

The Pfizer-BioNTech COVID-19 Vaccine is also known as COMIRNATY (COVID-19 Vaccine, mRNA). Comirnaty is U.S. Food and Drug Administration (FDA)-approved in individuals 16 years of age and older. Comirnaty is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS CoV 2) in individuals 16 years of age and older. Please refer to the full Prescribing Information for individuals 16 years of age and older for important treatment considerations for Comirnaty via the following link: (<https://www.pfizermedicalinformation.com/en-us/pfizer-biontech-covid-19-vaccine>). In the event this link does not work, please access the product's approved prescribing information at www.pfizer.com/products.

In individuals 12-15 years of age, the Pfizer-BioNTech COVID-19 Vaccine has not been approved or licensed by FDA but has been authorized for emergency use by FDA under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19). The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner. Please refer to the Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) including Full EUA Prescribing Information on important treatment considerations for the Pfizer-BioNTech COVID-19 Vaccine via the following link: <https://www.pfizermedicalinformation.com/en-us/patient/pfizer-biontech-covid-19-vaccine> or www.cvdvaccine.com. In the event this link does not work, please access the product's Fact Sheet or Prescribing Information at www.pfizer.com.

HAS THE EXPIRATION DATE ON THE PFIZER_BIONTECH COVID-19 LABELS BEEN EXTENDED? IF SO, FOR HOW LONG?

SELECT EUA PRESCRIBING INFORMATION

The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series.¹

Frozen Vials Prior to Use

Cartons of Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vials arrive in thermal containers with dry ice. Once received, remove the vial cartons immediately from the thermal container and preferably store in an ultra-low temperature freezer between -90°C to -60°C (-130°F to -76°F) until the expiry date printed on the label. This information in the package insert supersedes the storage conditions printed on the vial cartons.¹

Cartons and vials of Pfizer-BioNTech COVID-19 Vaccine with an expiry date of August 2021 through February 2022 printed on the label may remain in use for 3 months beyond the printed date as long as approved storage conditions between -90°C to -60°C (-130°F to -76°F) have been maintained.¹

For further information regarding the authorized use under the Emergency Use Authorization (EUA), please refer to the Fact Sheet for Vaccination Providers Administering Vaccine or EUA Prescribing Information for the Pfizer-BioNTech COVID-19 Vaccine.

Internal data

The expiry date printed on all current vial and carton labels reflects 6 months from manufacture. The intended long-term storage condition for Pfizer-BioNTech COVID-19 Vaccine has been extended to 9 months from the date of manufacture at -75°C ±15°C. Frozen vials stored or transported ONE TIME at -25°C to -15°C may be placed back at -90°C to -60°C if needed, as long as the total time at -25°C to -15°C has not exceeded two weeks. The shelf life for long term storage at -90°C to -60°C is not impacted by storage at -25°C to -15°C for a maximum of 2 weeks.²

WHICH VIALS DOES THE EXTENDED EXPIRATION DATE APPLY TO?

SELECT EUA PRESCRIBING INFORMATION

Cartons and vials of Pfizer-BioNTech COVID-19 Vaccine with an expiry date of August 2021 through February 2022 printed on the label may remain in use for 3 months beyond the printed date as long as approved storage conditions between -90°C to -60°C (-130°F to -76°F) have been maintained.¹

Updated expiry dates are shown below.¹Error! Bookmark not defined.

<u>Printed Expiry Date</u>		<u>Updated Expiry Date</u>
August 2021	→	November 2021
September 2021	→	December 2021
October 2021	→	January 2022
November 2021	→	February 2022
December 2021	→	March 2022
January 2022	→	April 2022
February 2022	→	May 2022

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Internal data

Cartons and vials with an expiry date of August 2021 through February 2022 printed on the label may remain in use for 3 months beyond the printed date as long as approved storage conditions between -90°C to -60°C (-130°F to -76°F) have been maintained. Updated expiry dates are shown above.²

The approved extended expiration date applies to all currently available batches that have not yet expired and which have been stored within recommended storage conditions, including storage for up to 2 weeks at -25°C to -15°C. For lots with printed expiration dates in May, June, and July 2021 which were maintained at the recommended storage temperature after their initial expiry, the extended stability time may be applied (3 months beyond the printed expiry date).²

If a lot expiring at or prior to 30 April 2021 was used within 3 months of the printed expiry date, and was not stored for longer than 5 days at 2-8°C (the allowable refrigerated storage period prior to 30 April 2021), the material would have been expected to meet quality standards.²

WERE CHANGES TO THE VACCINE REQUIRED TO ENABLE EXTENSION OF THE EXPIRATION DATE?

No changes have been made to the vaccine itself to enable extension of expiry dating. This change is based on stability data generated on batches manufactured over approximately the past nine months of COVID-19 vaccine development, from the batches that supplied early clinical trials through the commercial scale batches currently in production.²

WHEN WILL THE EXPIRATION DATES ON VACCINE CARTONS AND VIALS REFLECT THE EXTENDED EXPIRATION DATE OF 9 MONTHS AFTER THE DATE OF MANUFACTURE?

Global rolling change from 6 months to 9 months from the date of manufacture, will be market specific. Expiry date printed on all current vial and carton labels reflects 6 months from manufacture. Change over to printing 9 month expiries on vials and cartons will occur once all markets approve 9 month expiry.²

**IF THE VACCINE VIAL DOES NOT HAVE A DAY OF MONTH FOR THE EXPIRATION DATE,
WHICH DAY DOES IT EXPIRE?**

When stored at recommended temperatures as per the EUA Prescribing Information, the expiration date is the last day of the month.

REFERENCES

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1. Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccines including the Full EUA Prescribing Information. Pfizer/BioNTech.
 2. Pfizer-BioNTech COVID-19 Vaccine. Data on file (28). Pfizer.