-contr-el-covid-19">/vaccines-blood-biologics/preguntas-y-respuestas-sobre-comirnaty-vacuna-de-arnm-contr-el-covid-19</a> ))	February 8, 2022
<a href="https://www.cdc.gov/vaccines/covid-19/eui/index.html">CDC-issued Emergency Use Instructions (https://www.cdc.gov/vaccines/covid-19/eui/index.html)</a> (updated)	February 11, 2022

Showing 1 to 5 of 5 entries

## Pfizer-BioNTech Fact Sheets (English) and FAQs

Material	Audience	Vaccine Purpose	Vaccine Recipient Group	Last Updated
<a href="/media/159312/download">Fact Sheet (/media/159312/download)</a>	Healthcare Providers	Primary Series	6 months through 4 years, maroon cap (must dilute)	August 31, 2022
<a href="/media/159303/download">Dear Healthcare Provider Letter (/media/159303/download)</a>	Healthcare Providers	Primary Series	6 months through 4 years, maroon cap (must dilute)	June 17, 2022
<a href="/media/159313/download">Fact Sheet (/media/159313/download)</a>	Recipients and Caregivers	Primary Series	6 months through 4 years of age	June 28, 2022
<a href="/media/153714/download">Fact Sheet (/media/153714/download)</a>	Healthcare Providers	Primary Series and Booster	5 years through 11 years of age, orange cap (must dilute)	August 31, 2022
<a href="/media/153717/download">Fact Sheet (/media/153717/download)</a>	Recipients and Caregivers	Primary Series and Booster	5 years through 11 years of age	June 28, 2022
<a href="/media/153713/download">Fact Sheet (/media/153713/download)</a>	Healthcare Providers	Primary Series	12 years of age and older, purple cap (PBS formulation, must dilute)	August 31, 2022
<a href="/media/153715/download">Fact Sheet (/media/153715/download)</a>	Healthcare Providers	Primary Series	12 years of age and older, gray cap (Tris formulation, no dilution)	August 31, 2022
<a href="/media/161327/download">Fact Sheet (/media/161327/download)</a>	Healthcare Providers	Bivalent Booster	12 years of age and older, gray border	August 31, 2022

[^](#)  
Top ()

Material	Audience	Vaccine Purpose	Vaccine Recipient Group	Last Updated
<a href="/media/153716/download">Fact Sheet (/media/153716/download)</a>	Recipients and Caregivers	Primary Series and Bivalent Booster	12 years of age and older, purple and gray border	August 31, 2022
<a href="/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine-frequently-asked-questions">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)</a>	All	All	All	February 16, 2022

Showing 1 to 10 of 10 entries

## Pfizer-BioNTech Regulatory Information

Information	Date
<a href="/media/150386/download">Letter of Authorization (/media/150386/download)</a> (Reissued)	August 31, 2022
<a href="/media/159558/download">Letter Granting EUA Amendment (/media/159558/download)</a>	June 28, 2022
<a href="/media/159393/download">Decision Memorandum (/media/159393/download)</a>	June 17, 2022
<a href="/media/158909/download">Letter Granting EUA Amendment (/media/158909/download)</a>	June 1, 2022
<a href="/media/158575/download">Decision Memorandum (/media/158575/download)</a>	May 17, 2022
<a href="/media/157977/download">Letter Granting EUA Amendment (/media/157977/download)</a>	April 26, 2022
<a href="/media/157684/download">Letter Granting EUA Amendment (/media/157684/download)</a>	April 13, 2022
<a href="/media/157364/download">Decision Memorandum (/media/157364/download)</a>	March 28, 2022
<a href="/media/155863/download">Letter Granting EUA Amendment (/media/155863/download)</a>	January 31, 2022
<a href="/media/155549/download">Decision Memorandum Addendum (/media/155549/download)</a>	January 6, 2022
<a href="/media/155234/download">Decision Memorandum (/media/155234/download)</a>	December 30, 2021
<a href="/media/154869/download">Decision Memorandum (/media/154869/download)</a>	December 8, 2021
<a href="/media/154358/download">Decision Memorandum Addendum (/media/154358/download)</a>	November 19, 2021
<a href="/media/154357/download">Decision Memorandum (/media/154357/download)</a>	November 19, 2021
<a href="/media/153947/download">Decision Memorandum (/media/153947/download)</a>	October 29, 2021
<a href="/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-october-26-2021-meeting-announcement">Advisory Committee Meeting Information (/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-october-26-2021-meeting-announcement)</a>	October 26, 2021
<a href="/media/153482/download">Decision Memorandum (/media/153482/download)</a>	October 20, 2021
<a href="/media/152432/download">Decision Memorandum (/media/152432/download)</a>	September 24, 2021

 Top ()

Information	Date
<a href="#">Advisory Committee Meeting Information (/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-september-17-2021-meeting-announcement)</a>	September 17, 2021
<a href="#">Letter Granting EUA Amendment (/media/155676/download)</a>	September 1, 2021
<a href="#">Concurrence Letter (/media/151731/download)</a>	August 22, 2021
<a href="#">Decision Memorandum (https://www.fda.gov/media/151613/download)</a>	August 12, 2021
<a href="#">Letter Granting EUA Amendment (https://www.fda.gov/media/148877/download)</a>	May 19, 2021
<a href="#">FDA Decision Memorandum (/media/148542/download)</a>	May 10, 2021
<a href="#">Letter Granting EUA Amendment (/media/147390/download)</a>	April 6, 2021
<a href="#">Letter Granting EUA Amendment (/media/145493/download)</a>	January 22, 2021
<a href="#">Letter Granting EUA Amendment (/media/144955/download)</a>	January 6, 2021
<a href="#">FDA Decision Memorandum (/media/144416/download)</a>	December 11, 2020
<a href="#">Advisory Committee Meeting Information (/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-10-2020-meeting-announcement)</a>	December 10, 2020

Showing 1 to 29 of 29 entries

## Media Materials and Webcasts

Information	Date
<a href="#">Press Conference (https://youtu.be/QNFES1RLf1M) ↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer)</a>	August 31, 2022
<a href="#">Press Release (/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-pfizer-biontech-bivalent-covid-19-vaccines-use)</a>	August 31, 2022
<a href="#">Press Conference (https://youtu.be/5PPTrUOp-4g) ↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer)</a>	June 17, 2022
<a href="#">Press Release (/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-and-pfizer-biontech-covid-19-vaccines-children)</a>	June 17, 2022
<a href="#">Advisory Committee Webcast (https://youtu.be/lxm4UmlTGQ) ↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer)</a>	June 15, 2022
<a href="#">Press Release (/news-events/press-announcements/coronavirus-covid-19-update-fda-expands-eligibility-pfizer-biontech-covid-19-vaccine-booster-dose)</a>	May 17, 2022
<a href="#">Media Call (https://youtu.be/2ENukDcykt8) ↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer)</a>	March 29, 2022
<a href="#">Press Release (/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-second-booster-dose-two-covid-19-vaccines-older-and)</a>	March 29, 2022

↑  
Top ()

Information	Date
<a href="#">Press Release (/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-multiple-actions-expand-use-pfizer-biontech-covid-19-vaccine)</a>	January 3, 2022
<a href="#">Press Release (/news-events/press-announcements/coronavirus-covid-19-update-fda-expands-eligibility-covid-19-vaccine-boosters)</a>	November 19, 2021
<a href="#">Press Release (/news-events/press-announcements/fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use-children-5-through-11-years-age)</a>	October 29, 2021
<a href="#">Press Conference (https://youtu.be/WLbGnS-kqTY)</a> <a href="http://www.fda.gov/about-fda/website-policies/website-disclaimer">↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer)</a>	October 29, 2021
<a href="#">Advisory Committee Webcast (https://youtu.be/laaL0_xKmmA)</a> <a href="http://www.fda.gov/about-fda/website-policies/website-disclaimer">↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer)</a>	October 26, 2021
<a href="#">Press Release (/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-additional-actions-use-booster-dose-covid-19-vaccines)</a>	October 20, 2021
<a href="#">Media Call (https://youtu.be/rou7tf4vaUU)</a> <a href="http://www.fda.gov/about-fda/website-policies/website-disclaimer">↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer)</a>	October 20, 2021
<a href="#">Press Release (/news-events/press-announcements/fda-authorizes-booster-dose-pfizer-biontech-covid-19-vaccine-certain-populations)</a>	September 22, 2021
<a href="#">Advisory Committee Webcast (https://youtu.be/WFph7-6t34M)</a> <a href="http://www.fda.gov/about-fda/website-policies/website-disclaimer">↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer)</a>	September 17, 2021
<a href="#">Press Release (/news-events/press-announcements/fda-approves-first-covid-19-vaccine)</a>	August 23, 2021
<a href="#">Press Release (/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-vaccine-dose-certain-immunocompromised)</a>	August 12, 2021
<a href="#">FDA In Brief (/news-events/press-announcements/fda-brief-fda-authorizes-longer-time-refrigerator-storage-thawed-pfizer-biontech-covid-19-vaccine)</a>	May 19, 2021
<a href="#">Press Release (/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use)</a>	May 10, 2021
<a href="#">Press Conference (https://youtu.be/npjhwpConSw)</a> <a href="http://www.fda.gov/about-fda/website-policies/website-disclaimer">↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer)</a>	May 10, 2021
<a href="#">Press Release (/news-events/press-announcements/coronavirus-covid-19-update-fda-allows-more-flexible-storage-transportation-conditions-pfizer)</a>	February 25, 2021
<a href="#">Press Release (/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19)</a>	December 11, 2020
<a href="#">Press Conference (https://youtu.be/L0K3RsIZIP0)</a> <a href="http://www.fda.gov/about-fda/website-policies/website-disclaimer">↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer)</a>	December 11, 2020
<a href="#">Advisory Committee Webcast (https://youtu.be/owveMJBTc2l)</a> <a href="http://www.fda.gov/about-fda/website-policies/website-disclaimer">↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer)</a>	December 10, 2020

Showing 1 to 26 of 26 entries

**Translations of the Pfizer-BioNTech Fact Sheet for Recipients and Caregivers for 6 months through 4 years of age** Top ()

Fact Sheet	Vaccine Recipient Group	Language
<a href="#">HOJA INFORMATIVA PARA RECEPTORES Y CUIDADORES SOBRE LA VACUNA CONTRA EL COVID-19 DE PFIZER-BIONTECH PARA PREVENIR LA ENFERMEDAD DEL CORONAVIRUS 2019 (COVID-19) PARA USO EN NIÑOS DE 6 MESES A 4 AÑOS (/media/159762/download)</a> (June 17, 2022)	6 months - 4 years of age	Español (Spanish)
<a href="#">面向 6 个月至 4 岁的个体使用的用于预防 2019 年冠状病毒病 (COVID-19) 的辉瑞生物技术 COVID-19 疫苗的受种者和监护人员情况说明书 (/media/159760/download)</a> (June 17, 2022)	6 months - 4 years	中文 (Chinese, Simplified)
<a href="#">6개월에서 4세 사이의 개인에 사용하기 위한 2019 코로나 바이러스 질병(COVID-19) 예방을 위한 화이자-바이오엔텍 COVID-19 백신에 대한 수혜자 및 간병인을 위한 팩트 시트 (/media/159759/download)</a> (June 17, 2022)	6 months - 4 years	한국어 (Korean)
<a href="#">FACT SHEET PARA SA MGA TATANGGAP AT MGA NAG-AALAGA TUNGKOL SA BAKUNANG PFIZER-BIONTECH COVID-19 UPANG MAIWASAN ANG CORONAVIRUS DISEASE 2019 (COVID-19) PARA SA PAGGAMIT SA MGA INDIBIDWAL 6 NA BUWAN HANGGANG 4 NA TAONG GULANG (/media/159763/download)</a> (June 17, 2022)	6 months - 4 years	Tagalog (Tagalog)
<a href="#">PHIẾU THỰC TẾ DÀNH CHO NGƯỜI NHẬN VÀ NGƯỜI CHĂM SÓC VỀ THUỐC CHỮA BỆNH PFIZER-BIONTECH COVID-19 ĐỂ PHÒNG NGỪA BỆNH HẠI LÃO HÓA 2019 (COVID-19) ĐỂ SỬ DỤNG CHO CÁ NHÂN 6 THÁNG QUA 4 TUỔI (/media/159765/download) (/media/154074/download)</a> (June 17, 2022)	6 months - 4 years	Tiếng Việt (Vietnamese)

Showing 1 to 5 of 5 entries

## Translations of the Pfizer-BioNTech Fact Sheet for Recipients and Caregivers for 5 through 11 years of age

Fact Sheet	Vaccine Recipient Group	Language
<a href="#">HOJA INFORMATIVA DE VACUNAS PARA RECEPTORES Y CUIDADORES SOBRE LA VACUNA DE PFIZER-BIONTECH CONTRA EL COVID-19 PARA PREVENIR LA ENFERMEDAD DEL CORONAVIRUS 2019 (COVID-19) PARA USO EN PERSONAS DE 5 A 11 AÑOS (/media/153829/download)</a> (June 17, 2022)	5 - 11 years of age	Español (Spanish)

^  
Top ()

Fact Sheet	Vaccine Recipient Group	Language
<a href="/media/154061/download">为接种者和护理者提供的关于用于预防2019新冠肺炎（COVID-19）的辉瑞生物技术公司2019新冠肺炎疫苗以个人使用的信息概况说明书 5岁至11岁</a> (June 17, 2022)	5 - 11 years of age	中文 (Chinese, Simplified)
<a href="/media/154076/download">5 세에서 11 세에 해당하는사람들에게 코로나바이러스감염증 2019 (COVID-19)를 예방하기 위한화이저 (PFIZER)-바이오엔텍 (BIONTECH) 코비드-19 백신에 대한 환자 와 의료진을 위한 백신 정보지</a> (June 17, 2022)	5 - 11 years of age	한국어 (Korean)
<a href="/media/154071/download">BAKUNA IMPORMASYON FACT SHEET PARA SA MGA TUMANGGAP AT MGA TAGAPAG-ALAGA TUNGKOL SA PFIZER-BIONTECH COVID-19 BAKUNA UPANG MAIWASAN ANG CORONAVIRUS DISEASE 2019 (COVID-19) PARA SA PAGGAMIT SA MGA INDIBIDWAL 5 HANGGANG 11 TAONG GULANG</a> (June 17, 2022)	5 - 11 years of age	Tagalog (Tagalog)
<a href="/media/154074/download">BẢNG THÔNG TIN VỀ VẮC XIN DÀNH CHO NGƯỜI NHẬN VÀ NGƯỜI CHĂM SÓC VỀ VẮC XIN PFIZER-BIONTECH COVID-19 NHẪM PHÒNG NGỪA BỆNH CORONAVIRUS 2019 (COVID-19) ĐỂ SỬ DỤNG CHO CÁ NHÂN TỪ 5 TỚI 11 TUỔI</a> (June 17, 2022)	5 - 11 years of age	Tiếng Việt (Vietnamese)

Showing 1 to 5 of 5 entries

## Translations of the Pfizer-BioNTech Fact Sheet for Recipients and Caregivers for 12 years of age and older

Fact Sheet	Vaccine Recipient Group	Language
<a href="/media/144625/download">HOJA INFORMATIVA DE VACUNAS PARA RECEPTORES Y CUIDADORES SOBRE COMIRNATY (VACUNA DE ARNm CONTRA EL COVID-19) Y LA VACUNA DE PFIZER-BIONTECH CONTRA EL COVID-19 PARA PREVENIR LA ENFERMEDAD DEL CORONAVIRUS 2019 (COVID-19) PARA USO EN PERSONAS DE 12 AÑOS O MÁS</a> (June 17, 2022)	12 years of age and older	Español (Spanish)
<a href="/media/144615/download">关于复必泰 (2019核糖核酸新冠肺炎疫苗)以及辉瑞-BioNTech2019新冠肺炎疫苗预防2019新冠肺炎的接受者和护理者须知</a> (June 17, 2022)	12 years of age and older	中文 (Chinese, Simplified)
<a href="/media/144620/download">코로나바이러스감염증 2019 (COVID-19)를 예방하기 위한 코멀나티 (코비드-19 백신, 메신저 RNA)와 화이저 (PFIZER)-바이오엔텍 (BIONTECH) 코비드-19 백신에 대한 환자와 의료진을 위한 백신 정보지</a> (June 17, 2022)	12 years of age and older	한국어 (Korean)

↑  
Top ()

Fact Sheet	Vaccine Recipient Group	Language
<p><a href="#">FACT SHEET NG IMPORMASYON SA BAKUNA PARA SA MGA TANGGAP AT CAREGIVERS TUNGKOL SA COMIRNATY (COVID-19 VACCINE, mRNA) AT BAKUNA NA PFIZER-BIONTECH COVID-19 UPANG MAIWASAN ANG CORONAVIRUS DISEASE 2019 (COVID-19) (/media/144663/download)</a> (June 17, 2022)</p>	12 years of age and older	Tagalog (Tagalog)
<p><a href="#">TỜ DỮ KIẾN THÔNG TIN VỀ VẮC XIN DÀNH CHO NGƯỜI NHẬN VÀ NGƯỜI CHĂM SÓC VỀ COMIRNATY (VẮC XIN COVID-19, mRNA) VÀ VẮC XIN PFIZER-BIONTECH COVID-19 ĐỂ PHÒNG NGỪA BỆNH CORONAVIRUS 2019 (COVID-19) (/media/144626/download)</a> (June 17, 2022)</p>	12 years of age and older	Tiếng Việt (Vietnamese)

Showing 1 to 5 of 5 entries