

Annex A

<u>MA (EU) number</u>	<u>(Invented) name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of Administration</u>	<u>Immediate Packaging</u>	<u>Content (concentration)</u>	<u>Pack size</u>
EU/1/21/1618/001	Nuvaxovid	--1	Dispersion for injection	Intramuscular use	Vial (glass)	5 mL (10 doses)	10 multidose vials (100 doses)

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One dose (0.5 mL) contains 5 micrograms of the of SARS-CoV-2 spike protein* and is adjuvanted with Matrix-M.

Adjuvant Matrix-M containing per 0.5 mL dose: Fraction-A (42.5 micrograms) and Fraction-C (7.5 micrograms) of *Quillaja saponaria* Molina extract.

* produced by recombinant DNA technology using a baculovirus expression system in an insect cell line that is derived from Sf9 cells of the *Spodoptera frugiperda* species.