29th August 2023

COMIRNATY® ▼ Original/Omicron BA.4/5 (15/15 micrograms) per dose dispersion for injection (tozinameran/famtozinameran), COVID-19 mRNA Vaccine (nucleoside-modified)
European Marketing Authorisation number EU/1/20/1528/0008 and EU/1/20/1528/0009

Important shelf-life update for COMIRNATY® ▼ Original/Omicron BA.4/5 (15/15 micrograms) per dose dispersion for injection (tozinameran/famtozinameran), COVID-19 mRNA Vaccine (nucleoside-modified)

Dear Healthcare Professional,

We would like to inform you that on *5th July 2023* a new shelf-life at Ultra-Low-Temperature storage conditions has been approved in the European Union (EU) for COMIRNATY.

The Product Information for Comirnaty Original/Omicron BA.4/5 (15/15 micrograms) per dose dispersion for injection (tozinameran/famtozinameran), COVID-19 mRNA Vaccine (nucleoside-modified) has been updated with the new shelf-life for the frozen vial, that has been extended from 18 months to 24 months. The storage conditions remain unchanged (-90 °C to -60 °C).

The vaccine will be received frozen at -90 °C to -60 °C. Frozen vaccine can be stored either at -90 °C to -60 °C or 2 °C to 8 °C upon receipt. Within the 24-month shelf-life, unopened vials may be stored and transported at 2 °C to 8 °C for 10 weeks.

This 6-month extension applies to vials manufactured after this approval date.

In addition, 6 months or 12 months may be applied retroactively to vials manufactured prior to this approval as long as approved storage conditions between -90 °C to -60 °C have been maintained.

Updated expiry dates for the respective presentations of COMIRNATY are shown on the next page.

COMIRNATY Original/Omicron BA.4-5 (15/15 micrograms) per dose
Dispersion for injection
EU/1/20/1528/008, EU/1/20/1528/009, EU/1/20/1528/014
GTIN: 04260703260354, GTIN: 04260703260361, GTIN: 04260703260415

12 years and older, Ready to use, Grey Cap Vial

Approved Shelf Life at Packaging	Printed Date		Updated Expiry Date
12 Months	June 2023	→	June 2024
12 Months	July 2023	→	July 2024
12 Months	August 2023	→	August 2024
12 Months	September 2023	→	September 2024
12 Months	October 2023	→	October 2024
12 Months	November 2023	→	November 2024
18 Months	June 2024	→	December 2024
18 Months	July 2024	→	January 2025
18 Months	August 2024	→	February 2025
18 Months	September 2024	→	March 2025
18 Months	October 2024	→	April 2025

All vials with an expiry date of May 2025 and beyond will already reflect the 24 months shelf-life.

Footnote: All dates refer to the end of the calendar month.

In consequence of the extension of the shelf life, the handling of the EU-serialization for medicinal products according to the delegated Regulation (EU) 2016/161 must also be considered.
Please be aware that during the verification/decommissioning of the unique identifier an alert for the effected batches will appear that the package has expired. The labelled expiration date on the product and the stored data in the NMVS repository does not take the extended shelf life into account. Kindly share this information with the central pharmacy, wholesalers and persons authorised or entitled to supply Comirnaty.

COMIRNATY® ▼ Original/Omicron BA.4/5 (15/15 micrograms) per dose dispersion for injection (tozinameran/famtozinameran), COVID-19 mRNA Vaccine (nucleoside-modified) cannot be used for individuals under 12 years of age.

Please note that the supplementary information for COMIRNATY impacted by this change is being updated accordingly.

If you have any questions, please refer to the current approved Product Information for COMIRNATY at www.comirnatyglobal.com.

Detailed information on this medicine is available on the European Medicines Agency website at http://www.ema.europa.eu.

VISIT
www.comirnatyglobal.com
for more details.

Reporting of suspected adverse reactions

If you are concerned about an adverse event, it should be reported on a Yellow card. Reporting forms and information can be found at https://coronavirus-yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. When reporting please include the vaccine brand and batch/Lot number if available.

Alternatively, adverse events of concern in association with Comirnaty can be reported to Pfizer Medical Information on 01304 616161 or via www.pfizersafetyreporting.com.
Please do not report the same adverse event(s) to both systems as all reports will be shared between Pfizer and MHRA (in an anonymized form) and dual reporting will create unnecessary duplicates.

Company contact point

If you have any questions about this letter or for more information about COMIRNATY please contact Pfizer Medical Information at Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS or Telephone: 01304 616161.

Sincerely,

Pawel Widomski
Senior Director Global Regulatory Affairs CMC
BioNTech Manufacturing GmbH