28 February 2023

Important shelf-life update for Nuvaxovid dispersion for injection, COVID-19 Vaccine (recombinant, adjuvanted)

Marketing Authorisation number: PLGB 54180/0002

Dear Healthcare Professional,

We would like to inform you that on 24 February 2023 a Batch Specific Variation has been approved in the UK for Nuvaxovid Dispersion for Injection, COVID-19 Vaccine (recombinant, adjuvanted).

The product has been extended from 9 months to 12 months. The storage conditions remain unchanged (unopened vial should be stored at 2°C to 8°C, protected from light. Punctured vial should be used within 6 hours from the time of first needle puncture to administration and be stored 2°C to 25°C. The product should not be frozen).

The concerned batches affected by this variation and updated expiry dates are shown below:

Batch number	Approved Shelf Life at Packaging	Printed Expiry Date	Updated Expiry Date
4302MF024	9 months	February 2023	May 2023
4302MF025	9 months	March 2023	June 2023

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

Further information

For product information please refer to https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-nuvaxovid or https://uk.novavaxcovidvaccine.com/hcp.

Reporting of suspected adverse reactions

Nuvaxovid dispersion for injection, COVID-19 Vaccine (recombinant, adjuvanted)

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 timing and description of the reaction, and information about medical history and any concomitant medication.

Alternatively, adverse events of concern in association with Nuvaxovid can be reported to Novavax at +44 203 514 1838 or via an Adverse Event Reporting form located at www.novavaxmedinfo.com. Please do not report the same adverse event(s) to both systems as all reports will be shared between Novavax 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 Nuvaxovid please contact Novavax Medical Information at +44 203 514 1838 or submit your inquiry via the Medical Information Request Form located at www.novavaxmedinfo.com.

Yours sincerely

MUDr. Anna Hanzlíková

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