24 May 2022

COMIRNATY®, COVID-19 mRNA vaccine (nucleoside-modified)
European Marketing Authorisation number EU/1/20/1528/004 and EU/1/20/1528/005

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,

We would like to inform you that on 24 March 2022 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 10 micrograms/dose concentrate for dispersion for injection 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).

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 12-month shelf-life, unopened vials may be stored and transported at 2 °C to 8 °C for 10 weeks.

This 3-month extension applies to vials manufactured after this approval date.

In addition, 3-months or 6-months extension may be applied retroactively to vials manufactured prior to this approval. Cartons with an expiry date of March 2022 through May 2022 printed on the label 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. Cartons with an expiry date of August 2022 through December 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 have been maintained. Please consult below table for exceptions.

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

COMIRNATY 10 micrograms/dose,
Concentrate for dispersion for injection EU/1/20/1528/004, EU/1/20/1528/005

5 to 11 years old, Dilute to use, Orange Cap Vial

Approved Shelf Life at Manufacturing	Printed Date		Updated Expiry Date
6 Months	March 2022	→	September 2022[a]
6 Months	April 2022	→	October 2022[a]
6 Months	May 2022	→	November 2022[a]
6 Months	August 2022	→	November 2022[b]
9 Months	September 2022	→	December 2022
9 Months	October 2022	→	January 2023
9 Months	November 2022	→	February 2023
9 Months	December 2022	→	March 2023

[a] - Expiry date update combining 9- and 12-months shelf-life extension
[b] – Applicable to batches with printed expiry date corresponding to 9-months shelf-life.
All vials with an expiry date of April 2023 and beyond will already reflect the 12 months shelf-life.

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

COMIRNATY® ▼ 10 micrograms/dose concentrate for dispersion for injection (tozinameran), COVID-19 mRNA vaccine (nucleoside-modified) for children 5 to 11 years of age cannot be used for individuals 12 years of age and older.
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.

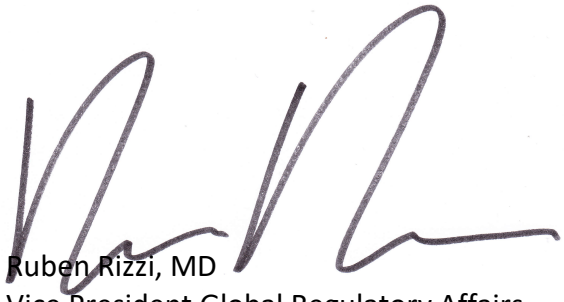
Alternatively, adverse events of concern in association with Comirnaty can be reported to Pfizer Medical Information on 01304 616161 or via www.pfizersafetyreporting.com.

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,



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