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21 March 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

Dear Healthcare Professional,

Applicable in GB only for PLGB 53632/0006

(not applicable in NI)

We would like to inform you that on 21 February 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 6 months to 9 months. The storage conditions remain unchanged (-90 °C to -60 °C).

Within the 9-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, the 3-month extension may be applied retrospectively only to vials with the following batch numbers:

Updated expiry dates are shown below:

Batch Number	Printed Expiry Date		Updated Expiry Date
FN4074	April 2022	→	July 2022
FN4075	April 2022	→	July 2022
FP0362	May 2022	→	August 2022

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

Vaccine may remain in use for 3 months beyond the printed date, as long as approved storage conditions between -90 °C and -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 9-month expiry date.

All vials in cartons with the original Pfizer label with an expiry date beyond May 2022 will already reflect the 9 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

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BioNTech Manufacturing GmbH