

COMIRNATY®/BioNTech-Pfizer COVID-19 Vaccine, COVID-19 mRNA vaccine (nucleoside-modified)
WHO EUL (EU/EMA): I8-370-43 EURO
WHO EUL (US/FDA): I8-370-43 AMRO

Important shelf-life update for COMIRNATY®, COVID-19 mRNA Vaccine (nucleoside-modified)

Dear Healthcare Professional,

We would like to inform you that WHO approved on 21 September 2021 a new shelf-life at Ultra-Low-Temperature storage conditions under the WHO Emergency Use Listing (EUL) recommendation for COMIRNATY/BioNTech-Pfizer COVID-19 Vaccine.

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 -25 °C to -15 °C for a single period of up to 2 weeks.

This 3-month extension applies to vials manufactured after the above indicated approval date.

In addition, this 3-month extension may be applied retroactively to vials manufactured prior to this approval. Cartons with an expiry date of June 2021 through March 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. Updated expiry dates are shown below.

| <u>Printed Date</u> | | <u>Updated Expiry Date</u> |
|---------------------|---|----------------------------|
| June 2021 | → | September 2021 |
| July 2021 | → | October 2021 |
| August 2021 | → | November 2021 |
| September 2021 | → | December 2021 |
| October 2021 | → | January 2022 |
| November 2021 | → | February 2022 |
| December 2021 | → | March 2022 |
| January 2022 | → | April 2022 |
| February 2022 | → | May 2022 |
| March 2022 | → | June 2022 |

All vials with an expiry date beyond March 2022 will already reflect the 9 months shelf-life.

Please note that all of the supplementary information on COMIRNATY/BioNTech-Pfizer COVID-19 vaccine impacted by this change has been updated accordingly.

If you have any questions, please refer to the current approved Product Information for COMIRNATY at www.comirnatyglobal.com.



VISIT
www.comirnatyglobal.com
for more details.

Sincerely,

A handwritten signature in black ink, appearing to read 'Ruben Rizzi', with a stylized, cursive script.

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