

29th August 2023

**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)
Marketing Authorisation number: PLGB 53632/0012**

Dear Healthcare Professional,

We would like to inform you that on *18th August 2023* a new shelf-life at Ultra-Low-Temperature storage conditions (-90 °C to -60 °C) has been approved in the UK for COMIRNATY®▼ Original/Omicron Original/Omicron BA.4/5 (15/15 micrograms) per dose dispersion for injection (tozinameran/famtozinameran), COVID-19 mRNA Vaccine (nucleoside-modified).

The Product Information 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.

In addition to this being applied to future batches, the 6-month extension may be applied retroactively to vials manufactured prior to this approval.

Updated expiry dates are shown below:

<u>Approved Shelf Life at Packaging</u>	<u>Printed Date</u>		<u>Updated Expiry Date</u>
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

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

Therefore, vaccine with an expiry date of June 2023 through October 2024 printed on the label may remain in use for 6 or 12 months beyond the printed date, as long as approved storage conditions between -90 °C to -60 °C have been maintained before thawing. The allowed 10 weeks storage and transportation at 2 °C to 8 °C is unchanged but vaccine must remain within the 24-month expiry date.

All vials in cartons with the original Pfizer label with an expiry date beyond May 2025 will already reflect the 24 months shelf-life and their shelf-life should not be extended further.

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

Further information

For product information please refer to
www.comirnatyeducation.co.uk.



Reporting of suspected adverse reactions

COMIRNATY®▼ Original/Omicron BA.4/5 (15/15 micrograms) per dose dispersion for injection (tozinameran/famtozinameran), COVID-19 mRNA Vaccine (nucleoside-modified) years is subject to additional monitoring. This will allow quick identification of new safety information.

Healthcare professionals and patients are asked to report any suspected adverse reactions associated with the use of COVID-19 vaccines to the Coronavirus Yellow Card reporting site at <https://coronavirus-yellowcard.mhra.gov.uk/> or via the free Yellow Card App (available from the Apple App Store or Google Play Store).

When reporting, please provide as much information as possible, including vaccine brand name and batch number, vaccination date, previously received doses, onset and description of the reaction, and information about medical history and any concomitant medication.

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.

Other suspected adverse drug reactions (ADRs) should be reported via the Yellow Card scheme. Report via the website <https://www.gov.uk/yellowcard>, the Yellow Card app, and some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals.

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.

Yours sincerely



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