

24 May 2022

**Important shelf-life update for
COMIRNATY® ▼ 10 micrograms/dose concentrate for
dispersion for injection (tozinameran),
COVID-19 mRNA Vaccine (nucleoside-modified) –
Children 5 to 11 years
Marketing Authorisation number: PLGB 53632/0006**

Dear Healthcare Professional,

We would like to inform you that on 20 May 2022 a new shelf-life at Ultra-Low-Temperature storage conditions (-90 °C to -60 °C) has been approved in the UK for COMIRNATY® ▼ 10 micrograms/dose concentrate for dispersion for injection (tozinameran), 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 9 months to 12 months. The storage conditions remain unchanged (-90 °C to -60 °C).

Within the 12-month shelf-life, unopened vials may be stored and transported at -90 °C to -60 °C.

In addition to this being applied to future batches, a 3-month or 6-month extension may be applied retroactively to vials manufactured prior to this approval.

- Vaccines with an expiry date of April 2022 and May 2022 (batches FN4074, FN4075 and FP0362 only) printed on the label were allocated a 6-month shelf-life at time of manufacture, so they may remain in use for 6 months beyond the printed date (to reflect combined 9- and 12-months shelf-life extension), as long as approved storage conditions between -90 °C to -60 °C have been maintained before thawing.
- Vaccines with an expiry date of August 2022 through December 2022 printed on the label were allocated a 9-month shelf-life at time of manufacture, so they may remain in use for 3-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 12-month expiry date. Please consult the following table.

Updated expiry dates are shown below:

<u>Approved Shelf-Life at Manufacturing</u>	<u>Printed Expiry Date</u>		<u>Updated Expiry Date</u>
6 months	April 2022	→	October 2022 (for batches FN4074 and FN4075 only)
6 months	May 2022	→	November 2022 (for batch FP0362 only)
9 months	August 2022	→	November 2022
9 months	September 2022	→	December 2022
9 months	October 2022	→	January 2023
9 months	November 2022	→	February 2023
9 months	December 2022	→	March 2023

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

All vials in cartons with the original Pfizer label with an expiry date beyond March 2023 will already reflect the 12 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.



Call for reporting

Healthcare professionals are reminded to continue to report suspected adverse reactions associated with COMIRNATY in accordance with the National spontaneous reporting system.

Reporting of suspected adverse reactions

Adverse events 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.

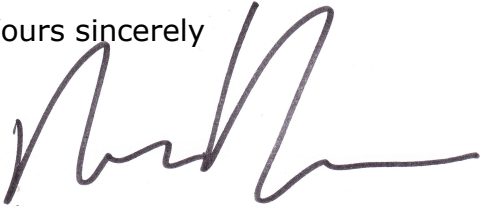
COMIRNATY® ▼ 10 micrograms/dose concentrate for dispersion for injection (tozinameran), COVID-19 mRNA vaccine (nucleoside-modified) – Children 5 to 11 years is subject to additional monitoring. This will allow quick identification of new safety information.

Please report ANY suspected adverse drug reactions (ADRs) to new drugs and vaccines identified by the black triangle▼ to the MHRA through the Yellow Card Scheme.

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

A handwritten signature in dark ink, appearing to read 'Ruben Rizzi', with a long horizontal flourish extending to the right.

Ruben Rizzi, MD
Vice President Global Regulatory Affairs
BioNTech Manufacturing GmbH