

24 February 2022

Dear Healthcare Professional

This communication is intended for Healthcare Professionals who administer NUVAXOVID.

NUVAXOVID COVID-19 Vaccine (5 micrograms of SARS-CoV-2 spike protein adjuvanted with Matrix-M) is indicated for active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 in individuals 18 years of age and older. NUVAXOVID is supplied as a 5 mL suspension in a glass vial with a stopper and an aluminium overseal with blue plastic flip-cap. Each vial contains 10 doses of 0.5 mL. An overfill is included in the vial to ensure that a maximum of 10 doses of 0.5 mL each can be extracted.

To ensure global supply of NUVAXOVID in a pandemic situation, the product is currently available in limited packaging configurations. The product and packaging (vial and carton label and pack insert) available in New Zealand is as supplied in Europe.

The following **highlighted** information, required in accordance with New Zealand legislation, is not included on the vial and carton label or is not aligned with the New Zealand Datasheet:

- Name and strength of the active ingredient on the vial and carton label - NUVAXOVID COVID-19 Vaccine **5 micrograms** adjuvanted [**SARS-CoV-2 rS (NVX-CoV2373)**]
- Medicine Schedule - **Prescription Medicine**
- The Dosage form as listed on the label is Dispersion for injection and in the Datasheet is **Suspension** for injection
- Store in a refrigerator (**2°C to 8°C**). Do not freeze.
- Supplier in New Zealand - **Biocelect New Zealand Ltd, Level 5, Wynn Williams House, 47 Hereford Street, Christchurch 8013, New Zealand.**

Action Required by Healthcare Professionals

- Follow all recommendations in the New Zealand Datasheet when administering NUVAXOVID, which can be found via the QR code on the package insert in your pack or at the following link - <https://www.medsafe.govt.nz/profs/Datasheet/n/Nuvaxovidinj.pdf>
- Share this information with other healthcare professionals involved in the administration of NUVAXOVID.

Medical Information

If you have any questions or require additional information regarding the use of NUVAXOVID please call Novavax on +64 4 974 9419 (Mn- Fr 9 am to 5 pm).

Reporting an Adverse Event

In New Zealand, suspected adverse events should be reported to Medsafe via routes outlined at <https://medsafe.govt.nz/safety/report-a-problem.asp>.

To report an adverse event or other safety issue involving NUVAXOVID, you can also call Novavax on +64 4 974 9419.

A handwritten signature in black ink, appearing to read "K. Herz", is positioned above the name and title of the sender.

Karl Herz
Managing Director
Biocelect New Zealand Limited