



19th August 2022

Direct Healthcare Professional Communication

**COMIRNATY[®], COVID-19 mRNA vaccine (nucleoside-modified)
European Marketing Authorisation number EU/1/20/1528/001**

**Important shelf-life update for
COMIRNATY[®] ▼ 30 micrograms/dose concentrate for dispersion for
injection (tozinameran), COVID-19 mRNA Vaccine (nucleoside-
modified)**

Dear Healthcare Professional,

We would like to inform you that on 01 August 2022 a new shelf-life at Ultra-Low-Temperature storage conditions has been approved in the European Union (EU) for COMIRNATY 30 micrograms/dose concentrate for dispersion for injection.

The Product Information has been updated with the new shelf-life for the frozen vial, that has been extended from 12 months to 15 months. The storage conditions remain unchanged (-90 °C to -60 °C).

Within the 15-month shelf-life, unopened vials may be stored and transported at -25 °C to -15 °C for a single period of up to 2 weeks and can be returned to -90 °C to -60 °C.

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

In addition, 3-months, 6-months or 9 months extension may be applied retroactively to vials manufactured prior to this approval.

Cartons with an expiry date of February 2022 to March 2022 printed on the label may remain in use for 9 months beyond the printed date (to reflect combined 9-, 12- and 15-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 June 2022 through December 2022 printed on the label may remain in use for 6 months beyond the printed date, as long as approved storage conditions between -90 °C to -60 °C have been maintained.

Updated expiry dates are shown on the next page for COMIRNATY 30 micrograms/dose concentrate for dispersion for injection, Purple cap.

<u>Approved Shelf Life at Manufacturing</u>	<u>Printed Expiry Date</u>		<u>Updated Expiry Date</u>
6 Months	February 2022	→	November 2022 ^a
6 Months	March 2022	→	December 2022 ^{a, b}
9 Months	June 2022	→	December 2022 ^b
9 Months	July 2022	→	January 2023
9 Months	August 2022	→	February 2023
9 Months	September 2022	→	March 2023
9 Months	October 2022	→	April 2023
9 Months	November 2022	→	May 2023
9 Months	December 2022	→	June 2023

a - Expiry date update combining 9, 12- and 15-months shelf-life extension
b - Due to implementation of the change in shelf-life from 6 to 9 months in October 2021, two different printed expiry dates could be extended to December 2022.

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

Please note that all of the supplementary information on 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

COMIRNATY® ▼ 30 micrograms/dose concentrate for dispersion for injection (tozinameran), COVID-19 mRNA Vaccine (nucleoside-modified) is subject to additional monitoring. This will allow quick identification of new safety information.

Suspected adverse reactions associated with COVID-19 vaccines should be reported to the MHRA through the MHRA's Coronavirus Yellow Card reporting site at <https://coronavirus-yellowcard.mhra.gov.uk> or via the Yellow Card app.

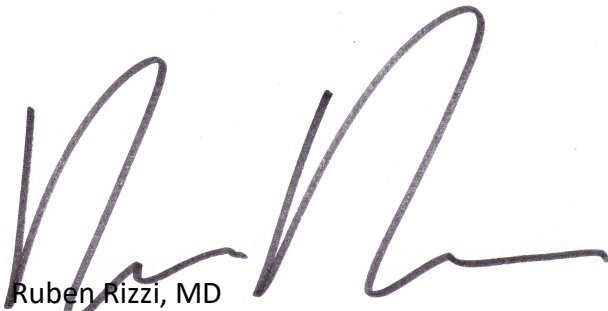
When reporting please provide as much information as possible, including information about medical history, any concomitant medications, onset, treatment dates, and vaccine product brand name and batch number.

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 require 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,

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

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