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20th December 2022

Important shelf-life update for COMIRNATY®▼3 micrograms/dose concentrate for dispersion for injection (tozinameran), COVID-19 mRNA Vaccine (nucleoside-modified) – Children aged 6 months to 4 years Marketing Authorisation number: PLGB 53632/0008

Dear Healthcare Professional,

We would like to inform you that on *16th December 2022* a new shelf-life at Ultra-Low-Temperature storage conditions (-90 °C to -60 °C) has been approved in the UK for COMIRNATY®▼ 3 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 12 months to 18 months. The storage conditions remain unchanged (-90 °C to -60 °C).

Within the 18-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 6-month extension may be applied retroactively to vials manufactured prior to this approval.

Updated expiry dates are shown below:

Approved Shelf Life at Packaging	Printed Date		Updated Expiry Date
9 Months	October 2022	→	July 2023[a]
9 Months	November 2022	→	August 2023[a]
12 Months	April 2023	→	October 2023
12 Months	June 2023	→	December 2023
12 Months	September 2023	→	March 2024
12 Months	October 2023	→	April 2024
12 Months	November 2023	→	May 2024

[a] - Expiry date update combining 12- and 18-months shelf-life extension

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

Therefore, vaccine with an expiry date of October 2022 through November 2023 printed on the label may remain in use for 6 or 9 months beyond the printed date, as long as approved storage conditions between -90 °C to -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 18-month expiry date.

All vials in cartons with the original Pfizer label with an expiry date beyond May 2024 will already reflect the 18 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.

Reporting of suspected adverse reactions
COMIRNATY®▼ 3 micrograms/dose concentrate for dispersion for injection (tozinameran), COVID-19 mRNA vaccine (nucleoside-modified) – Children aged 6 months to 4 years is subject to additional monitoring. This will allow quick identification of new safety information.

Healthcare professionals and patients are asked to report any suspected adverse reactions associated with the use of COVID-19 vaccines to the Coronavirus Yellow Card reporting site at https://coronavirus-yellowcard.mhra.gov.uk/ or via the free Yellow Card App (available from the Apple App Store or Google Play Store).

When reporting, please provide as much information as possible, including vaccine brand name and batch number, vaccination date, previously received doses, onset and description of the reaction, and information about medical history and any concomitant medication.

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.

Other suspected adverse drug reactions (ADRs) should be reported via the Yellow Card scheme. Report via the website https://www.gov.uk/yellowcard, the Yellow Card app, and some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals.

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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