

Medicinal product no longer authorised

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/1/21/1580/001	VidPrevyn Beta	-- ¹	Solution and emulsion for emulsion for injection	Intramuscular use	Antigen solution: vial (glass); Adjuvant emulsion: vial (glass)	Antigen solution: 2.5 ml; Adjuvant emulsion: 2.5 ml (10 doses)	10 multidose vials + 10 multidose vials (100 doses)

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After mixing, one dose (0.5 mL) contains 5 micrograms of SARS-CoV-2 spike protein (B.1.351 strain)* and is adjuvanted with AS03. AS03 adjuvant is composed of squalene (10.69 milligrams), DL- α -tocopherol (11.86 milligrams) and polysorbate 80 (4.86 milligrams).

*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.