



September 2021

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

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

Dear Healthcare Professional,

We would like to inform you that on 10 September 2021 a new shelf-life at Ultra-Low-Temperature storage conditions has been approved in the European Union (EU) for COMIRNATY.

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 and can be returned to -90 °C to -60 °C.

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

Sincerely,



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



VISIT
www.comirnatyglobal.com
for more details.